UiB NANO 310 - 23 Aug 2019

Challenges in risk assessment and risk management of nano particles

Prof Dr. Jeroen P. van der Sluijs







SVT: Senter for vitenskapsteori

- Inter-faculty interdisciplinary research centre in UiB, established in 1987
- Vitenskapsteori: research on research
- Double competence:

be able to **understand from the inside** what is going on in your field **AND** be **philosophically informed** about, and be able to **critically reflect on** and cope with, the **epistemic and normative presuppositions** of your own approach and your field of research

 Critical reflection on relation between science and society



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.

Ch-Ch syndrome 1986





"The issue of quality control in science, technology and decision-making is now appreciated as urgent and threatening. The experiences of Chernobyl and Challenger, both resulting from lapses of quality control, illustrate this problem. We have described the "Ch-Ch Syndrome": the catastrophic collapse of sophisticated mega-technologies resulting from political pressure, incompetence and cover-ups (Ravetz et al., 1986)." "The destructive impact of our industrial system on the natural environment is another manifestation of the Ch-Ch syndrome. Here the phenomena are less dramatic but more pervasive. The pathologies of the industrial system are transferred out, so that it degrades its environment while running "normally". This contradiction affects more than particular high technologies; the very place of science in our civilization is called into question."

Funtowicz & Ravetz 1990





Complex - *uncertain* - risks

Decision Stakes

Typical characteristics:

- Decisions urgent
- Stakes high
- Values in dispute
- Irreducible & unquantifiable uncertainty



- Assessment: models, scenarios, assumptions, extrapolations
- (hidden) value loadings in problem frames, indicators chosen, assumptions made
- **Knowledge Quality Assessment!**

Approaches to the conception and assessment of risk

- the actuarial approach (using statistical predictions);
- the toxicological and epidemological approach (including ecotoxicology);
- the engineering approach (including probabilistic risk assessment PRA);
- economic approach (cost-benefit)
- the psychological approach (including psychometric analysis);
- social theories of risk;
- cultural theory of risk (using group grid analysis).

Social function of various approaches to risk



Asbestos

"Looking back in the light of present knowledge, it is impossible not to feel that opportunities for discovery and prevention of asbestos disease were badly missed."

From what year is this quote?

Asbestos

- "Looking back in the light of present knowledge, it is impossible not to feel that opportunities for discovery and prevention of asbestos disease were badly missed."
 - Thomas Legge, Chief Medical Inspector of Factories, in *Industrial Maladies*, (1934)

Asbestos case

1898	UK Factory Inspector Lucy Deane warns of harmful and 'evil' effects of asbestos dust
1906	French factory report of 50 deaths in female asbestos textile workers and recommendation of controls
1911	'Reasonable grounds' for suspicion, from experiments with rats, that asbestos dust is harmful
1911 and 1917	UK Factory Department finds insufficient evidence to justify further actions
1918	US insurers refuse cover to asbestos workers due to assumptions about injurious conditions in the industry
1930	UK Merewether Report finds 66 % of long-term workers in Rochdale factory with asbestosis
1931	UK Asbestos Regulations specify dust control in manufacturing only and compensation for asbestosis, but this is poorly implemented
1935–49	Lung cancer cases reported in asbestos manufacturing workers
1955	Doll establishes high lung cancer risk in Rochdale asbestos workers
1959–60	Mesothelioma cancer in workers and public identified in South Africa
1962/64	Mesothelioma cancer identified in asbestos workers, in neighbourhood 'bystanders' and in relatives, in the United Kingdom and the United States, amongst others
1969	UK Asbestos Regulations improve controls, but ignore users and cancers
1982-9	UK media, trade union and other pressure provokes tightening of asbestos controls on users and producers, and stimulates substitutes.
1998–99	EU and France ban all forms of asbestos
2000–01	WTO upholds EU/French bans against Canadian appeal

UK asbestos imports and predicted mesothelioma deaths



Figure 5.1.





Assessing health & environmental

RIVM 2015 on nano risks



- Existing risk assessment is insufficient to determine harmfulness to people and the environment
- Some nanoparticles known to be harmful
- Large uncertainties / knowledge gaps
- Rapid pace of new developments requires pragmatic approach
- e.g. self-organizing materials
- "Safe innovation"

Some challenges

- Particle toxicology is fundamentally different from classic toxicology
- Speed with which nanomaterials hot 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

Risk

- "chance or possibility of loss or bad consequence"
- the possibility, with a certain degree of probability, of damage to health, environment and goods, in combination with the nature and magnitude of the damage.



Paracelsus (1493-1541)

Founder of toxicology

"The poison is in the dose"



Nicolaas Beets (1814-1903) Dutch poet

"Een mens lijdt het meest door het lijden dat hij vreest, doch dat nooit op zal dagen. Zo heeft hij meer te dragen dan God te dragen geeft..."

"A man suffers the most from the suffering he fears but that never will show up. That gives him more to endure than God gave him to bear."

THE LEARNING CURVE

FEATURE

Researchers say that some chemicals have unexpected and potent effects at very low doses – but regulators aren't convinced.

BY DAN FAGIN

nature International weekly journal of science

ear the end of an adventurous life spent wandering the fortress towns of central Europe, clashing with bloodletters and other tradition-bound healers of the day, the irascible sixteenth-century physician Paracelsus wrote a defence of his unorthodox use of mercury, opium and other potentially dangerous medicines. "All things are poison, and nothing is without poison: the dose alone makes a thing not poison," he wrote. Centuries later, after many of his once-radical ideas found wide acceptance, Paracelsus's pronouncement would be distilled into a pithy phrase that became foundational dogma for the modern science of toxicology: "the dose makes the poison."

The contemporary interpretation of Paracelsus's famous declaration, for which he is often called the father of toxicology, is that dose and effect move together in a predictably linear fashion, and that lower exposures to a hazardous compound will therefore always generate lower risks. This idea is not just a philosophical abstraction; it is the core assumption underlying the system of chemical-safety testing that arose in the mid-twentieth century. Risk assessors typically look for adverse effects of a compound over a range of high doses and, from there, extrapolate downwards to establish health standards — always assuming, like Paracelsus, that chemicals toxic at high doses are much less risky at lower, real-world levels.

IHE EARNING CURVE

NEWS FEATURE

Researchers say that some chemicals have unexpected and potent effects at very low doses – but regulators aren't convinced.

BY DAN FAGI

But what if the Paracelsian presumption is wrong? What if, for a large and potent class of compounds, lower doses pose higher risks? A growing number of academic researchers are making just such a claim for endocrine disrupters, a large group of synthetic chemicals able to interact with cellular hormone receptors. These compounds, which range from the common weed killer atrazine and the plasticizer bisphenol A (BPA) to the antibacterial agent triclosan (used in cleansers) and the vineyard fungicide vinclozolin, don't play by the usual rules of toxicology. On the basis of conventional high-dose testing, regulators have set maximum acceptable levels for each of them that assume all doses below that level are safe. But academic researchers who have studied a wider range of doses, including very low ones found in the everyday environment, say that their experiments usually do not generate the tidy, familiar 'ski-slope' dose-response graphs of classic toxicology. Instead, most endocrine disrupters have 'nonmonotonic' dose-response curves, meaning that their slopes change at least once from negative to positive, or vice versa, forming 'U' shapes, inverted 'U's or even stranger shapes that resemble undulating Chinese dragons (see 'Curious curves').

Critical Reviews in Environmental Science and Technology, 43:1823–1867, 2013 Copyright © 2013 Crown copyright ISSN: 1064-3389 print / 1547-6537 online DOI: 10.1080/10643389.2012.671750

Nanopesticides: State of Knowledge, Environmental Fate, and Exposure Modeling

M. KAH,¹ S. BEULKE,² K. TIEDE,² and T. HOFMANN¹ ¹Department of Environmental Geosciences, University of Vienna, Vienna, Austria ²Food and Environment Research Agency, Sand Hutton, York, England

Published literature has been reviewed in order to (a) explore the (potential) applications of nanotechnology in pesticide formulation, (b) identify possible impacts on environmental fate, and (c) analyze the suitability of current exposure assessment procedures to account for the novel properties of nanopesticides within the EU regulatory context. The term nanopesticide covers a wide variety of products and cannot be considered to represent a single category. Many nanoformulations combine several surfactants, polymers, and metal nanoparticles in the nanometer size range. The

Nanopesticides

Search criteria	All years	% published in the period 2007–2011 ^a
Nanopesticide (NP)	3,232	65
NP and microemulsion	408	49
NP and nanoemulsion	56	89
NP and nanodispersion	32	17
NP and nanocapsule	312	38
NP and solid lipid nanoparticle	7	100
NP and nanoclay	20	85
NP and nanosilver	117	74
NP and TiO ₂	10	70

Note. Data retrieved from http://www.freepatentsonline.com/search.html. ^aUp to April 2011.

Increasing the solubility of poorly water-soluble a.i.			
Micro-emulsion	Nano-emulsion	Nano-dispersion	
(6-50 nm)	(20-200 nm)	(50-200 nm)	

Slow/targeted release and protection against premature degradation				
	Soft ma	trix	Hard r	natrix
Polymer-base	ed	Solid lipid	Porous hollow silica	LDH and clays
(10-300 nm)		(200 nm-100 µm)	(100-200 nm)	(µm range)
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LDH = layered double hydroxides



a.i. = active ingredient

Nanoformulations aim to

- To increase the apparent solubility of poorly soluble active ingredients
- to release the active ingredient in a slow/targeted manner
- to protect against premature degradation.

Nanoformulations are thus expected to

- have significant impacts on the **environmental fate** of active ingredients
- introduce new ingredients for which the environmental fate is still poorly understood (e.g., nanosilver).
- new toxic properties.

Adaptations of current exposure assessment approaches will be necessary

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)



Human Risk Assessment

Use and occurrences

Exposure

Uptake (inhalation,

ingestion, skin)

Tissue distribution

Concentration at target

organ

Į

Use and occurrences

Environmental Risk

Assessment

Emission and distribution in air, water, soil

Uptake in target species (inhalation, ingestion, skin)

Distribution in species

Concentration at target organ

Toxic effect – correlation with exposure

Risk Assessment

Definition: what are nanoparticles?

How to measure nanoparticles?

What makes nanoparticles hazardous?

Which characteristics of nanoparticles to measure?

How do nanoparticles interact with their surroundings?

Transformation – how do nanoparticles change during their lifetime?

Which – additional and nano specific – tools/approaches needed to assess the risk of a nanoparticle?

Dose with toxic effect

Risk Assessment

1) Dimensionality



2) Morphology





4) Uniformity & agglomeration state

3) Composition





(Buzea et al. 2007, doi: 10.1116/1.2815690)

Examples of harmful effects

- Impairment of functioning of human macrophages
 - Disruption/triggering of inflammation mechanisms
 - Disruption of tissue- / vasculair recovery
- Harmful for lungs
 - Inflammation
 - Pulmonary fibrosis
 - Carbon nanotubes may act similar as asbestos
- Disruption of brain and nerval system
 - Inflammation -> increase in stress hormone cortisol
 - Reduction of cellular energy -> depolarisation mitochrondial membrane -> apotosis
- Cell damage
 - DNA damage
- Eco toxicity
 - Damage to plants, animals, micro-organisms and ecosystems



Schematics of human body with pathways of exposure to nanoparticles, affected organs, and associated diseases from epidemiological, *in vivo* and *in vitro* studies (Buzea et al. 2007 doi: 10.1116/1.2815690).

Risks of exposure

- Risks depends on:
 - Toxicity
 - Shape and other properties of the particle
 - Bioaccumulation
- Exposure of humans
 - Inhalation
 - Oral ingestion
 - Skin
 - Nose-to-brain through nerves
 - Other yet undiscovered routes?
- Fate in the human body?
 - Can it enter cells?
 - Blood-brain barrier?

Particle Deposition in the Lungs



In the desert of ignorance about nano risks....

"Thank God! A panel of experts!"

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. Lkelihood for long-term UFP exposure to be causally related to all cause mortality, cardiovascular and respiratory

morbidity and lung cancer was rated **medium**.

\leftarrow	Pathway 1A	UFP trigger an acute inflammatory response in the lungs, eventually promoting pulmo- nary or systemic inflammation and atherosclerosis, which can lead to a cardiac event.
\leftarrow	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

Knowledge on health effects of ultra fine particles versus synthetic nano particles (Borm e.a. 2008)

Can one extrapolate from known effects of ultra fine particles from fuel combustion (soot etc) to effects of synthetic nano particles (Carbon Black, Carbon nanotubes, TiO2, Au, MnO2 etc)?

Effect ultra fine particles	Status for synthetic nano particles (type)
Inflammation bronchial tubes & lungs	Confirmed in test animals (CNT)
Cardiac dysrhythmia (diesel soot)	Confirmed in test animals (CNT, CB)
Disruption vasco-regulation	Confirmed in test animals (TiO2, CB)
Inflammation/disruption brain function	Confirmed in test animals (Au, MnO2, C)
Excabration asthma – COPD	Unknown
Effect on blood coagulation	Confirmed in virto & vivo (CNT)
Effect not known or found	Formation of granuloma in peritoneal

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

Hazard assessment rule of thumb

- The higher on the list, the more measures should be taken to avoid exposure
- i. Fibrous shape and en insoluble;
- ii. Substances of which the chemical has special properties (carcinogenic, mutagenic, reprotoxic, sensibilising);
- iii. Insoluble (and not in one of the prior categories);
- iv. Soluble and not in one of the prior categories.

(Borm et al, 2008)

Health Council advice 2006

- Persistent synthetic nano-particles require a precautionary approach
- Map the environmental fate of the particles in the entire life cycle of products: waste phase!?
- Treat existing substances marketed in nano shape as novel substances under the REACH framework
- International coordination of toxicity tests
- Risk governance and public dialogue

Nanomaterial	Type of application	Function
Ag	Disinfecting sprays, textiles, cosmetics, food packaging, household products, paint	Antibacterial activity
TiO ₂	Sunscreens, textiles, paint, paper, plastics	White pigment, UV- filter, antibacterial activity, antifouling water purification
ZnO	Sunscreens	White pigment, UV- filter
SiO ₂	Cosmetics	Anti-caking agent
Carbon black	Cosmetics, tires	Colorant, UV absorber, reinforcing agent, filler
CNT	Sporting goods Shielding	Strength Electric conductivity

Table 4.1 Frequently applied nanomaterials in consumer products

Risk assessment institutions

- REACH
- SCCS (Scientific Committee on Consumer Safety)
- SCENIHR (Scientific Committee of Emerging and Newly Indentified Risks)
- EFSA (European Food Safety Authority)

Nanoparti cle	Scope of RA	Performed by	General Result/remarks
ZnO	Use as UV filter in sunscreens	SCCS	Considered safe for use when inhalation exposure is excluded*
TiO ₂	Use as UV-filter in sunscreens	SCCS	Considered safe for use when inhalation exposure is excluded*
ETH-50	Use as UV-filter in sunscreens	SCCS	Considered safe for use when inhalation exposure is excluded*
MBBT	Use as UV-filter in Sunscreens	SCCS	No opinion – insufficient data**
Carbon Black	Use as a colorant in cosmetics	SCCS	Considered safe for use when inhalation exposure is excluded*
Ag	Nanosilver: safety, health and environmental effects and role in antimicrobial resistance	SCENIHR	Additional effects of wide-spread use cannot be ruled out (human and environment)

Table 3.2: Overview of substance specific risk assessments in the EU

Foreseen RA			
SiO ₂ (different nano forms)	Use in leave-on and rinse-off cosmetics products	SCCS	Mandate for opinion; Opinion to be expected in end of 2014 early 2015
Food additives	Food applications	EFSA	Re-evaluation of food additives, specifically on nano forms (2020).
SiO ₂ (several nano forms)	Substance characterization / nanoparticles, toxicity of different forms of the substance	Substance evaluation in REACH	Substance evaluation focuses a.o. on nano forms of the material (2014)
Ag	Nanoparticles/ Ecotoxicity of different forms of the substance; Environmental fate	Substance evaluation in REACH	Substance evaluation focuses a.o. on nano forms of the material (2014)
TiO2	Nanoparticles/ Ecotoxicity of different forms of the substance; Environmental fate	Substance evaluation in REACH	Substance evaluation focuses a.o. on nano forms of the material (2014)

Recommendations

- Extended participation
- Diversify risk analysis methods (to early for harmonization -> avoid anchoring)
- Monitoring!!!
- More critical reflection on nano-innovation: nanoethics
- Classify nano particles and products according to potential risk
- Labeling
- Separate collection and treatment of nano waste?

Rule of thumb for acceptability of risks (Vlek &Stallen, 1981)

- 1. Expected benefits should be big enough
- Worst case scenario should not be too catastrophic
- The activity should be (perceived) to be controlable

Ingredients for risk acceptance

(Otten & Vlek, 1989; nrs 1-3 from ICRP)

- 1. Benefit and necessity must be clear
- 2. Minimise probability of negative effects (ALARA)
- 3. Set limits for the maximum negative effects Optimal freedom of choice
- 4. Perception of sufficient controllability
- 5. Activity is understandable and transparent
- 6. No incidents and undue reassurance

with thanks to Charles Vlek

Levels of intervention

- 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.

(Weiss, 2003)

https://link.springer.com/article/10.1023/A:1024847807590

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

https://link.springer.com/article/10.1023/A:1024847807590

Conservation of misery ("risk migration") classic example

- NH_3 -> acute health risk
- Propane -> explosion risk
- CFC -> ozone layer
 - –1987 Montreal Protocol
- PFC -> greenhouse gas
 1997 Kyoto protocol
- HFCs (HFO-1234yf)

Types of risk migration / risk transformations

- Physical change
- Interpretational change
- Translational (replacing one risk with another)
- Diffusional (adding to a stock of risk)

Busby et al (2012)

Recent example

Review article

Non-exhaust PM emissions from electric vehicles

Victor R.J.H. Timmers^{a,*}, Peter A.J. Achten^b

^a University of Edinburgh, Edinburgh EH8 9YL, UK ^b INNAS BV, 15 Nikkelstraat, 4823 AE Breda, Netherlands

HIGHLIGHTS

- A positive relationship exists between vehicle weight and non-exhaust emissions.
- Electric vehicles are 24% heavier than their conventional counterparts.
- Electric vehicle PM emissions are comparable to those of conventional vehicles.
- Non-exhaust sources account for 90% of PM₁₀ and 85% of PM_{2.5} from traffic.
- Future policy should focus on reducing vehicle weight.

Atmospheric Environment 134 (2016) p.10-17

Historic cases

- Asbestos for isolation
 - Shifts short term fire risk to long term health risk
- Halocarbons for refrigeration
 - shifts small scale, near-term risk to a global environmental risk
- Neonicotinoid insecticides
 - shifts a human health risk and risks for birds of prey to an ecological and food security risk (pollinator loss) and risks for insectivorous birds
- Hydrogen-powered road traffic vehicles
 - Shifting environmental and safety risks to other environmental and safety risks
- Nanotech products
 - shifts an environmental issue (material and energy consumption) to a health and environmental issue.

LED lamp and risk migration

- Unprecedented brightness of the (point)light source
- Unidirectional nature of LED light, analogy with risks of laser light
- Blue light hazard
- Blue light as endocrine disruptor: melatonin and the biological clock
- Indoor emissions of toxic substances from plastics used in LED lamps
- Electro-safety issues
- Impact of light quality on labour productivity

Led lamp: Blue Light Hazard ?? 420–490 nm melatonine regulation??

- a. Daylight spectrum
- b. Incandescent lamp spectrum
- c. LED spectrum compared to daylight

Blue Light Hazard

Blue-light hazard function

Cajochen e.a. 2011 Evening exposure to a light-emitting diodes (LED)backlit computer screen affects circadian physiology and cognitive performance

LED-backlit screen emitted 3.32 times more light in the blue range between 440 and 470 nm than the non-LED-backlit screen. This is the major factor contributing to the observed effects."

https://dspace.library.uu.nl/bitstream/handle/1874/314855/Risk_Migration_Sustainable_Innovation_Final_Report.pdf

Blue light issues

- Attention of research community is growing (rapidly increasing amount of publications)
- On the agenda of International Electrotechnical Commission
- German Vornorm 2009

Factors that hamper early detection of unintended negative side effects

- lack of critical reflection on risks and benefits
- bias in appraisal of risks and benefits
- required level of proof
- inadequate risk assessment
- data gaps
- lack of monitoring
- institutional factors
- interests / power

Top 10 of circumstances / characteristics of risk migration

Rank	Circumstance / characteristic	# cases
1	Lack of systems analytic approach	37
2	Incomplete life cycle assessment	27
3	Lack of critical reflection on risks and promised benefits	25
4	No incentives to meet ALARA	25
5	Persistence and/or bioaccumulation	17
6	Ignoring ignorance	14
7	Novel material / special unfamiliar properties	11
8	Mismatch novel aspects and authorization tests / standards etc	10
9	Unreflective upscaling from small scale experiences	9
10	Non standard situations	4

Plurality and uncertainty in risk assessment: lessons learned

• Diversity of the knowledge base:

It must be based on the full spectrum of available scientific knowledge;

Robustness of the knowledge claims

- Include uncertainty, dissent and criticism in the analysis, synthesis and assessments;
- Make thorough Knowledge Quality Assessment the key task in the science policy interface and develop a joint language to communicate limitations to our knowledge and understanding clearly and transparently
 - Bayesian likelihood terminology is misleading, it unduly suggests certainty;
- Make use of information of non-scientific sources (local knowledge)
 - But scrutinize this information and be clear on its status;
- **Clarify values, stakes and vested interests** that play a role in research and in the political and socioeconomic context within which the research is embedded.

(Maxim and van der Sluijs, 2007

https://www.sciencedirect.com/science/article/pii/S0048969707000095