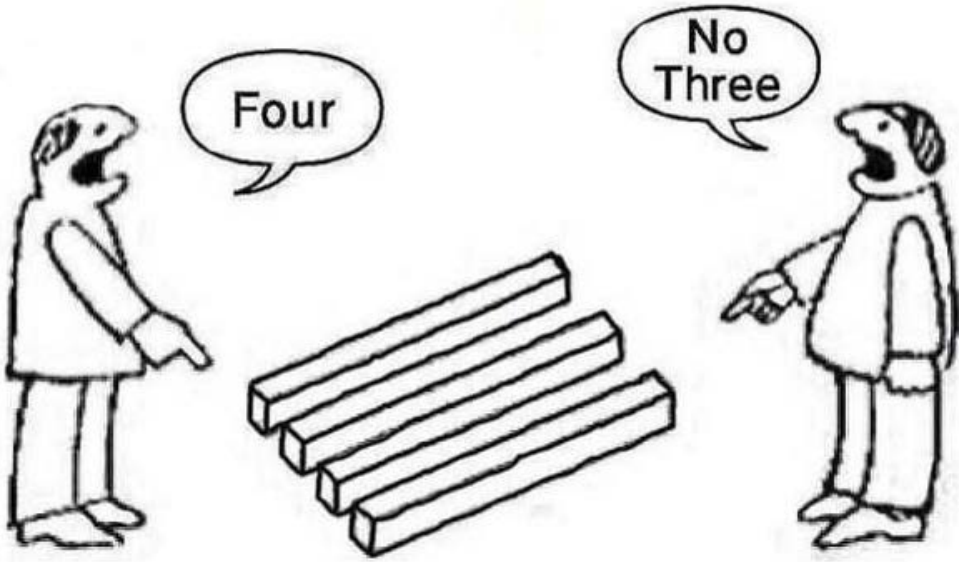
Scientific Controversy

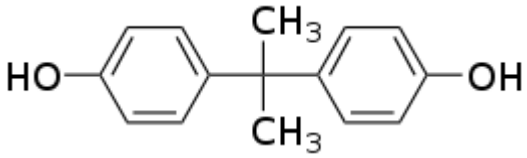
Institutional, Societal and Epistemic dimensions



Jeroen P. van der Sluijs @Jeroen_vdSluijs

Senter for vitenskapsteori

Bisphenol A controversy



Professor fights against plastic

Vom Saal says obesity linked to chemical.

By JACOB LUECKE of the Tribune's staff
Published Sunday, March 4, 2007

Plastic companies use bisphenol-A to make a lot of things - food containers, water bottles and even baby bottles. But there's only one thing Fredrick vom Saal would like the industry to do with it: Take it off the market.

Vom Saal, a biology professor at the University of Missouri-Columbia, has studied bisphenol-A for more than a decade. The chemical is essentially a female sex hormone similar to estrogen. Plastic companies have long used it to make rigid, clear containers, many of which are used for food.

"This is one of the highest-volume produced chemicals in the world. It's in everybody's bodies, and it's a very potent sex hormone," he said. "It's just nuts that it's being used the way it is."

Vom Saal's research, which includes testing the chemical on lab mice, has shown a variety of ill effects. For example, embryonic and infant mice exposed to small amounts bisphenol-A tend to become obese as adults. He surmises the same chemical could be behind the current rise in human obesity.

"When is the obesity epidemic occurring? Over the last couple decades," he said. "Over the last couple of decades you've have over a fourfold increase in bisphenol-A production and use. If you look at the increase in obesity and increase in bisphenol-A use, they absolutely line up."

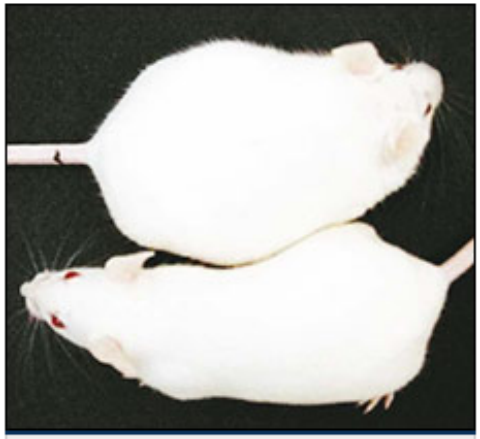
Chemicals May Play Role in Rise in Obesity

By Elizabeth Grossman
Special to The Washington Post
Monday, March 12, 2007; Page A06

Too many calories and too little exercise are undeniably the major factors contributing to the obesity epidemic, but several recent animal studies suggest that environmental exposure to widely used chemicals may also help make people fat.

The evidence is preliminary, but a number of researchers are pursuing indications that the chemicals, which have been shown to cause abnormal changes in animals' sexual development, can also trigger fat-cell activity -- a process scientists call adipogenesis.

The chemicals under scrutiny are used in products from marine paints and pesticides to food and beverage containers. A study by the Centers for Disease Control and Prevention found one chemical, bisphenol A, in 95 percent of the people tested, at levels at or above those that affected development in animals.



GRAPHIC

Science for sale – Bisphenol A

Congress: Science for Sale?

Congress Launches Probe Into Firm's Work on Chemical Used to Make Many Plastic Bottles

*..a confidential Weinberg Group document ...in which the firm suggested to DuPont ... several ways it could **help "shape the debate"** about one of its chemical products. The firm proposed ... "**constructing a study to establish" that DuPont's chemical was safe**, and arranging the publication of papers "dispelling the alleged nexus" between the company's chemical and its alleged harmful effects on humans."*

ABC News 6 Feb 2008

http://abcnews.go.com/Blotter/story?id=4252096&page=1

Exclusive:
'Science for Sale' Probe Deepens

A scientific consulting firm once crowed of its success in delaying the cancellation of a harmful drug by 10 years, congressional investigators say.
Lawmakers have more tough questions for the Weinberg Group, which has been accused of "manufacturing uncertainty" about research to benefit its corporate clients and their products.

ABCNews, March 11, 2008,

http://abcnews.go.com/Blotter/story?id=4428347&age=1

ENDOCRINE DISRUPTERS

Controversy Continues After Panel Rules on Bisphenol A

A federal advisory panel has poured itself the proverbial half-glass of water after digesting the latest studies on the human health risks of an estrogenlike chemical used to make plastics. The chemical industry has proclaimed that the panel's verdict last week confirms its contention that bisphenol A is safe. But environmentalists say the report has been tainted by industry and downplays the risks. Away from the fray, some scientists say the panel's comments about the chemical's effects on the developing brain represent heightened concern compared with previous formal reviews.

Bisphenol A is found in everything from some beverage and baby bottles to the linings of food cans. Small amounts can leach out into food, and most people likely have detectable levels in their blood. These parts-per-billion levels are well below the safe dose set by the Environmental Protection Agency (EPA). In 1997, however, reproductive biologist Frederick vom Saal and others at the University of Missouri, Columbia, found that very low levels fed to pregnant mice could enlarge the prostates of their male offspring. Industry studies couldn't replicate the results, but a review concluded that the results were valid (*Science*, 27 October 2000, p. 695).

How safe? Polycarbonate baby bottles are one source of the controversial chemical bisphenol A.

Since then, other scientists have reported low-dose effects in rodents. Some findings have raised alarms, such as an increase in chromosomal abnormalities in the eggs of mice, discovered after bisphenol A leached from plastic mouse cages (*Science*, 4 April 2003, p. 31). Epidemiology studies have linked bisphenol A and human health problems, such as breast cancer and early puberty. In the first formal U.S. review of bisphenol A, the National Toxicology Program's (NTP's) Center for the Evaluation of Risks to Human Reproduction formed a 12-member expert panel to review more than 500 studies.

Controversy accompanied the first meeting of academic, federal, and industry scientists in March: An environmental group pointed out that the contractor preparing a draft report had done work ▶

Kaiser, 2007, Science DOI: 10.1126/science.317.5840.884a

NEWS FEATURE

THE LEARNING CURVE

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

Near the end of an adventurous life spent wandering the fortress towns of central Europe, clashing with blood-letters 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.

http://www.nature.com/news/toxicology-the-learning-curve-1.11644?WT.ec_id=NEWS-20121030

NEWS FEATURE

THE LEARNING CURVE

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

BY DAN FAGIN

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 'non-monotonic' 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').

OPEN ACCESS Freely available online

PLOS ONE

Holding Thermal Receipt Paper and Eating Food after Using Hand Sanitizer Results in High Serum Bioactive and Urine Total Levels of Bisphenol A (BPA)

Annette M. Hormann[1], Frederick S. vom Saal[1], Susan C. Nagel[2], Richard W. Stahlhut[1], Carol L. Moyer[1], Mark R. Ellersieck[3], Wade V. Welshons[4], Pierre-Louis Toutain[5,6], Julia A. Taylor[1]*

1 Division of Biological Sciences, University of Missouri, Columbia, Missouri, United States of America, **2** Department of Obstetrics, Gynecology and Women's Health, University of Missouri, Columbia, Missouri, United States of America, **3** Department of Statistics, University of Missouri, Columbia, Missouri, United States of America, **4** Department of Biomedical Sciences, University of Missouri, Columbia, Missouri, United States of America, **5** Université de Toulouse, INPT, ENVT, UPS, UMR1331, F- 31062 Toulouse, France, **6** INRA, UMR1331, Toxalim, Research Centre in Food Toxicology, F-31027 Toulouse, France

Abstract

Bisphenol A (BPA) is an endocrine disrupting environmental contaminant used in a wide variety of products, and BPA metabolites are found in almost everyone's urine, suggesting widespread exposure from multiple sources. Regulatory agencies estimate that virtually all BPA exposure is from food and beverage packaging. However, free BPA is applied to the outer layer of thermal receipt paper present in very high (~20 mg BPA/g paper) quantities as a print developer. Not taken into account when considering thermal paper as a source of BPA exposure is that some commonly used hand sanitizers, as well as other skin care products, contain mixtures of dermal penetration enhancing chemicals that can increase by up to 100 fold the dermal absorption of lipophilic compounds such as BPA. We found that when men and women held thermal receipt paper immediately after using a hand sanitizer with penetration enhancing chemicals, significant free BPA was transferred to their hands and then to French fries that were eaten, and the combination of dermal and oral BPA absorption led to a rapid and dramatic average maximum increase (Cmax) in unconjugated (bioactive) BPA of ~7 ng/mL in serum and ~20 µg total BPA/g creatinine in urine within 90 min. The default method used by regulatory agencies to test for hazards posed by chemicals is intra-gastric gavage. For BPA this approach results in less than 1% of the administered dose being bioavailable in blood. It also ignores dermal absorption as well as sublingual absorption in the mouth that both bypass first-pass liver metabolism. The elevated levels of BPA that we observed due to holding thermal paper after using a product containing dermal penetration enhancing chemicals have been related to an increased risk for a wide range of developmental abnormalities as well as diseases in adults.

Citation: Hormann AM, vom Saal FS, Nagel SC, Stahlhut RW, Moyer CL, et al. (2014) Holding Thermal Receipt Paper and Eating Food after Using Hand Sanitizer Results in High Serum Bioactive and Urine Total Levels of Bisphenol A (BPA). PLoS ONE 9(10): e110509. doi:10.1371/journal.pone.0110509

Editor: David O. Carpenter, Institute for Health & the Environment, United States of America

Received August 13, 2014; **Accepted** September 23, 2014; **Published** October 22, 2014

‘analysis of controversies’

- ‘analysis of controversies’ focuses on disputes, which highlight the social contradictions inherent in many decisions about science and technology, in order to describe the special interests, vital concerns, and hidden assumptions of various actors (Nelkin, 1992).

Stakeholders can agree or disagree on different levels:

Ideological view. This is the deepest level of disagreement and can lead to very different views of whether there is a problem or what it is. One can hold the view that a radically different ideological starting point is required. Ideological argumentation focuses typically on ideology and alternative societal orders.

Problem setting and goal searching. Groups may agree on the existence of a problem, but not on identifying precisely what the problem is, how to formulate it, and what the end goal or solution point should be.

Problem solving. Groups may agree on the existence of a problem and further agree on policy goals but disagree on the strategies and instruments required to reach the goal. Problem solving argumentation typically focus on effectiveness, side effects, and efficiency of methods.

Outcomes and fairness. Groups often care about the fairness of solutions to problems, but can hold different views on what constitutes fair outcomes. For example, one can hold the view that the policy at hand does not serve the public interest or public wellbeing. Fairness argumentation focuses typically on public interest, unexpected societal side effects, and distributive justice.

http://www.nusap.net/downloads/detailedguidance.pdf

Value mapping and Argumentative Analysis

	Stake-holder 1	Stake-holder 2	Stake-holder n	Agreement	Dis-agreement
Ideological view					
Problem setting and goal searching					
Problem solving					
Outcomes and fairness					

Understanding uncertainty & dissent in risk controversies

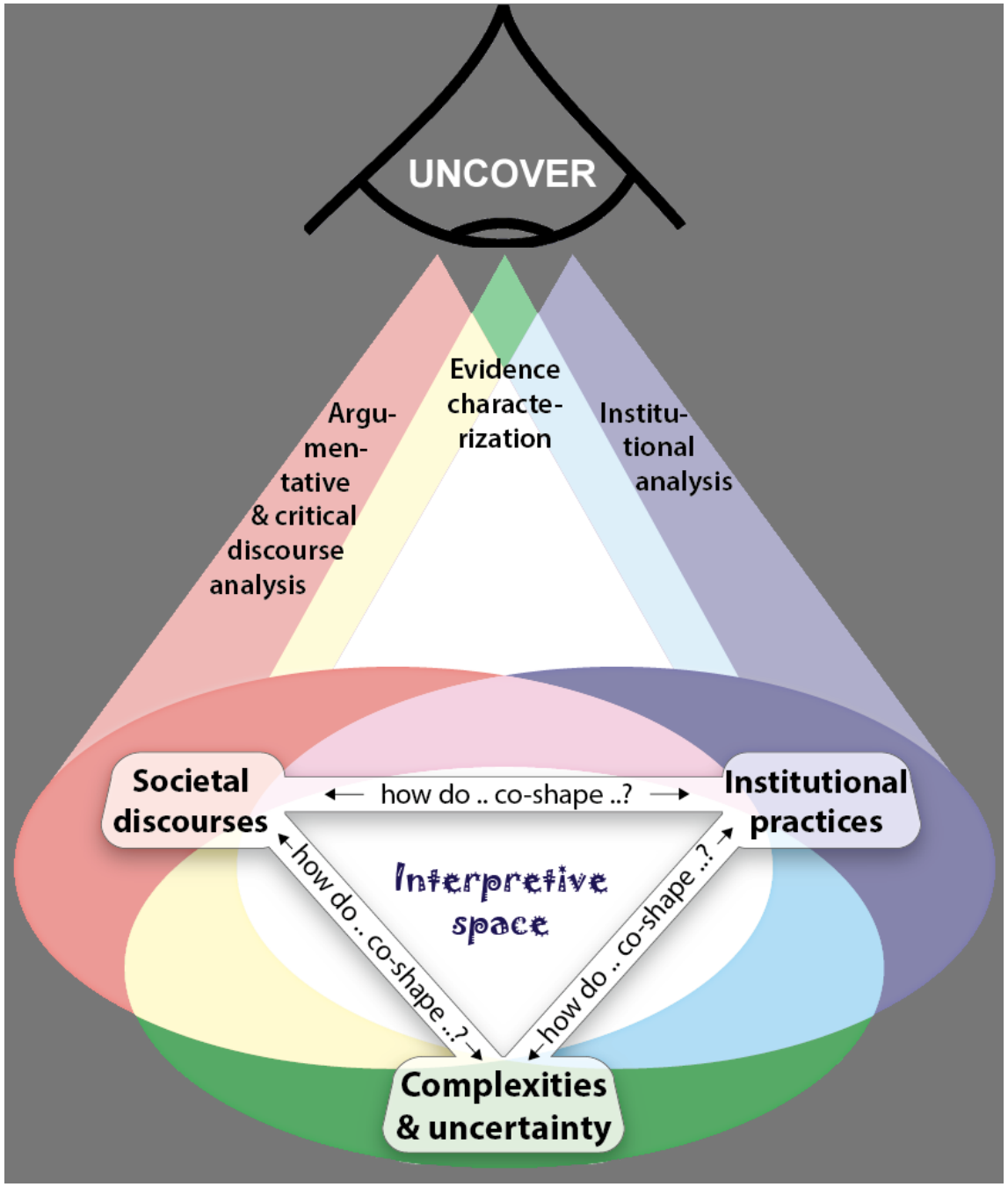
- *How are epistemic, institutional, and societal dimensions of scientific controversies on complex risks interwoven*
- *How can the science-policy interface on such risks be improved to better cope with deep uncertainty and scientific dissent?*

Understanding scientific controversy

- **Find generic patterns** of interwovenness of **scientific**, **societal** & **institutional** dimensions
- Understand why experts disagree and on what
- Clarify what is deeply uncertain and why

To enable & promote:

- More responsible treatment of uncertainty and scientific dissent
- Knowledge utilisation in full awareness of its limitations



New way of looking at scientific controversies

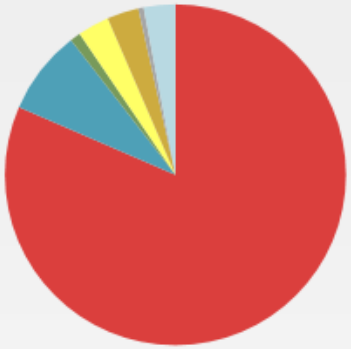
"By shining light on its dynamics from 3 different perspectives (discourse analysis, evidence characterization, institutional analysis) it seeks to reveal how 3 key factors (deep uncertainties; societal discourses; institutional practices) co-shape one another to produce the typical patterns that can be observed in scientific controversies."

Van der Sluijs, 2014

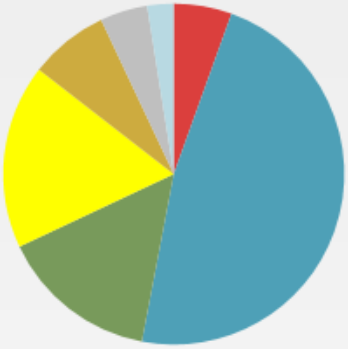

LISTEN TO
THE SCIENCE
BAN

Whose science counts?

Beekeepers

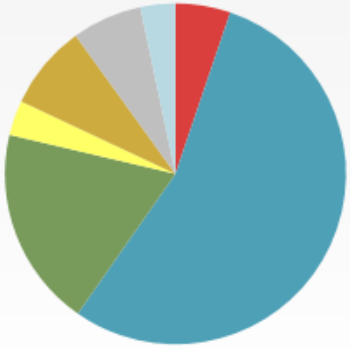


Authorisation board

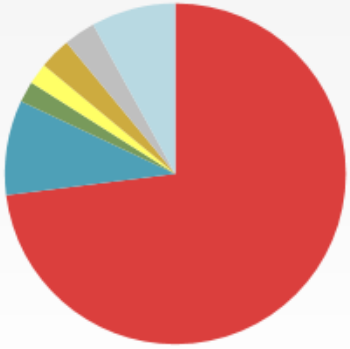


Ministry of Agriculture

Bayer

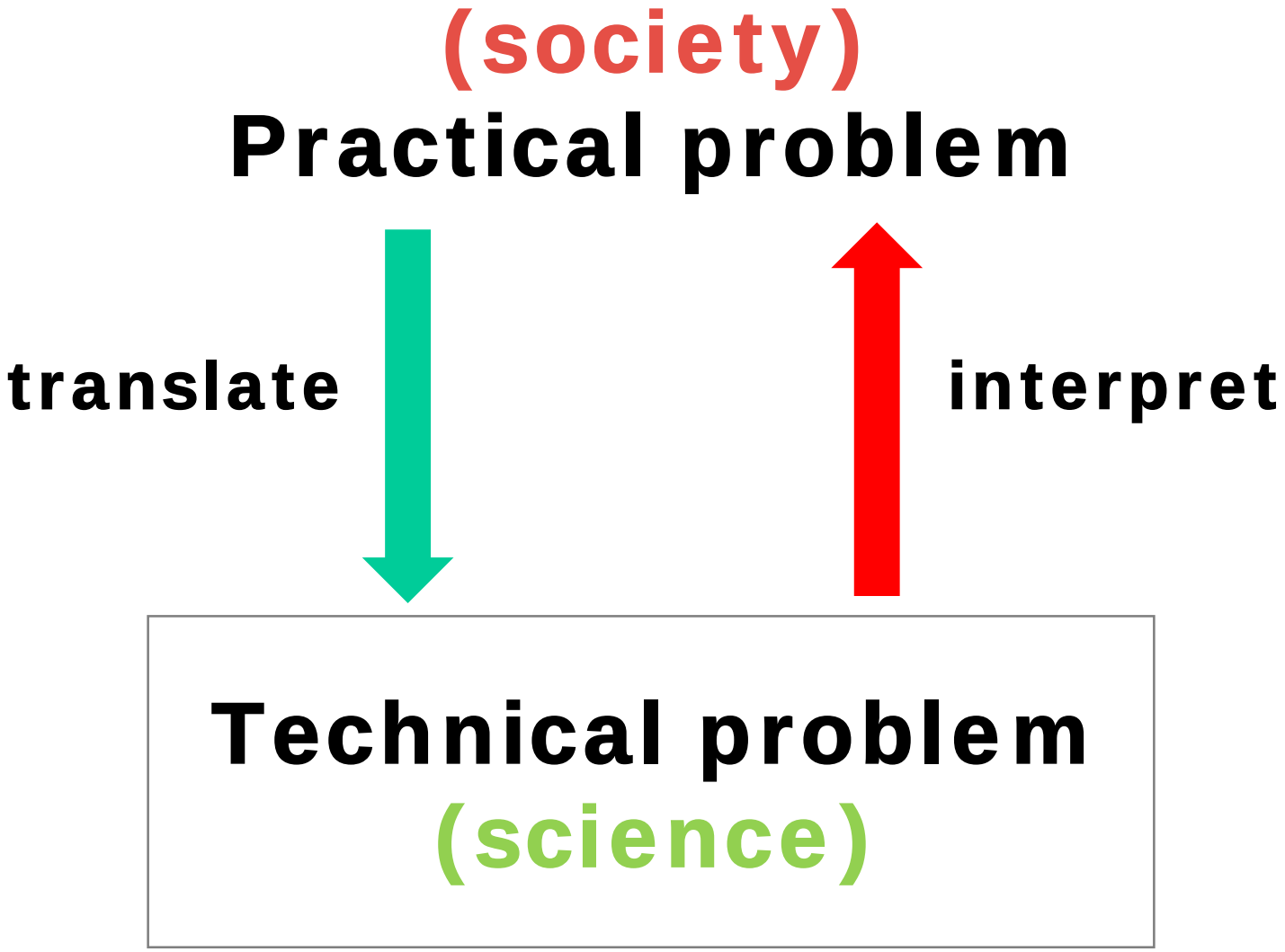


Academic researchers



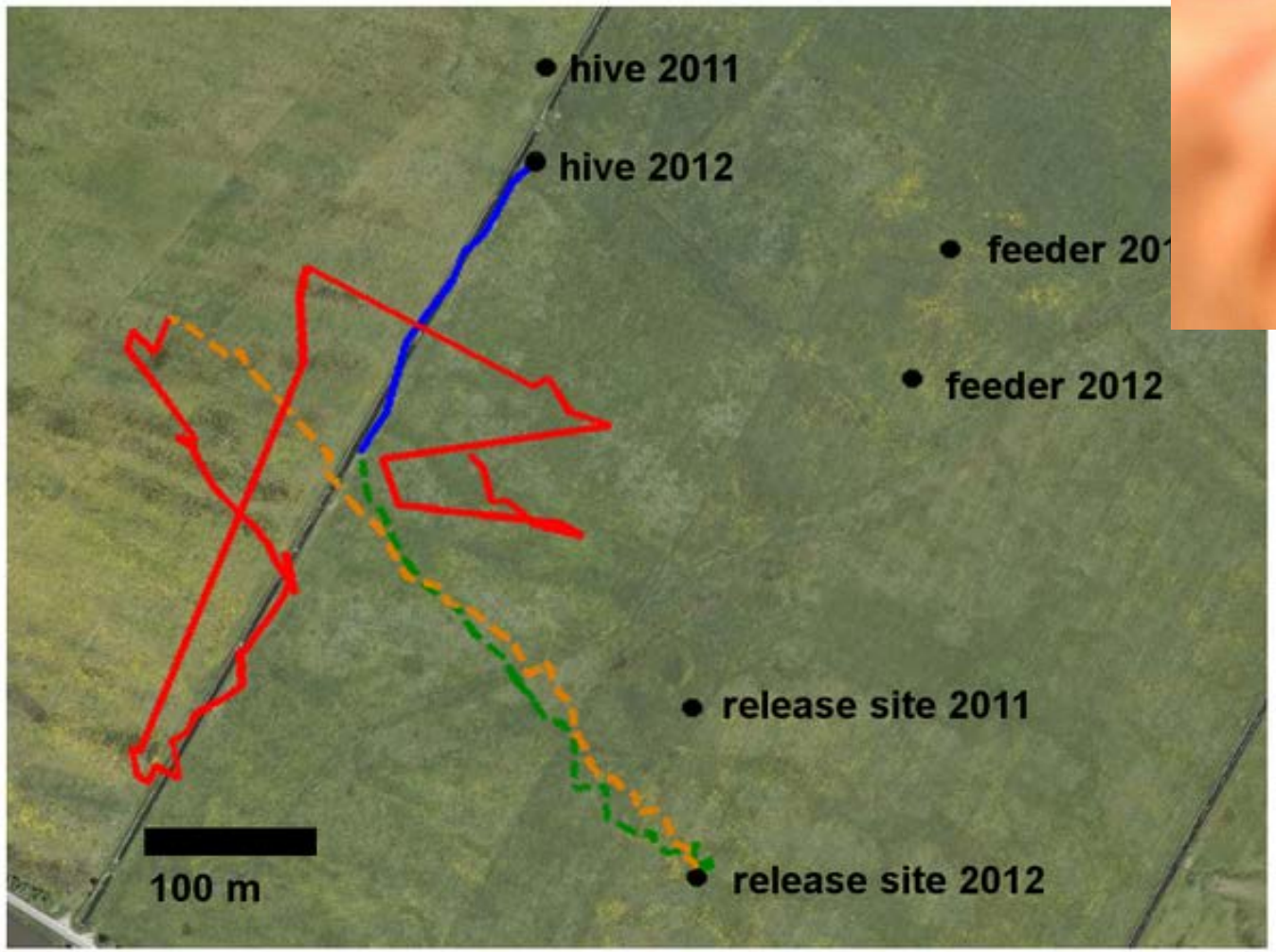
- Neonic pesticdes
- Diseases
- Pollen
- Sunflower strains
- Climate
- Genetics

(Maxim & Van der Sluijs, 2010)



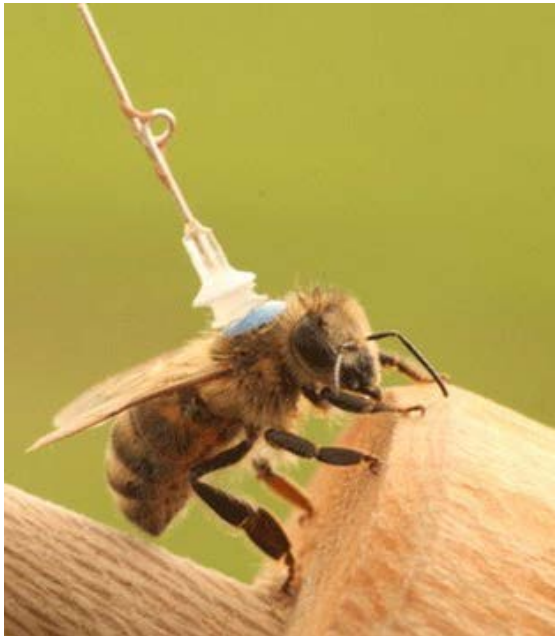
Ravetz, J., 1971, Scientific Knowledge and its Social Problems, Oxford University Press.

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



Yellow-Red
Thiacloprid-bees

Green-Blue
Control bees

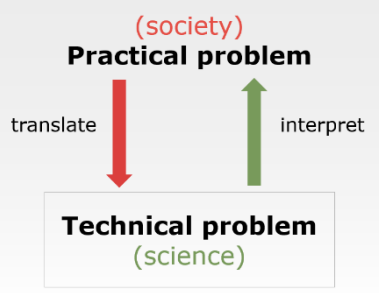


Fischer J, Müller T, Spatz A-K, Greggers U, et al. (2014) Neonicotinoids Interfere with Specific Components of Navigation in Honeybees. PLoS ONE 9(3): e91364. doi:10.1371/journal.pone.0091364
http://www.plosone.org/article/info:doi/10.1371/journal.pone.0091364

PLOS | ONE

Interpretive space **in scientific assessment results from 3 key sources:**

- **Translational diversity:** The multitude of ways in which risk issues can be translated into technical problems that science can address



- **Argumentative flexibility:** The multitude of tenable styles of scientific reasoning in expert interpretations of evidence
- The existence of **deep uncertainty** (manufactured and actual) in the science.

“Revolving Doors” ... between regulators and Corporations they regulate

“Dr Helen Thompson, a key government scientist whose research was used by ministers to argue against a ban on pesticides thought to harm bees is to join Syngenta, the chemical giant which manufactures one of the insecticides”.

Thompson led a field project intended to test the effect of neonicotinoids on bumblebees. However, the study was criticised as flawed after the near ubiquitous use of the insecticides led to the contamination of colonies meant to be pesticide-free controls”.

Guardian 26th July 2013.

Slide by Dr. David Gee

Conflicts of interest in regulatory science

Example: ICPBR Bee Brood Working Group (2008)

- Composition: 2 representatives of the industry, 3 of governmental agencies and 1 of a consulting company working for industry; academic scientists and beekeepers absent
- Proposed thresholds for considering a pesticide as being of low risk for the bee brood:
  - 30% loss of bee brood
  - 50% of eggs or other larval stages
- For beekeepers: unacceptable (these values = hives weakened on the long term)

Correspondence

Biodiversity reports need author rules

Two representatives from the agrochemical industry are among 40 authors of a fast-track assessment of pollinators by the Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES; see go.nature.com/q8lll2). In our view, to support the credibility of assessment results, the IPBES needs a policy requiring authors to declare all funding sources, positions held and other potential conflicts of interest.

It is unclear how the IPBES deals with conflicts of interest. Their second plenary meeting last December postponed a decision on the matter. Authors are nominated by IPBES member states and other stakeholders to "reflect the range of scientific, technical and socio-economic views and expertise; geographical representation …; the diversity of knowledge systems …; and gender balance". But the IPBES has no explicit rules for nomination or selection.

IPBES assessments could lead to far-reaching policy interventions, with financial implications for industry sectors (for example, in mining after assessment of land degradation and restoration, or for transport after invasive-species assessment). Given the role of agrochemicals in pollinator decline (J. van der Sluijs *et al. Environ. Sci. Pollut. Res.* http://doi.org/xcx; 2014), it is our view that scientists funded by such corporations should not be lead authors or coordinating lead authors on such assessments.

We also suggest that the IPBES publishes the names of all nominated authors, along with their nominators and justification for their appointment.

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Philip J. K. McGowan *Newcastle University, UK.*
Jeroen van der Sluijs *University of Bergen, Norway.*
hochkirch@uni-trier.de

doi:10.1038/516170c

www.tfsp.info

The New York Times | BUSINESS DAY

Scientists Loved and Loathed by an Agrochemical Giant

With corporate funding of research, "there's no scientist who comes out of this unscathed."

By DANNY HAKIM DEC. 31, 2016

EXETER, England — **The bee findings were not what Syngenta expected to hear**.

The pesticide giant had commissioned James Cresswell, an expert in flowers and bees at the University of Exeter in England, to study **why many of the world's bee colonies were dying**. **Companies like Syngenta have long blamed a tiny bug called a varroa mite, rather than their own pesticides, for the bee decline.**

Dr. Cresswell has also been skeptical of concerns raised about those pesticides, and even the extent of bee deaths. But **his initial research in 2012 undercut concerns about varroa mites as well. So the company, based in Switzerland, began pressing him to consider new data and a different approach.**

Looking back at his interactions with the company, Dr. Cresswell said in a recent interview that "**Syngenta clearly has got an agenda.**" In an email, he summed up that agenda: "**It's the varroa, stupid.**"

...

For Dr. Cresswell, 54, the foray into corporate-backed research threw him into personal crisis. Some of his colleagues ostracized him. He found his principles tested. **Even his wife and children had their doubts. "They couldn't believe I took the money,**" he said of his family. "They imagined there was going to be an awful lot of pressure and thought I sold out."

https://www.nytimes.com/2016/12/31/business/scientists-loved-and-loathed-by-syngenta-an-agrochemical-giant.html

Science for sale

on the interaction between scientific researchers and their clients

Royal Netherlands Academy of Arts and Sciences, 2005

“because of … decreasing public funding of research, universities and research institutes become too dependent on specific external research contracts.”

Derailments occur:
“the design of research, the collection and interpretation of data are sometimes adjusted to provide a favourable outcome for the client and the publication of research findings is sometimes prevented, delayed or adapted to the needs of the client. This applies to contract research funded by governments as well as interest groups and industry.”

http://www.knaw.nl/Content/Internet_KNAW/publicaties/pdf/20051083.pdf

Volkskrant investigation 2008

Quarter of professors is sponsored

- Amost one fourth of the 5,481 professorial chairs at Dutch Universities is directly or indirectly sponsored by external parties.
- Outlier is Wageningen University, with 36 % sponsored chairs

Source: frontpage “Volkskrant” (Dutch Newspaper) 12 April 2008

CoI : an early definition

"A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by ***a secondary interest****"*

Thompson DF (1993) *Understanding financial conflicts of interest*. N Engl J Med 329:573–5761993).

Slide by Dr. David Gee

Conflicts of Interest include:

- Direct: employment, stock ownership, grants, patents.
- Indirect: honoraria, consultancies to sponsoring organizations, mutual fund ownership, paid expert testimony.
- "Conflicts can also exist as a result of personal relationships, academic competition, and intellectual passion. Eg
- A relative who works at the company whose product the researcher is evaluating.
- A self-serving stake in the research results (e.g. potential promotion/career advancement based on outcomes).
- Personal beliefs that are in direct conflict with the topic he/she is researching.

(Elsevier)

Slide by Dr. David Gee

Some of the strategies used

- Selective funding of research adressing favourable questions;
- Keeping important (but unwelcome) aspects ouside the scope of research;
- Making (favourable) assumptions and underpinning these rethorically rather than factual;
- Deliberately faulty experimental design to obtain desired results;
- Intentional misapplication of statistics;
- Hiding unwelcom uncertainties / magnifying welcome uncertainties;
- Improper generalization;
- Removal of unwelcome results, ignoring unwelcome knowledge;
- Prohibition of disclosure of outcomes or prolongued embargo (IPR);
- Tampering of data from literature, observation or experiment;
- Knowingly wrong or biased representation of others' findings;
- Fabrication of data /fraud;
- Drawing of intentionally false concusions / firmer than justified;
- Promote wrong interpretations by the media;
- Disobligue colleagues in order to influence the scientific and societal debate;
- Feigning of expertise (acquisition, media, hearings);
- Spin doctor techniques against unwelcome knowledge;
- Gohst writing;
- Pal review (nepotism);

“Manufacturing Scientific Doubt”

“Doubt is our product since it is the best means of competing with the ‘body of fact’ that exists in the mind of the general public.”

From an executive at Brown & Williamson, Tobacco Company, 1969.

See EEA chapters on Beryllium, tobacco, leaded petrol, climate change etc. And Michaels 2009: Oreskes,2010 on manufacturing doubt.

Slide by Dr. David Gee

Tobacco Industry manipulation of Research

- Fund Research supporting Tobacco
- Red herrings: fund research on OTHER causes of lung cancer
- Hide industry role in that research
- Publish only pro Tobacco research
- Suppress “inconvenient truths”
- Criticise such “truths” & attack the messengers
- Change scientific standards
- Disseminate tobacco research to lay press
- Dialogue directly with policymakers, or via “front” organisations

Liz Bero, chapter in “Late Lessons from Early Warnings2, EEA, 2013

Slide by Dr. David Gee

Categories of
Deceitful Tactics and Abuse of the Scientific Process

source: P.H. Gleick, Pacific Institute, 2007

http://www.pacinst.org/publications/testimony/Gleick_Senate_Commerce_2-7-07.pdf

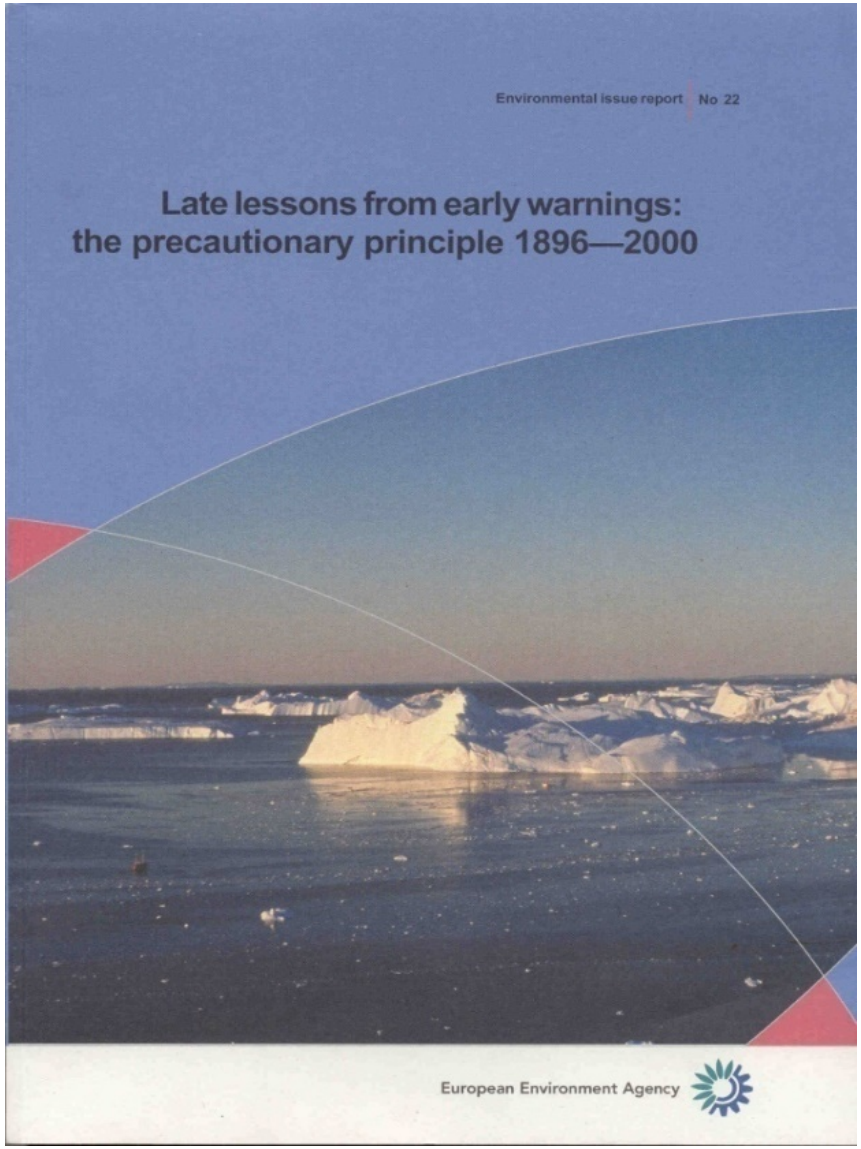
- Appeal to Emotion (appeal to ridicule, fear etc)
- Personal ("Ad Hominem") Attacks
- Mischaracterizations of an Argument
- Inappropriate Generalization
- Misuse of Facts (inadequate sample)
- Misuse of Uncertainty
- False Authority
- Hidden Value Judgments (ideologies)
- Scientific Misconduct (fabrication etc.)
- Science Policy Misconduct (Packing Advisory Boards, selective funding)

Counterweight

- Codes of conduct *(=if power balance remains unchanged this is "end of pipe!")*
- Multi-disciplinary broad expert panels
- Include minority views in scientific advice (Health Council)
- Organise systematic scrutiny and critical reflection (KQA)
- Investigative journalism
- Extended Peer Review: Blogosphere
- Contra-expertise / Science shops
- Community Based Auditing
- Crowd financing of contra-research
- Critical Discourse Analysis
- Audits

Revision of research funding required:
More independent funding, increase academic freedom!

2001



2013

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF

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

34 case studies in the "Late Lessons" reports…

'Environmental chemicals'

- Beryllium
- PCBs
- CFCs
- TBT antifoulants
- Mercury
- Environmental Tobacco
- 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
- Lead

'Micro technologies'

- Nano
- GMOs & Agro-ecology

Animal feed additives

- BSE, 'mad cow disease'
- Beef hormones
- Antibiotics

- Asbestos

Pharmaceuticals

- Contraceptive pill
- DES

Radiations

- X-rays
- Mobile phones
- Nuclear accidents

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European Environment Agency

Types of Biases:

"Reasoning often starts with established conclusions and works back to find "facts".

Its not lack of knowledge or understanding-but "motivational reasoning" .... which confirms your own bias and writing off inconvenient truths"

From evidence based policymaking to policy based evidence making..

"Seeing Reason: human brains skew facts", D jones , New Scientist, Dec 3rd 2016

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Some Biases in Research & Risk Assessment

- **Methodological biases towards false negatives**

- **Intellectual bias *ie commitment to a paradigm; authored previous evaluation/RA***

- **Reporting biases**

- **Funding bias: See the Vatican and its seeking of scientists who would contradict Galileo. See histories of Asbestos, Lead, some Pharma, Tobacco, BPA, & Mobile phones..where source of funding strongly predicts nature of the results**

See chapters on Precautionary Science & on Precaution, "Late Lessons from Early Warnings," 2013

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Direction and magnitude of biases?

What is the main direction of error in epidemiological and experimental studies ,and their interpretation.....?

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Methodological Biases: Environmental Health Sciences and Their Main Directions of Error

SCIENTIFIC STUDIES	SOME METHODOLOGICAL FEATURES	MAIN[1] DIRECTIONS OF ERROR:
Experimental	•High doses	**False positive**
Studies	•Short (in biological terms) range of doses	False negative
(Animal)	•Low genetic variability	False negative
	•Few exposures to mixtures	False negative
	•Few Foetal-lifetime exposures	False negative
	•High fertility strains	False negative (Developmental/reproductive endpoints)

[1] Some features can go either way (e.g.inapproriate controls) but most of the features mainly err in the direction shown in the table

(Gee, Bailar, Grandjean,2004, Gee 2008, Grandjean,2013, Gee,2014)

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Observational	•Confounders	**False positive/negative**
Studies	•Inappropriate controls	**False positive/negative**
(Wildlife &	•Non-differential exposure misclassification	False negative
	•Insensitive outcome measures	False negative
Humans)	•Inadequate follow-up	False negative
	•Lost cases	False negative
	•Simple models that do not reflect complexity	False negative
	•Multi-causality	False negative
Both	•Publication bias towards positives	**False positive**
	•Reporting bias	False negative
Experimental And	•Scientific cultural pressure to avoid false positives	False negative
Observational Studies	•Low statistical power (e.g. From small studies)	False negative
	•5 % probability level to minimise chances of false positives	False negative
	•Funding bias	False negative

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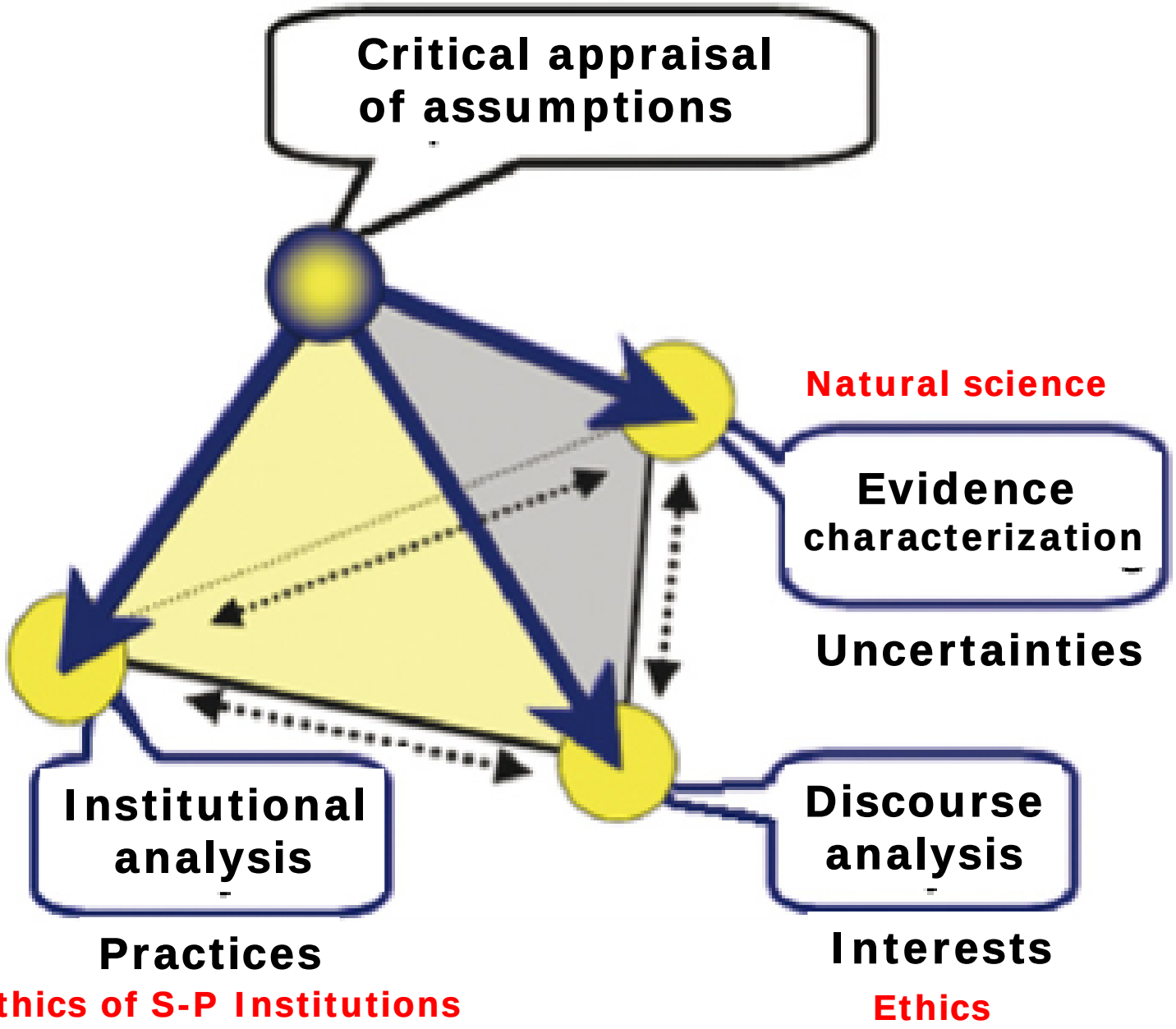
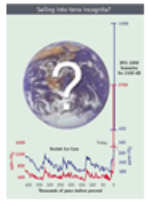
Knowledge Quality Assessment (KQA)



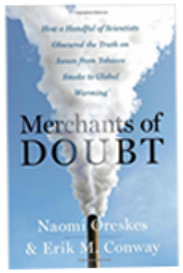
(Van der Sluijs, 2013)

Analytical framework to assess the interactions between epistemic, institutional and societal dimensions of risk controversies



Evidence characterization & Knowledge Quality Assessment

Deep scientific uncertainty & complexity



Scientific Knowledge

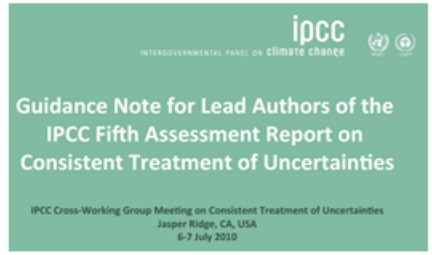
How do scientific complexity & deep uncertainty shape the societal discourse

how does the societal discourse shape scientific complexity & deep uncertainty

Substantial assumptions

how do scientific complexity & deep uncertainty shape the institutional practices

how do the institutional practices shape scientific complexity & deep uncertainty



Critical appraisal of assumptions

IPBES responds on conflicts of interest

Societal assumptions

Regulatory assumptions

Argumentative & critical discourse analysis

Interests

Societal discourse

Regulatory Risk Assessments

Institutional practices (of regulatory risk appraisal)

Institutional analysis of Science Policy Interface

how does the societal discourse shape institutional practices

how do the institutional practices shape the societal discourse

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