How can Risk Assessment & Management embrace the real world of the dearth of data, multiple stressors, & accumulative harm?

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Summary

A. Challenges from the real world:

- the dearth of data
- limitations of risk assessments
- complexity, uncertainties, surprises
- multi-causality
- accumulative & inequitable harm
- divergent evaluations of the “same” evidence

B. Some realistic responses to the real world?

- Comparative Hazard Assessment of Chemical Group
- Alternative options for meeting needs
- More relevant Research
- Equitable cost sharing
- Prudent avoidance of harm via “actionable knowledge”

Challenges from the real world

History and Insight complement Foresight & Precaution.

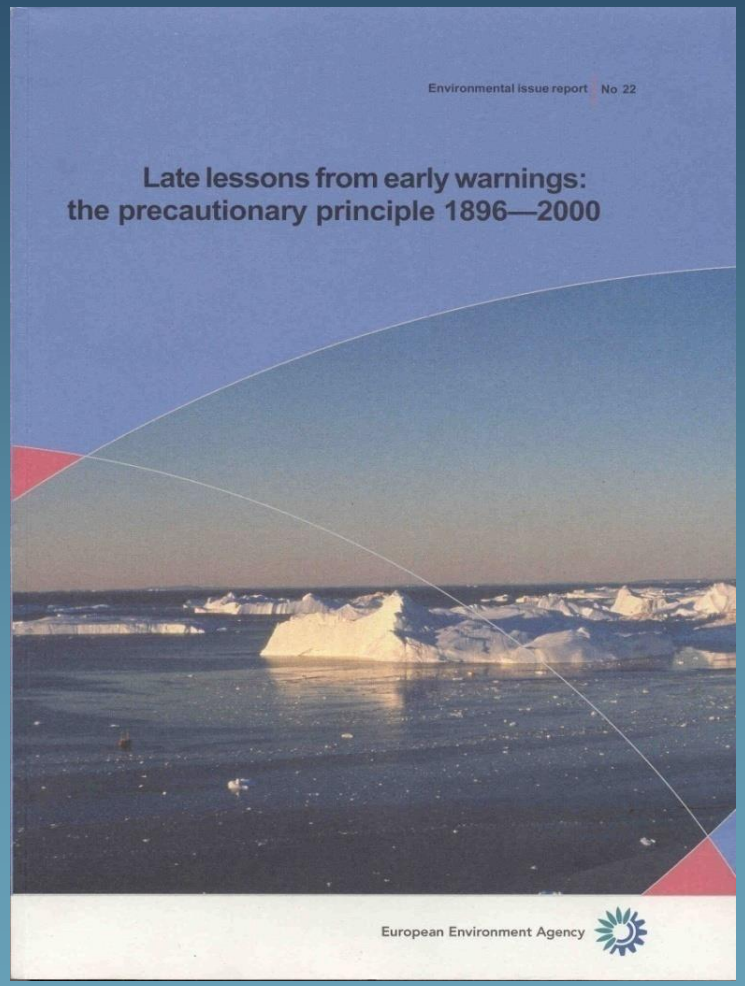
"History can offer something altogether different from scientific rules, namely insight….

..we study history in order to see more clearly into the situation in which we are called upon to act".

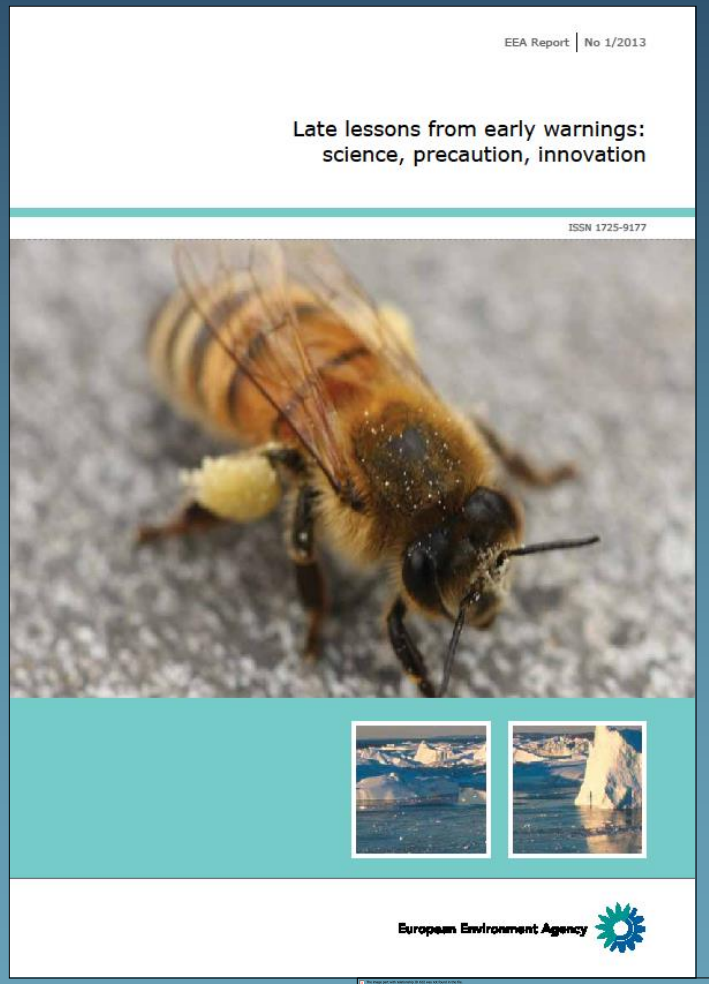
Collingwood R.G. Autobiography, 1939, cited in Preface, McGlade J, "Late Lessons from Early Warnings", EEA, 2013

Homo Sapiens (tragicus?) as slow learners?

2001



2013



34 case studies in ”Late Lessons” EEA, 2001/13

‘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**

Animal feed additives

- BSE, ‘mad cow disease’
- Beef hormones
- Antibiotics

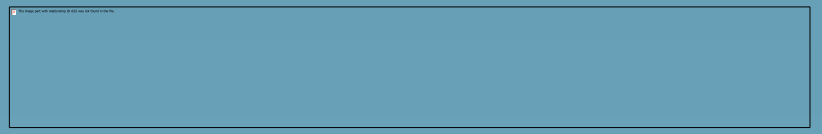
- Asbestos

Pharmaceuticals

- **Contraceptive pill**
- DES

Radiations

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



and 8 “horizontal “ chapters..

- the **“12 late lessons”** from **vol 1**…

..and in **vol 2**:

- **the precautionary principle;**
- **false positives;**
- **precautionary science;**
- **costs of inaction;**
- **protection of Late victims & early warning scientists;**
- **why businesses ignore early warnings;**
- **Conclusions.**

Late Lessons from Vol 1

- “Acknowledge & respond to **ignorance** as well as uncertainty and risk
- Provide **adequate research and long term monitoring** into early warnings
- Account for **real world** conditions
- Take full account for **assumptions & values**
- Adopt **diverse and adaptable technologies** to minimise costs of “surprises” and maximise benefits of innovation”
- Plus 5 others….

Late Lessons from vol 2..

- Give **more weight to natural, human, & social capitals** than economic/financial capital via more use of **precaution**, prevention, control at source and **polluter pays** principles (EU Treaty)
- Acknowledge **complexity & multi-causality** when inferring causality
- Use **lower strengths of evidence** for precautionary actions
- Seek & use **lay, local, professional knowledge & citizen science**
- **Develop broader more transparent risk assessments**
- **Build more effective, adaptable, participatory and cooperative systems of governance of innovation.**

Late Lesson 5, 2001: "Account for the real world"

- MTBE: storage tank leakage
- BSE: slaughter house (mal) practices
- Asbestos: "controlled (mis)use"
- TBT: sea microlayer accumulation
- PCBs: "controlled (mis)use; large spatial range; bioaccumulation
- Animal feed antibiotics: "controlled (mis)use"; mixtures
- Fisheries collapse: simplistic single stock models
- Beef Hormones: sensitive sub groups (young boys)

"Late Lessons from Early Warning" EEA, 2001

The dearth of data

Toxicity

- Of 2,500 >1k tons pa chemicals there is only c. 15 % that have sufficient data for a minimal OECD risk assessment (EEA, 99 & 2006).

- Of 1814 REACH dossiers for 1k ton chemicals "only one was fully compliant", 58% were "non compliant" and 42% could not be assigned.

  (Umweldbundesamt, 2015)

Exposure

- There is very little data on most exposures to ecosystems and people, particularly sensitive groups (e.g. children, frogs, bees)

“New challenges for Risk Assessment” EU

ECOLOGICAL RISK ASSESSMENT

“The approaches in current use for ecological risk assessment …….lack environmental realism. This entails high uncertainty…..has to be addressed by the application of uncertainty/safety/default factors”.

Scientific Committees, EU, 2013 , “Addressing the new challenges for Risk Assessment”

“New models are necessary for”:

- “The development of realistic scenarios, especially to predict temporal and spatial variations as well as bioavailability of chemicals;
  -
- Assessment of specific organism parameters to extend the applicability of bioaccumulation models in aquatic and terrestrial systems;
- Description of the food web path of chemicals, especially for terrestrial systems”.

“Human Risk Assessment”

- *“There is a trend/need to change the basis of risk assessment from the one based on standard tests to one that is centred on modes of action.*
- *more appropriate test selection through advancement of in silico approaches – such as (Q)SAR and read-across.*

- *A paradigm shift is likely from a hazard-driven process to one that is exposure-driven.*
- *And with “the progressive replacement of in vivo laboratory animal tests by in vitro tests”*

EU 2013

Unrealistic Risk Assessment for neonicotinoid pesticides and Bees

- Wrong risk regime: ie for **sprayed not sytemic** pesticides.
- **"Low" exposures** to bees assumed to be safe.
- **Neglect of sub-lethal & chronic** and **colony level effects.**
- **Neglect of systemic effects within hives cf bees**
- **Inadequate evaluation of multi-causality and complexity.**
- No/little **representation of beekeepers** & relevant academic researchers
- Independent critiques of RAs need **data access & transparent evaluations:** but these not available

"Late Lessons from Early Warnings", Bees chapter, Maxim L. & van den sluijs R, EEA, 2013

Some unrealities of Risk Assessments

- metabolites (PCBs, DDT)….
- adjuvants (glyphosphate)…..
- mixtures (diesel fumes, tobacco smoke, EDCs)….
- co-stressors (noise & solvents; smoking & radiations/asbestos)….
- bio-accumulations…(PCBs, DDT)
- sensitive sub groups (children/foetus; immuno-compromised, bivalves)….
- Non monotonic D/R curves (some radiations, BPA, lead, many pharmaceuticals)

……..are largely ignored, or downplayed.

Some unrealities of Risk Assessments

- Only one agent per RA at high doses
- Small nos of test subjects/animals
- Few foetal to lifetime (>2 yrs rodents) exposure studies
- Limited end points (few neurotox, developmental effects)
- Simplistic "uncertainty factors"
- Industry funded GLP studies dominate = good process but not usually the best science
- Most academic studies ignored
- study data confidential
- few independent studies.

Some Biases in Research & Risk Assessment

- **Methodological bias: mainly** towards false negatives

- **Funding** bias: See histories of Asbestos, Lead, some Pharma, Tobacco, BPA, & Mobile phones..where source of funding strongly predicts nature of the results

- **Intellectual bias**

- **Reporting & publication biases.**

Grandjean, Precautionary Science, Late Lessons,EEA ,2013

Two recent critiques of conventional risk assessment

- "Risk Assessment's insensitive toxicity testing may cause it to fail"

Buonasante et al. Environmental Research 135, 2014

- Environmental risk assessment of chemicals and nanomaterials: the best foundation for regulatory decision making?

Syberg K & Foss Hansen S., Science of the Total Environment, 541,2016.

Expect inconsistency from complexity & variability in ecology..

"the complexity of environmental factors and of bee colonies means that the same conditions can never be reproduced.

A particular combination of such factors arising in a field experiment ***cannot be considered representative of "average" environmental conditions*** *to which honey bees could be exposed"*

Maxim L ,van der Sluijs, R. "Systemic insecticides and honeybees" in Late Lessons, EEA, 2013.

Expect “Inconsistency” from Complexity in Environmental Health ……

"Consistency in nature does not require that all, or even a majority of studies find the same effect.

If all studies of lead showed the same relationship between variables, one would be startled, perhaps justifiably suspicious“

Needlemann (1995) ”Making Models of Real World events: the use and abuse of inference, Neurotoxicology and Teratology, vol 17, no. 3.

Expect “surprises” in scientific knowledge…

- From ***vertical to horizontal transferability*** of **antibiotic resistance via animal feed**
- From TSE diseases (**scrapie)** being limited to sheep, then transferable to cattle **(BSE),** then to humans (CJD)
- From ***probabilistic risk assessments to cascades of unexpected events*** and “incidents beyond assumptions” **(Fukushima)**
- From ***placental protection to foetal toxicity*** **(Minamata)**
- From ***single to multi-causality*** **(climate change; bee damage, cancer)**

the unrealistic search for the single cause..of all impacts.. at all levels!?

"The Risk Assessment ***does not allow us to demonstrate*** *that maize seed dressing with Gaucho can be* ***solely*** *responsible, at* ***national*** *level, for* ***all colony losses, behavioural troubles, honey bee mortalities, or general decline in honey production"***

French Commission for Toxic Products , 2002: see "Seed dressing systemic insecticides and honeybees", Maxim L. & van der Sluijs,J., Late Lessons from Early Warnings, EEA 2013.

or embrace multi-causality….

*“Gaucho…is of concern (on maize) as **one** of the **explanatory elements** **for the weakening of the bee populations observed** despite the ban of Gaucho in sunflowers.”*

Multifactor study of the Honeybee Colonies Decline, French Scientific & Technical Committee, 2003, see Late Lessons, Bees chapter

Expect Exposures to expand over time…..

- **producers, users, bystanders:** Asbestos, DBCP, Be
- **Family:** asbestos, tobacco
- **Environmental:** asbestos, lead,DBCP, tobacco, PCBs,
- **Consumers:** BPA; nano;
- **Next generations:** radiations, Mercury, DES, climate changes
- **Target to non target species:** pesticides, PCBs, TBT, the Pill

Expect the Nature of Harm to expand….

- **Asbestos**: 1929 asbestosis; 1954 lung cancer; 1959 mesothelioma, 2012 throat & other cancers
- **Tobacco**: 1951 lung cancer; 2012 many cancers, foetal harm; heart disease
- **PCBs**: 1960s bird reproduction;2012s neurological harm in children; soil contamination
- **Lead**: 1979 brain damage in children; 2012 heart disease, strokes, criminality in adults
- **Minamata:** 1950 brain damage & neurological; 1960s birth defects 1990s childrens IQ & behavioural
- **DES**: 1970 vaginal cancer; 1980s reproductive problems; 2012 breast cancer; sons repro harm;

Expect harm to be caused at lower & lower levels of exposure…

- Asbestos
- Lead
- PCBs
- Mercury
- TBT
- Radiations
- BPA….etc

….often with, eventually, no known threshold…

eg Lead (EFSA,2012), carcinogens (IARC)

“safe” exposure limits always come down…….

Costs of harm are largely paid by victims, insurance, and taxpayers…which inhibits innovation

- The **"external" costs of harmful agents** (eg biological & ecological damage and remediation) are rarely internalised into their market prices……

- a breach of the "polluter pays " principle..

- And **innovations on safer controls and smarter substitutes are held back** by "cheap" but harmful agents …..

Divergent Evaluations of “same” evidence on Tricholoroethylene

1995 IARC:

Positive animal & human evidence, plausible risk

1996 ACGIH:

Negative animal & human evidence, implausible risk

Ruden, C. 2001.

Conflicting evaluations of the BPA evidence

- “no health concern for dietary exposure, low health concern for aggregate exposure” (EFSA 2015)
- “ a potential risk to unborn children” (ANSES, France, 2013)
- “the doses that reliably produce effects in animals are 1-4 magnitudes of order lower than the current LOAEL..and many should be considered adverse” (Vandenberg et al 2014)

Some real world Initiatives to minimise harm and maximise innovation?

- independent, sensitive, & transparent toxicity testing,
- comprehensive & independent systematic reviews of evidence
- alternatives assessments
- radical green chemistry
- comparative hazard assessment of groups of chemicals
- From chemical products to chemical services
- More relevant research
- Stakeholder involvement in risk analysis
- Responsible innovation
- Precautionary prevention based on “actionable evidence”

Towards more systematic reviews of chemicals

"Implementing systematic review techniques in chemical risk assessment: challenges, opportunities, & recommendations", in press, Whaley et al, Environmental International.

Eg Navigation Guide (Woodruff & Sutton 2014), OHAT guide (Rooney et al 2014)

See also Gies and Soto chapter on BPA, Late Lessons, EEA, 2013

Toxics Use Reduction Institute (TURI)'s AA Process Guidance (2006)

BizNGO's CAA Protocol (2012)

European Chemicals Agency's Guidance on the Preparation of an Application for an Authorisation (2011)

NAS Framework to Guide Selection of Chemical Alternatives (2014)

The Interstate Chemicals Clearinghouse (IC2) AA Guide (2013)

US EPA Design for the Environment's AA Methodology (2011)

California's Department of Toxic Substances Control Stage 1 Alternatives Assessment Guide (2015)

Comparative hazard assessment of chemical Groups?

EG c 200 pesticides allocated to 3 groups: red (ban), orange (phase out), green (OK-but monitor) .

UK Coop Farms and shops/Howard V.

Car industry urges chemical industry to provide sustainable substitutes

In a letter to the European Chemical Industry Council (Cefic) Acea asks that chemical manufacturers “take responsibility” for the alternatives that have similar intrinsic properties to the hazardous chemicals they replace.

Chemwatch Nov 5 2015

Chemicals: from Products to Services.

UNIDO has launched a global programme that promotes the application of **chemical leasing** in industry in 10 developing countries.

The hydrocarbon solvent supplier supervises the application of the solvent in the process of cleaning equipment at General Motors Egypt and receives payment per vehicle produced instead of solvents sold and the supplier takes back the solvent waste for recycling.

Solvent consumption is reduced from 1.5 L to 0.85 L per vehicle.

“No evidence of Harm” is not the same as “evidence of no harm”……

...because no ***relevant* or *reliable* research** is available,

..or because of the limitations on what *could* be known with existing scientific methods, under **complexity and multi-causality**; and

...ecological/biological effects can take long time to appear.

EU Research: on developing products or protecting People/Environments?

EU Public Research 1994-2013	"Products"	"Protection" (EHS)
Nanotechnology (2002-2013)	5 billion	112 million **(2%)**
Biotechnology(1994-2013)	7.5billion	273 million **(4%)**
Information Communications Technology/EMF(2004-2013)	19 billion	18 million **(0.09%)**

“Scientific Inertia” in chemicals Research

- An analysis of 78 environmental and health journals 1899-2009 revealed most research focused on “well known” chemicals PCBs, sulphur dioxide, benzene, asbestos, TBT, MBTE and DES.
- **There were 15,000 articles published between 2000-2009 on lead, mercury and DDT alone.**
- **Only 352 articles researched 8 of the emerging, large production chemicals identified as priorities by the US EPA, eg 1,3-Dichlorobenzene.**
- There were no articles on five other US priority chemicals.

Responsible Innovation: adaptable technologies with a social purpose…?

- Expect **"surprises"** so promote **diverse, robust, adaptable, technologies"** (EEA,2001)
- Promote **responsible research & innovation for social purposes (EEA,2013)**
- **With public engagement in choosing strategic innovation pathways to 2050 eg on food, energy.**
- **Avoid technological lock in and pathway dependence**
- Promote **"midstream modulation"** of innovation pathways

"Innovations for peoples and planet more than for patents, profits and power" (Gee,2014)

Internalise “external” health & environmental costs into market prices

- Via taxes and tradable permits on harmful agents
- As on CFCs, pesticides, solvents, NOx, Carbon dioxide, TURA toxic chemicals, tobacco
- Introduced at the outset of possible/probable harm..
- With taxes /unit pollution rising in line with expanding knowledge of harm…
- **…with revenues used to fund innovations in better alternatives…(TURA toxics; US CFCs)**

The EEA working definition of the Precautionary Principle

"The PP provides justification for public policy actions in situations of ***scientific complexity, uncertainty and ignorance****, where there may be a need to act in order to avoid, or reduce,* ***potentially serious or irreversible threats to health and/or the environment****, using an* ***appropriate strength of scientific evidence****, taking into account the* ***pros and cons of action and inaction****, and their distribution".*

"More or less Precaution?", p649, Late Lessons from Early Warnings, EEA, 2013

Use of the Precautionary Principle stimulates innovation by:

- stimulating debate & action on alternative technological & social options for meeting needs

- bringing forward by years /decades the

innovations that were stimulated by the late regulatory actions

And saves billions in avoided damage costs that could have been spent on innovation.

Well-designed environmental regulations stimulate innovation

- **Incremental innovation from current firms, e.g., unleaded gasoline,**
- **More stringent regulations lead to radical/disrupting innovation from new entrants, e.g., displacement of Monsanto's PCBs by Dow Silicone's dielectric transformer fluid**

See Ashford N, MIT, 1978-2012: Porter M et al,Harvard Business School, 1995-2005; OECD, 2014

UK Environmental Regs benefit Society

"where £1 is spent on regulation (mainly by businesses and public authorities), there is a £3 return to society: mainly economic benefits to business and the public, and environmental and health benefits".

Emerging Findings from Defra's Regulation Assessment First update covering 2012
February 2015

A case for creating a new Nobel Prize in Transdisciplinary Science

David Gee

Genevieve Dewez

Susan Jobling

Institute of Environment, Health and Societies