Late Lessons from Early Warnings: A Retrospective Look At Learning About Precaution

CHE partnership call

April 16 2013

Socratic Questions on Emerging Environmental Health Hazards

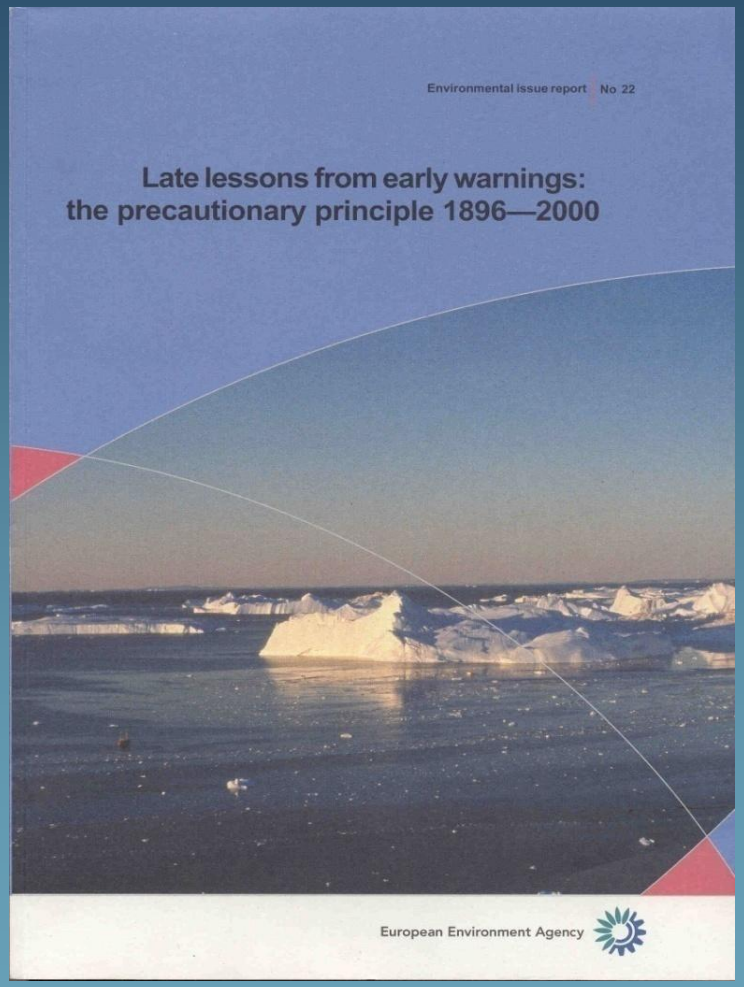
- What ***is*** known?
- What ***could be*** known, given **available tools** and **scientific complexity**?
- What **ought to be done** with what we do know to *prevent* harm…..
- ….**before we know too much** about the harm that was not prevented?

"To Know and not to Know: to Act or not to Act?"

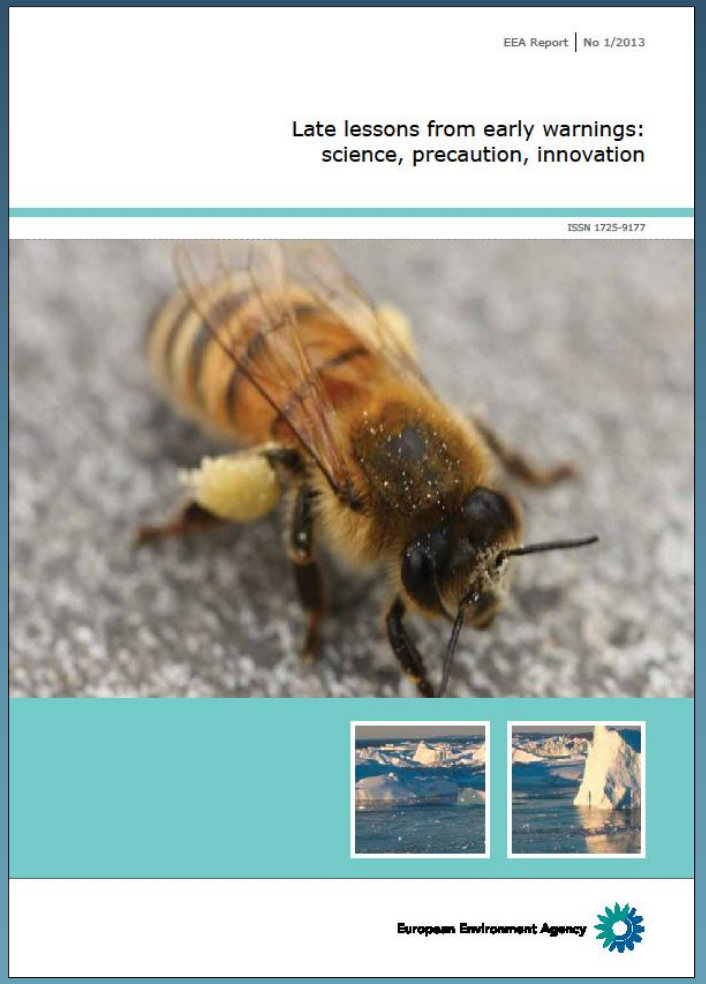
(P1, "Late Lessons from Early Warnings",EEA, 2001)

Homo Sapiens (tragicus?) as slow learners
Two volumes

2001



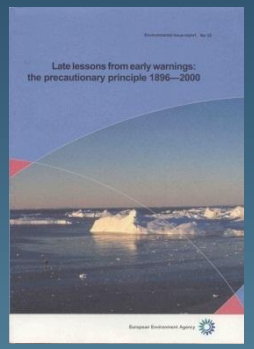
2013

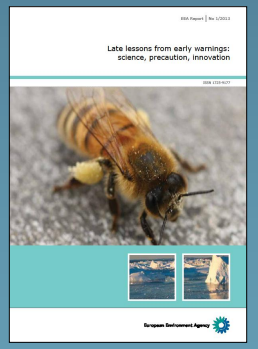


European Environment Agency

Two volumes - 2001 and 2013

- A thousand years or so of histories of well-known and emerging hazardous agents that have or may cause harm to people and ecosystems
- A thousand pages in two volumes
- 34 case study chapters





'never waste a tragedy'

European Environment Agency

34 case studies

'Environmental chemicals'

- Beryllium
- PCBs
- CFCs
- TBT antifoulants
- Mercury
- 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

Structure and content of case studies

- When was first plausible early warning?
- Where did that knowledge come from and what argumentation was used?
- What did societies do with that knowledge?
- What were the pros and cons of action or inaction?
- What can we learn about creating less harm in the future?

And 9 ‘horizontal’ chapters

- ‘12 late lessons’ in vol. 1
- 8 chapters in vol. 2
  - Ecosystems
  - ***Costs of inaction***
  - Precautionary science
  - ***The precautionary principle***
  - False positives
  - Protection of early warnings scientists
  - Conclusions

Substantive Content of Vol 2

"The relationship between knowledge and power lies at the heart of Volume 2. In many chapters, the implicit links between the sources of scientific knowledge about pollutants, changes in the environment and new technologies, and strong vested interests, both economic and paradigmatic, are exposed".

Preface LL v 2.

Aim of Late Lessons Vol 2

"..it is hoped that this volume will enable communities and people to become more effective ***stakeholders and participants in the governance of innovation*** *and economic activities in relation to the associated risks to humans and the planet".*

Preface LL 2.

New Governance structures needed

….if we are to respond more responsibly to the early warning signals of change, we will need to ***re-design our style of governance to one which reflects a future defined by the local and specific rather*** *than only the global and the average".*

Preface, LL2

3 Key lessons –Part A

- There was more than sufficient evidence for much earlier action;
- slow and sometimes obstructive behaviour by businesses whose products endangered workers, the public and the environment;
- the value of independent scientific research and risk assessments.
- Divergent evaluations of “same” evidence (BPA)

lessons from the degradation of natural systems –Part B

- issues of nature of scientific evidence as the basis for action/inaction,
- the multiple, often complex factors and feedback loops in play, many of which are not fully understood,
- the interfaces between science, policy and society
- how all actors can move together towards necessary actions in the context of heightened systemic risks, and substantial unknowns.

Part B

- Need for better institutional fit to managemnt demands of scientifically and socially complex ecosystems.
- Care with substitues (Booster biocides,ceramic fibres, benzene & MTBE, HFCs, systemic pesticides)
- Impacts on non target species
- Synthetic & natural hazards(pill,chlorine,lead asbestos

Part B

- EDCs and pharmaceuticals in environment
- Wildlife signals
- Extremely low but harmful exposure levels
- “high” Costs of removal from waste water (Swiss not so) plus secondary benefits eg pharma
- Complexity and uncertainty
- “externalising ”of costs (climate change)
- Manufacture of doubt (Climate change, tobacco, Be,)
- Handling of uncertainty (floods)
- Disciplinary and instituinal “silos”

Part C :some newly emerging and large-scale products, technologies:lessons

- societies are not making the most use of the costly lessons that can be gleaned from their histories.
- the novel and challenging nature of the issues;
- poorly or inconsistently evaluated information;
- strong opposition by the corporate and scientific establishments of the day;
- Favouring the status quo and the short term by institutions, practices and cultures

Part C –lessons

"illustrates the value of bottom up as well as top down approaches to innovations in ensuring that the directions of technological pathways, the equitable distributions of benefits, costs and knowledge ownership, and the diversity of locally sensitive technological options are relevant to the food, energy and ecosystems crises".

Better institutional fit to ecosytems needs

Some Costs of Inaction & Justice- Part D

- Costs and benefits of action are asymmetrical
- costs are short term, easily calculated & e exaggerated: distribution is specific
- Benefits are often long term,hard to calculate;and widely distributed
- High costs of inaction: demonstrated by multidisciplinay estimations

Benefits of action on CFCs

- Benefits of action from 1987 come mainly from 20 million skin cancers & 130 million cataract cases avoided (UNEP, 2009)
- And from "secondary benefits" of GHG reduction = 215 Gtons of CO2Eq over 2 decades=2150 billion Euro @ 10 E /tonCO2Eq= 0.5 % OECD GDP.

(Skou Andersen & Owain Club, "Costs of Inaction" chapter in "Late Lessons from Early Warnings", EEA, 2013).

Justice: and better reactions from Business?

- Early warners need protection
- Victims need better/quicker no fault compensation
- Wider use of precautionary, up front liability bonds from oil spillage & nuclear to large scale technologies potentially hazardous technologies eg GMOs Nano, mobile phones?
- legal innovations to cover joint liabilities and harm expansion, like asbestos.
- Reasons for business opposition need better analysis & options for cghanging course encouraged.

Science for precautionary decisonmaking

- Goals of science differt from policy making
- Much scientific research inertia
- No evidence of harm is usually not evidence of no harm
- Scientific methods err on generating false negatives
- Over use of statitical significance undr use of confidence intervals

More or Less Precaution?

- More useful EEA definition?
- Different strengths of evidence for different situations
- Opposition from vested economic& intellectual interests
- Low Knowledge/ignorance ratio needs more & independent research on hazards cf products
- Public engagement in onnovatikon and risk assesssment

Prevention & Precaution

- **Prevention: acting on known risks** eg on asbestos in 1990s; smoking in 1950s; fossil fuels in 2020s

- **Precaution**: **acting on suspected but uncertain and potentially costly hazards** eg asbestos in 1930s; smoking in 1950s; fossil fuels in 1990s

Common definitions of the PP

- See PP chapter in Late Lessons 2 for 13 definitions.
- All can justify action to **reduce harm in face of scientific uncertainty**
- But: no **explicit clarification of the strength of evidence needed to justify action**...ie in the "evidentiary space" below "scientific certainty"?
- And they are couched in **triple negatives** eg Rio definition.. and
- The **context ,case specificity, and proportionality of actions** are implicit..

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 or the environment, using ***appropriate strengths of scientific evidence,*** and taking into account the likely ***pros and cons*** of proportionate actions and inactions".

"More or Less Precaution?", Gee, Late Lessons 2)

Bradford Hill on different Strengths of Evidence, 1965

- ***"relatively slight evidence"*** for pregnancy pill ban
- ***"fair evidence"*** for reduced/eliminated exposure to probable carcinogenic oil at work
- ***"very strong evidence"*** for public restrictions on smoking, "fatty" diets, or burning coal.

Bradford Hill, The Environment & Disease: Association or Causation?", Proc Roy. Soc Med ,1965, 58, 295-300.

Some Strengths of Scientific Evidence….

- **Beyond all reasonable doubt**
  (scientific causality & criminal law)
- **Reasonable certainty**
  (Int Panel Climate Change(IPCC), 2007)
- **Balance of probabilities/evidence**
  (IPCC, 2001; civil law)
- **Strong possibility** (IARC on ELF, 2002; on RF 2011)
- **Reasonable grounds for concern** (EU Commission on PP, 2000)
- **Scientific suspicion of risk** (Swedish Chemicals Law, 1975)
- **"Pertinent information"** (WTO SPS justifying member state actions to protect health)

*which are appropriate for different purposes, depending mainly on the **costs of being wrong** in acting/not acting*

The “appropriate” strength of evidence for precautionary action is an ETHICAL choice, not a Scientific issue

*Who loses what from **being wrong** in acting, or not acting, early enough to prevent harm?*

Short term economic interests?

Or the **longer term health & wellbeing of people and their environments?**

The PP and regulations can stimulate Innovation

- Porter (Harvard Business School)1995,2005
- Ashford (MIT) 1978 ,2012
- EEA: Well designed environmental taxes stimulate innovation(EEA 2012)
- Not using the PP leads to **"technological monopolies**" e.g. '**cheap' (ie costs externalised** to society) asbestos, benzene, PCBs, CFCs, leaded petrol, fossil fuels which ***stifle innovation*** for decades
- **"False positives"?** Only 4 of 88 analysed were FPs –see Late Lessons chapter, Foss Hansen.

Asbestos *Exposures* expand: to producers, users, bystanders, families, the public..

- Asbestos **users** (eg **insulators,construction**) were more at risk than asbestos **producers**…..
- It was therefore a "stupid mistake" (Julian Peto, 1998) to focus studies on factory workers, not users.
- Many mesothelioma deaths are now
  - **domestic** (washing overalls, children of asbestos workers, Newhouse ,1965) and
  - **environmental** (living near mines and factories (Dutch Health Council,2010;
  - **teachers** (UK Select Comm on Asbestos in schools 2013.)
- ***Lessons for nano, BPA & other chemicals where product users are more at risk?***

Exposure expansion in other case studies

- Lead-global
- Tobacco-environmental.foetus
- Mercury-global, foetus
- DDT-global: helped inspire POPs treaty
- CFCs-global
- Fossil fuels -global

Nature of the Harm expands with time & is caused by ever lower levels of exposure.

- **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 in adults

  And all caused by lower, then lower, levels of exposure usually with no known threshold…eg EFSA ,Lead ,2012.

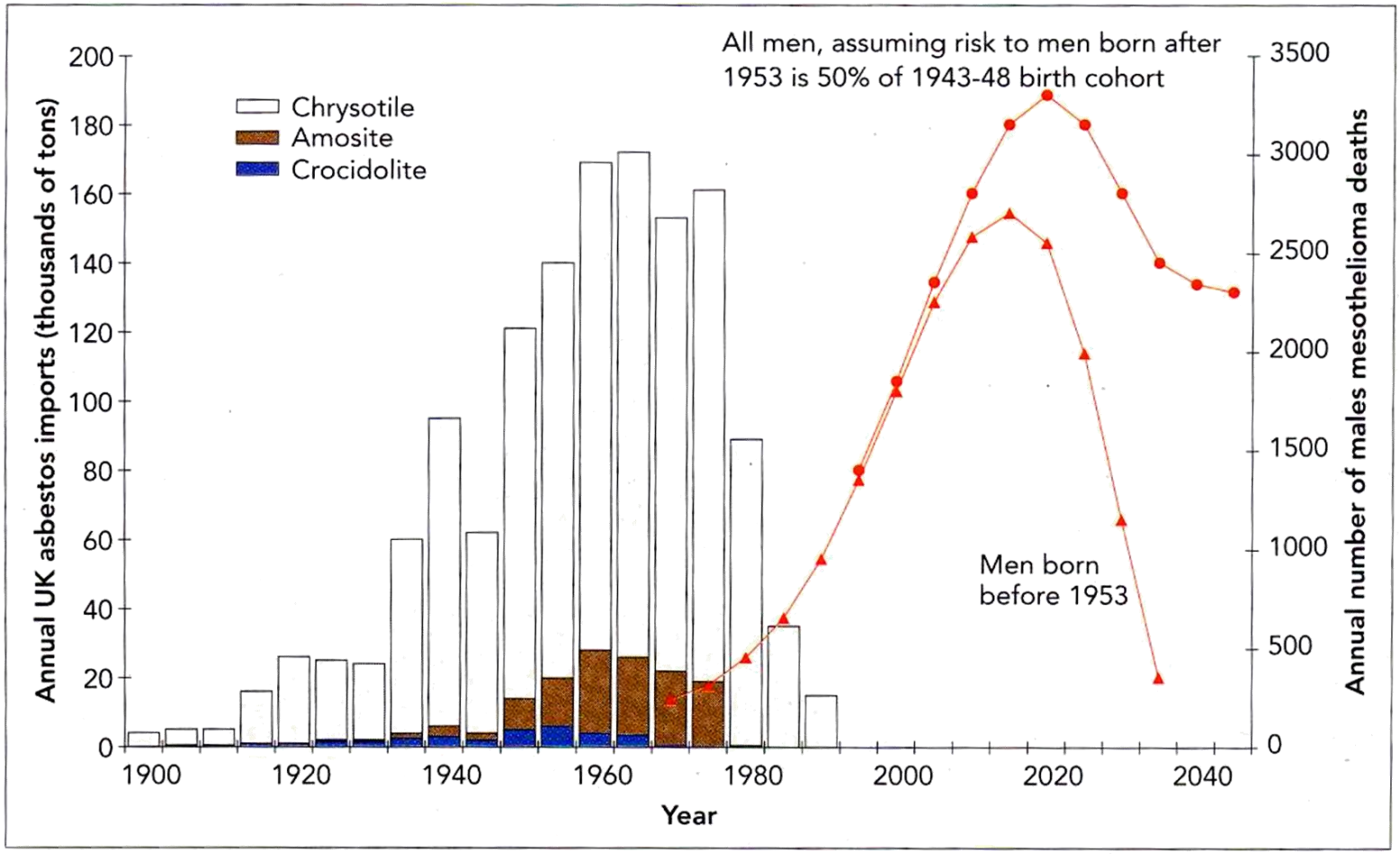
Asbestos: the Early Warning,1898

"the evil effects of asbestos have also instigated a microscopic examination...clearly revealed was the sharp glass-like jagged nature of the particles, and when they are allowed to rise and to remain suspended in the air of the room in any quantity **the effects have been found to be injurious as might have been expected"**

Lucy Deane, Factory Inspector ,1898, cited in "Asbestos: from magic to malevolent mineral", Late Lessons from Early Warnings 1 EEA,2001, p11)

Predicted Asbestos Deaths

UK asbestos imports and predicted mesothelioma deaths



Some Costs of inaction: Asbestos

- 2000-2035: **400b euro** in costs to society-EU **cancers only**
- Asbestos Removal..? Billions…
- Near collapse of Lloyds Insurance via US asbestos compensation cases

The real costs of Asbestos were mainly paid by victims, insurance co's, and taxpayers…

- The "external" or social costs of asbestos (e.g. costs of harm, contamination, and safe removal) were **never internalised into the market price of asbestos……**
- which meant that **innovation on substitutes was stifled** by **"cheap", monopolistic** asbestos…..
- and research/treatment/removal costs were **paid mainly by taxpayers**:
- a breach of the **"polluter pays " principle**

Lessons for endocrine disrupters; from DES,TBT, birth control Pill

1930s: animal studies had demonstrated the carcinogenicity of DES

1954 study showed that DES did not actually work

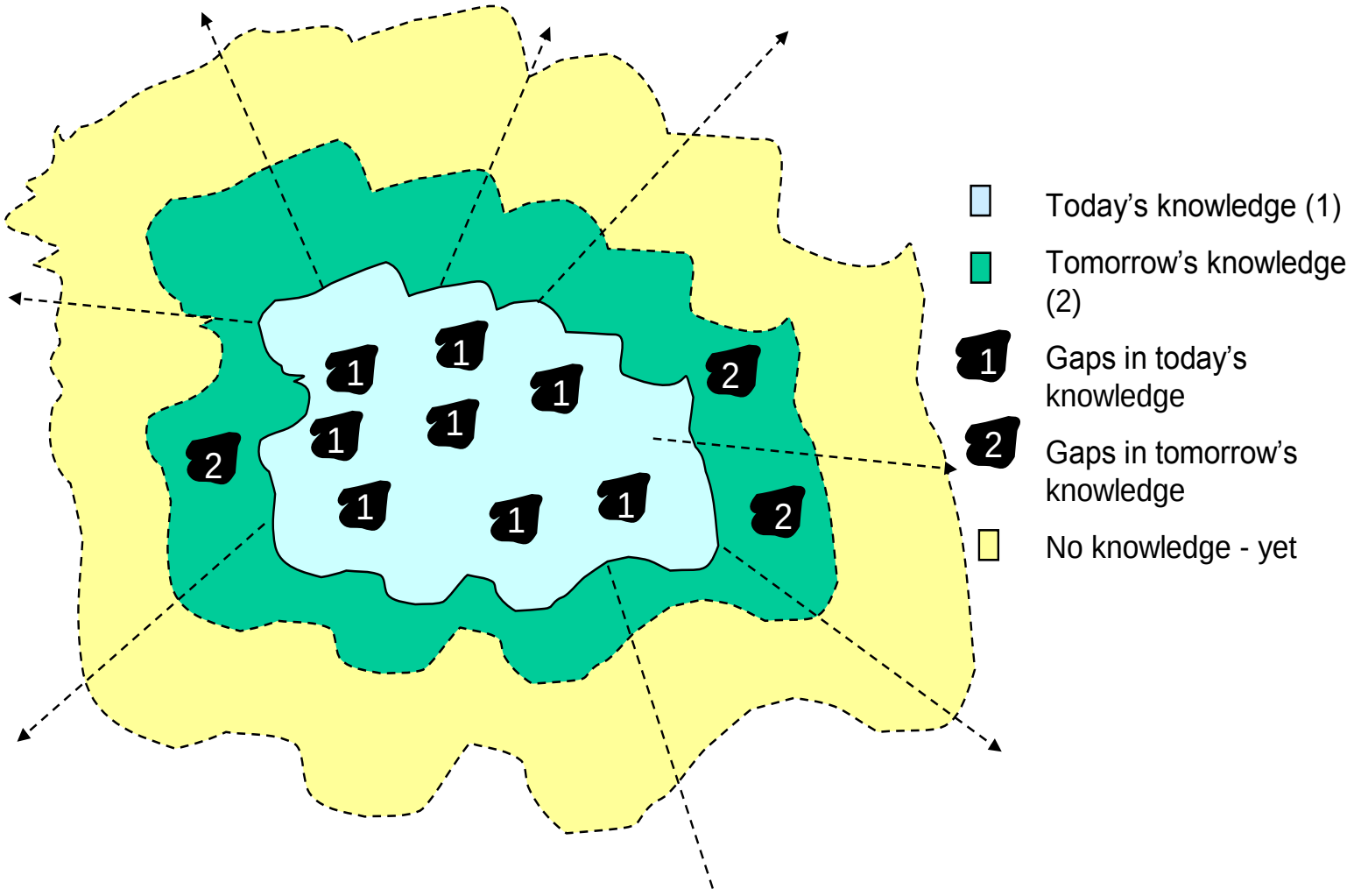
Precautionary action then would have prevented at least some of the **cancers and/or reproductive problems in the young daughters and sons, and now their children,** of the women who took the DES pregnancy pill in the 50s/60s which was banned in 1970 after 7 cases of vaginal cancer in DES daughters.

See chapters on **TBT (vol 1) and contraceptive pill (vol2): sex changes in sea snails and river fish.**

Timing of dose is critical..

Lessons for other endocrine disrupters?

‘Knowing’ and not knowing: A dynamic expansion……



….and “complexity” increases.

European Environment Agency

“Acknowledge complexity, variability, uncertainty”(Late Lessons 2)

- “much harm eg from cancers and climate change to decline in bees and in children’s IQ is caused by **co-causal factors acting independently or together in complex systems** ”
- **“Low dose effects** can be greater than high doses” (radiations, BPA)
- **“Varying susceptibilities** from age, sex, immune state, stress, genes, epigentics…“
- **“there are often continuums from “effects” to “adverse” effects..”**
- **“But sometimes with thresholds & tipping points…”**
- **“Systems level effects are** not predictable from individual cells/organisms/events eg cancers;bee colonies; climate
- More **transparency about uncertainties** in risk assessments.

Problems with initial/later RAs for Gaucho Pesticide & bees*.

- **Wrong exposure estimates**
- Acute effects only
- Wrong risk regime : application rate/LD50
- **No/little representation of beekeepers & academic researchers**
- **Over reliance on GLP studies (procedural quality not scientific quality/relevance**
- Inappropriate standard tests.
- **Independent critiques of RAs need data access & transparent evaluations** but these not available

** Maxim & van der Sluis, Late Lessons 2.*

Further Problems with RAs…

- specialised researchers are not involved enough eg bee experts; endocrinologists

- **Poor and intransparent Uncertainties analysis (see also *"Environmental Decisions in the Face of Uncertainty" IOM,USA,2013***

- Analysis of "expert judgements" on causal mechanisms has shown **divergent evaluations of same evidence: unwelcome knowledge is often ignored; assumptions, values, reasonings often intransparent**

Detailed quality analysis of risk assessments is needed at least for the most toxic molecules
(Maxim & van der Sluis)

The **"Authoritative but unsubstantiated Assertion"** on Asbestos, 1906.

"One hears, generally speaking, that considerable trouble is now taken to prevent the inhalation of the asbestos dust so that the disease is not so likely to occur as heretofore".

Dr Murray, evidence to UK Government Inquiry into Industrial Diseases.

The “authoritative but unsubstantiated assertion of safety” on CFCs..

the ***“only thing that has accumulated so far is a number of theories”,***

(Prof Scorer, New Scientist, 19 June , 1975....in response to the 1974 “early warning” theory of Rowland & Molina about the accumulations of CFCs probably causing an ozone hole---for which they later got a Nobel prize…

See also Leaded petrol, climate change, Gaucho & bees, cell phones chapters for similar assertions about early warnings..

The Classical Bradford Hill "criteria" for causation, 1965 & 2013 ***given multi-causality and complexity ?***

Strength of association..**only weak/medium from multi-causality**?
Consistency..**expect inconsistency from complexity?**
Temporality..**less clear with multi-causality?**
Specificity of effect…**multi-effects?**
Biological gradient ie linear dose/effect..**non-linear effects?**
Biological plausibility….**in complex,unknown, novel situations?**
Coherence…**ditto**
Analogy…make more use of the relevant "known"
Experiment ie prevention **worked…not easy to show under multi-causality**

…..so what weight should we attach to each in 2013?

Bradford Hill, The Environment & Disease: Association or Causation?", Proc Roy. Soc Med ,1965, 58, 295-300.

"Consistency" of research results?

Expect inconsistency from Complexity

***"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)

(See Needleman & Gee, "Lead makes the mind give way", and PP chapter Late Lessons 2)

Bradford Hill recognised his “criteria” were asymmetrical

The ***presence*** of the “criteria” provides good evidence ***for*** causation; but

their ***absence*** may not provide good evidence ***against*** a real association.

And, given what we now know about multi-causality and complexity in biological & ecological systems,

this asymmetry is now larger than in 1965

Is "Negative" Evidence really Non-Positive Evidence?

- "***No evidence of Harm"*** is not the same as ***"evidence of no harm"……***

- Because ***no relevant research*** is available **or** because of the **limitations on what *could* be known with existing methods, under complexity and multi-causality.**

What is the "**Knowledge/Ignorance Ratio**" & **Research Focus**?

- The K/I ratio is **high** (much Knowledge, little Ignorance) for **Asbestos**, after 111 years of research since first "Early Warning" in 1898…
- But the K/I is **low** (little Knowledge, much Ignorance) for most **Chemicals, Nanotech, GMOs, EMF/RF**, ….
- Partly because there has been much more Research Expenditure into **Technological Applications** than on **Hazards**

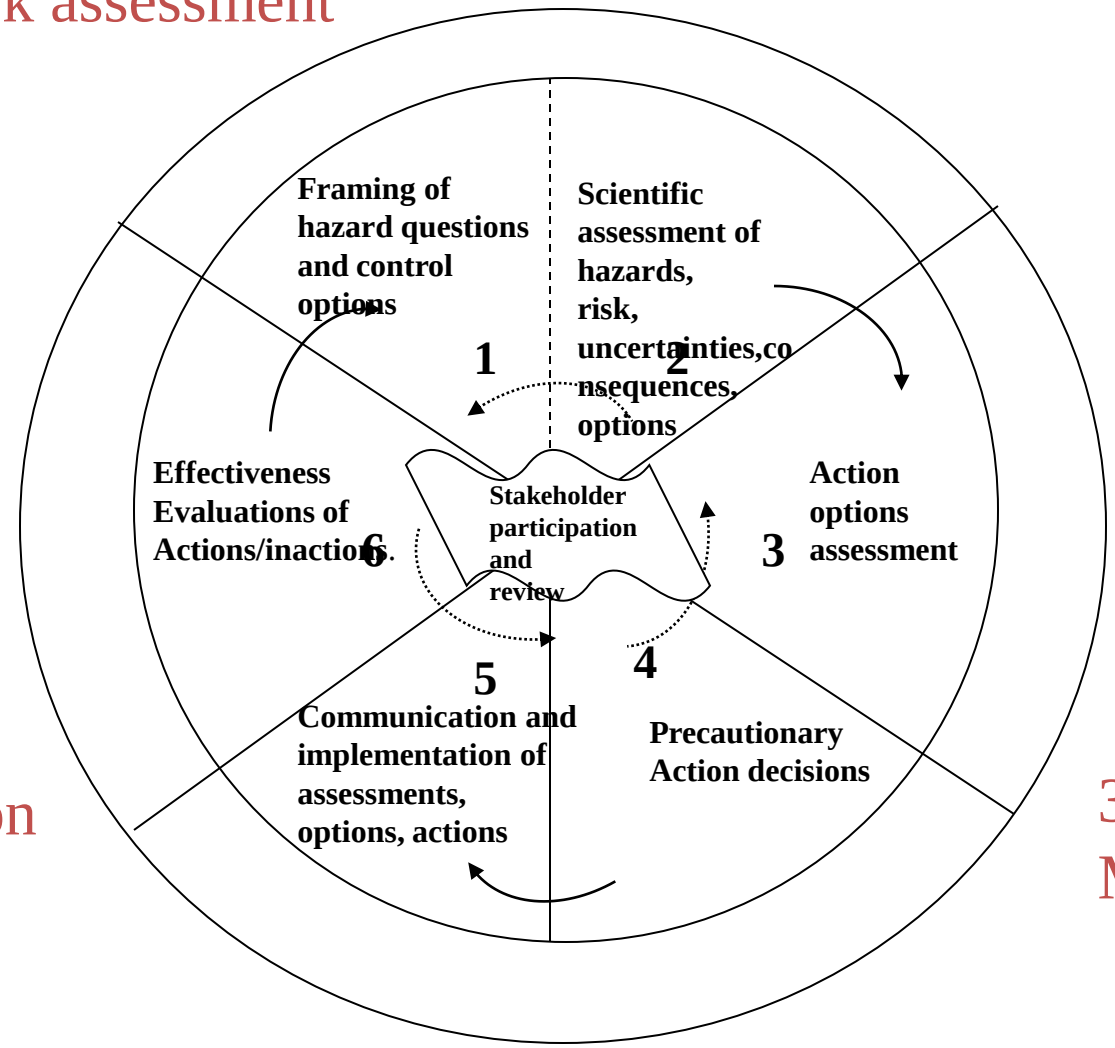
See Nano, GMOs, EMF chapters in "Late Lessons", vol 2, EEA, Jan 2013.

Research: how much to develop products and to protect People/Environments?

EU Public Research 1994-2013	"Products"	"Protection"
Nanotechnology (2002-2013)	5 billion	112 million **(2%)**
Biotechnology(1994-2013)	3.5billion	203 million **(8%)**
Information Communications Technology/EMF(2007-2013)	20 billion	9 million **(0.005%)**

A Participatory & Precautionary Framework for Hazard & Risk Analysis.

1+2 Risk assessment



5+6 Risk Communication

3+4 Risk Management

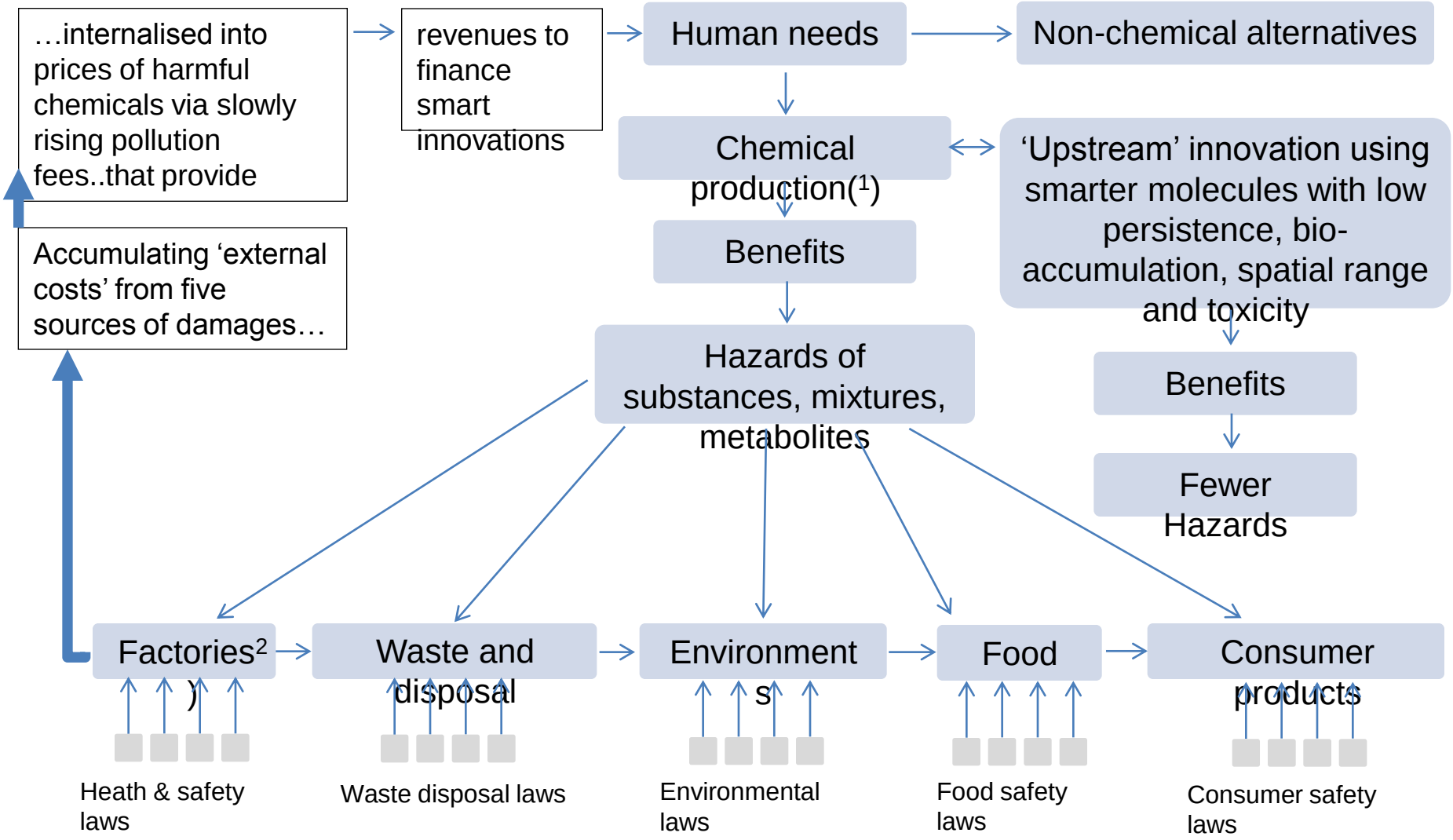
EEA ,based on NRC,(1996) , US Presidential Commission on Risk (1997), UK Royal Commission on Environmental Pollution (1998) , and NAS, "Science and Decisions," 2009

More incentives to avoid harm, more justice for victims?

- Up front, redeemable **precautionary liability bonds** from creators of large scale new technologies & products?
- **Internalisation of external costs** of damage to health & ecosystems as they occur via taxes & regulations…with revenues being used to fund research into smarter alternatives?
- **No fault & precautionary compensation** for victims?

(See chapter 24, Carl Cranor, Late Lessons 2)

Approaches to hazardous chemicals: upstream innovations? or downstream 'fingers in the dyke'?



(1) Many industrial chemicals originate as by-products (and 'wastes') of other industrial activities, especially oil production

(2) Plus harm to worker's families e.g. from asbestos, lead, beryllium, radiation etc