

“From historical insights to policy foresight: some ‘late lessons from early warnings’ about chemical hazards”.

David Gee

EEA (Retired), Senior Adviser, Science ,Policy, Emerging Issues.

Visiting Fellow, IEHS, Brunel University, London.

Oct 1st 1977 to Oct 1st 2020: a personal reflection..

- Oct 1st 1977: the Safety Representative Regs come into UK Law..
- Helping to start my working life “On the Edge” of science & policymaking in Occupational Public & Environmental Health..
- 1988 the “toxics/ societal trade off” personal agreement with ICI CEO..
- Writing EEA 1999 Report *“Chemicals in Europe: low doses, high stakes?”* which influenced REACH creation..
- Oct 1st 2020: presentation to the Chemical Stakeholder Forum on some key insights 1974-2020.



Europe in Bloom: a living façade at the EEA Copenhagen



BIODIVERSITY

Summary

- *“Late Lessons from Early Warnings”* EEA, 2001, 2013
- **Contexts**: our Scientific & Chemical worlds
- **Mixtures** & Groups: from tobacco smoke to PFASs
- **Incentives & Innovations**: from SO₂, CFCs, TURA, & Pthalates to Electronics toxics & Marijuana!
- **Controlling Complexity via Robust Simplicity?**
- **The Innovation and Foresight (precautionary) Principles.**
- **Some Benefits of chemicals regulations**

34 case studies in 2 vols EEA 2001, 2013

RED= 24 chemicals chapters

BOLD= Vol 2

'Environmental chemicals'

- **Beryllium**
- PCBs
- CFCs
- TBT antifoulants
- Mercury
- Tobacco
- Perchloroethylene
- Booster biocides
- DBCP
- DDT
- Vinyl chloride
- Bis phenol 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 v Agroecology

Animal feed additives

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

- Asbestos

Pharmaceuticals

- Contraceptive pill
- DES

Radiations

- X-rays
- Mobile phones
- Nuclear: Fukushima

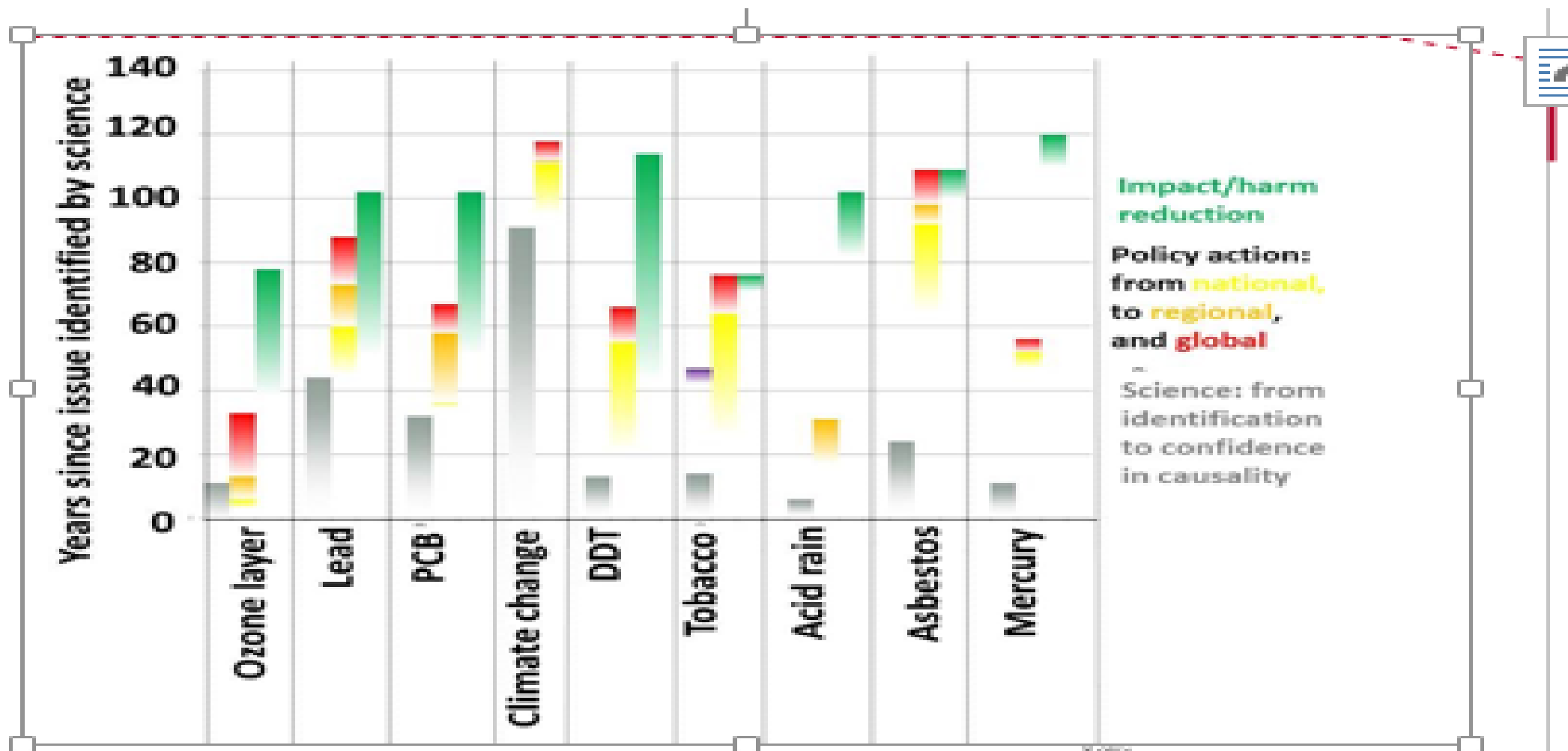


Useful truths' take years to be 'generally received'

*“You will see that the opinion of this mischievous effect from **lead** is at least 60 years old; and you will observe with concern how long a useful truth may be known and exist, before it is generally received and practiced on”*

Benjamin Franklin, 1818.





Source: Produced by UNEP colleagues based on EEA reports^{10,11} and various sources cited in the text of this section.

Notes: The timeline for ozone layer and lead are provided in the text, those for PCB^{12,13}, climate change^{14,15}, DDT^{16,17}, tobacco¹⁸, acid rain¹⁹, asbestos²⁰, mercury²¹ can be found in the footnotes.

Research eventually shows that **Exposures** expand over time.....

- producers, users, bystanders eg insulators, plantation workers, passive smokers **Asbestos/DBCP/Be**
- **Domestic:** asbestos mesothelioma deaths from washing overalls; children of **asbestos workers; smokers families**
- **Environmental:** **asbestos; lead, DBCP** in water; tobacco; **PCBs; benzene**
- **Consumers:** **Asbestos, PCBs, Mercury, BPA; Nano;**
- **Next generations:** **Asbestos, radiations, Mercury, DES,** Tobacco, climate changes
- **Target to non target species:** **Goucho** & Bees; Polar bears & fish from **PCBs**; oysters from **TBT**; fish from the **contraceptive Pill**

& the **Nature of Harm** expands over time....

- **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**
- **Minamata**: 1950 brain damage & neurological; 1960s birth defects 1990s childrens IQ & behavioural
- **DES daughters**: 1970 **vaginal cancer**; 1980s reproductive problems; 2012 **breast cancer**; **sons** reproductive harm.

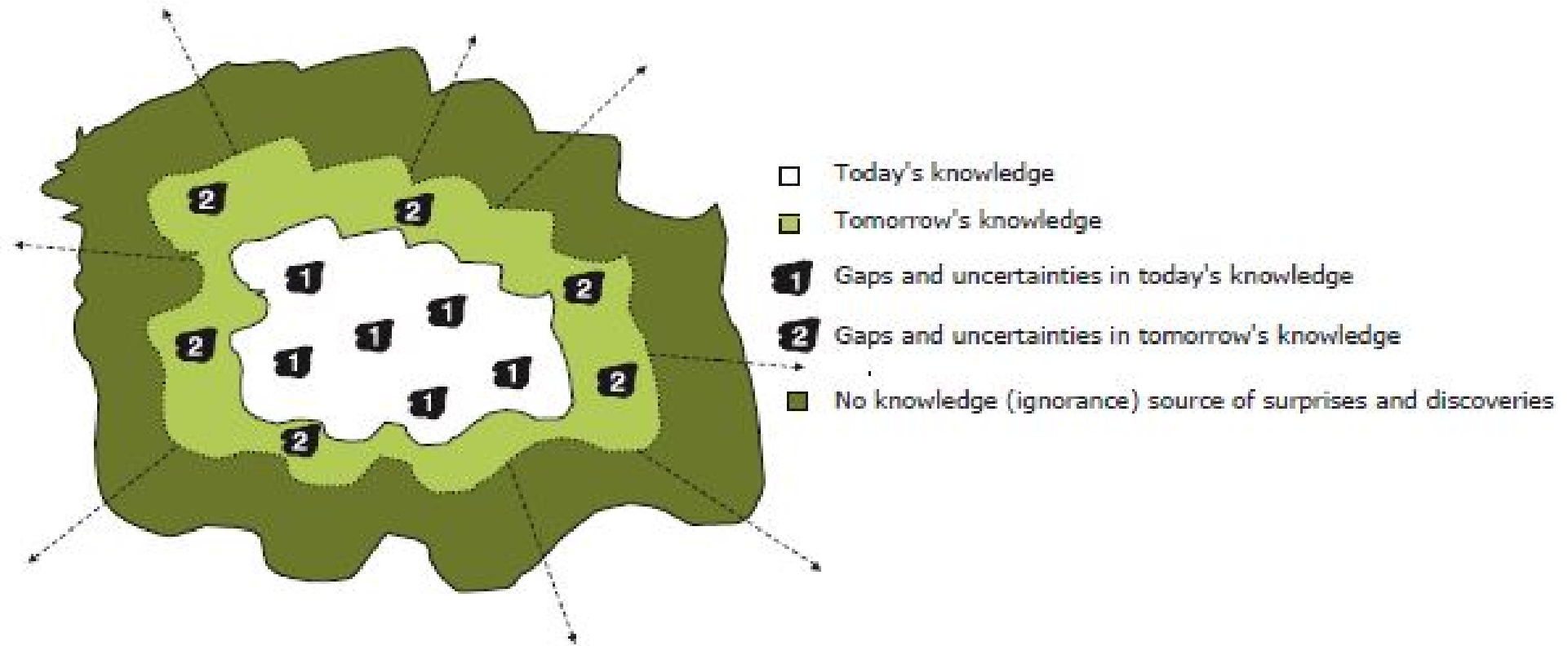
And harm is caused at lower & lower levels of exposure...

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

*often with, eventually, no known threshold...
eg Lead (EFSA, 2012).*

** “safe” limits always come down.....with rare exceptions*

Knowledge expands.....
..as does complexity, uncertainty &
ignorance ("nescience").....



Acknowledge Scientific Ignorance (*“nescience”*)

- “Manage risk, **uncertainty, and ignorance**”
- “Identify/reduce **“blind spots”** in the science”

(Two of the “!2 Late Lessons” from “*Late Lessons from Early Warnings*” vol 1)

***“Knowledge is a big subject. Ignorance is bigger
And it is more interesting”***

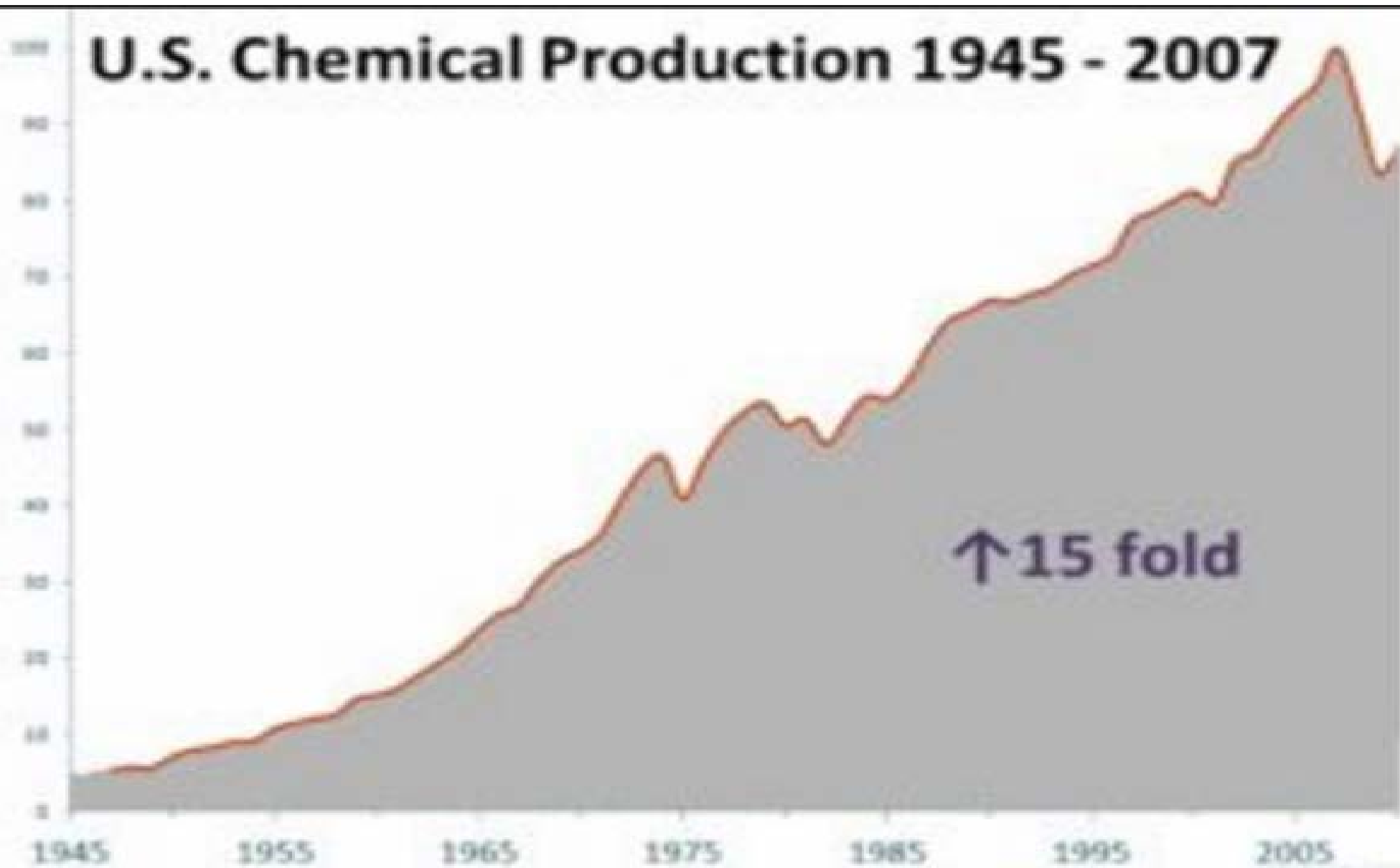
“Ignorance: How it Drives Science” Stuart Finstein, MIT, 2012

Some Implications of Complexity

- Expect “inconsistency” in research results from complexity, variability, multi-causality..
- “Coaxing causality from complexity” will not be easy..
- The asymmetry in Bradford Hill’s 9 “features “ of evidence for causality is greater than in 1965..
- Requiring use of lower strengths of evidence for timely action.....
- And increased education/awareness of these implications...

See “*The Language of Links between A and B*” ,Gee, Oct 2020.

U.S. Chemical Production 1945 - 2007



Data from: U.S. Federal Reserve Board, Division of Research and Statistics



Program on Sustainable Development and the Environment

Beneficial Chemical production/consumption is shifting...but chemicals are mainly hazardous

*“A **shift in production** has taken place and is still taking place, principally from the EU, the United States and Japan, principally **to China, Brazil, Russia and India.**”*

“Less than 50% of all chemical products (in numerical terms) are classified as hazardous to health but

80% of the **quantity** is hazardous to health”

Chemicals often present hidden & **complex** hazards.....

- With exposure to complex mixtures of chemicals in consumer products
- and to endocrine disrupting...
- **neuro-toxic..a/o**
- **immuno-developmental** chemicals
- Often during **sensitive** “windows of vulnerability” eg pregnancy (causing intergenerational effects); **childhood**; and old age
- **Some with “Low dose”** effects ie **greater than at high doses**.....
- with **persistent & bio-accumulative** impacts on **people and ecosystems, sometimes outside the EU**, e.g. in **the Arctic**:
- **& now in the (to be “isolated”) UK...**

Mixtures are the reality: and often the more harmful exposures..

*“So prolonged **exposure to aldehyde mixtures** **may have a more serious risk** to respiratory system in animal and human than the expectation based on the toxicity of single aldehyde, even at environmentally relevant concentrations”.*

*Yet **“95% of studies in toxicology** still have been devoted to studies of **single chemicals so far**” (1998)”*

“The multiplex interactions and molecular mechanism on genotoxicity induced by formaldehyde and acrolein mixtures on human bronchial epithelial BEAS-2B cells” .Environment International, 143, 2020.

*Sen Zhang et al, China National **Tobacco** Quality Supervision & Test Center.*

Mixtures and Metabolic Syndrome?

- “*Metabolic syndrome (MetS)* patients have a considerably increased risk for non communicablediseases, which poses a **serious burden on public health**.
- MetS was **negatively** associated with Mg and Se and **positively** associated with Ba and Hg.
- With **significant dose-response relationships** between Mg, Se, Ba and Hg and MetS,
- **suggesting that multiple elements may be involved in MetS**”.

“Multiple-element exposure and metabolic syndrome in Chinese adults”. Zhang, et al, School Pub Health, Capital Medical Uni., Beijing.

Mixtures of Metals?

*“The results **suggest that** prenatal exposure to lead, chromium, stibium and strontium **may affect** TV and/or AGD in infant boys.*

***Potential mechanisms** for the **complex metal interactive effects** during **vulnerable periods** are worthy of further investigation”*

Associations of prenatal exposure to multiple metals with testicular volume and anogenital distance in infant boys: A longitudinal cohort study. Lulu Huang, et al Dept of Occ and Environmental Health, School of Public Health, Guangxi Medical University, Nanning, China. Env Int ,2020.

BFRs/PBDEs as “Legacy” toxics...via “Essential Uses”?

- “Polybrominated diphenyl ethers (PBDEs), **a class of** brominated flame retardants (BFRs), **ubiquitous environmental pollutants** in electrical appliances, plastics, and furniture upholstery.
- mounting evidence **demonstrates that** human exposure to PBDEs is **associated with thyroid hormone disruption, neurodevelopmental deficits**, and other adverse human health outcomes
- PBDEs are **relatively persistent** with the potential for **long-range transport** and **bioaccumulation** in wildlife and humans
- Stockholm Convention for POPs listed commercial **penta- and octa-BDEs** in 2009, and **deca-BDE** in 2017
- Banned or phased out by most major global entities, PBDEs are **continuously detected in the environment** due to
- their register of **specific exemptions and stocks in in-use** products”. (**“Essential uses”?**)

“Accumulation and translocation of polybrominated diphenyl ethers into plant under multiple exposure scenarios” Hongkai Zhu et al , Coll. of Env. Science and Engineering, Nankai University, China

Neonicotinoid pesticides mixtures ...and children?

- “Six *neonicotinoids* (thiamethoxam, clothianidin, imidacloprid, acetamiprid, nitenpyram, and dinotefuran) and *three metabolites* (N-desmethyl-thiamethoxam, N-desmethyl-clothianidin, and N-desmethyl-acet-amiprid) were detected *in 81.3% of urine samples of children.*
- “Toxic Trespass”?
- *Tap water and fresh vegetables* were potential sources.
- *A low risk was posed on children's health by the neonicotinoids”*

“Predictors, sources, and health risk of exposure to neonicotinoids in Chinese school children: A biomonitoring-based study” Wang H et al School of Public Health, Fudan University, Shanghai, Env Int., 2020

Mixtures and Groups: from Tobacco Smoke to PFAS

- Tobacco Smoke-c 3000+ substances
- Welding Fumes-c 00s of substances
- Hot Rubber Fume-c 00s of substances
- Paints in shipyards-c 00s of substances
- Dioxines-c dozens of substances?
- PFASs-c 3000+ substances

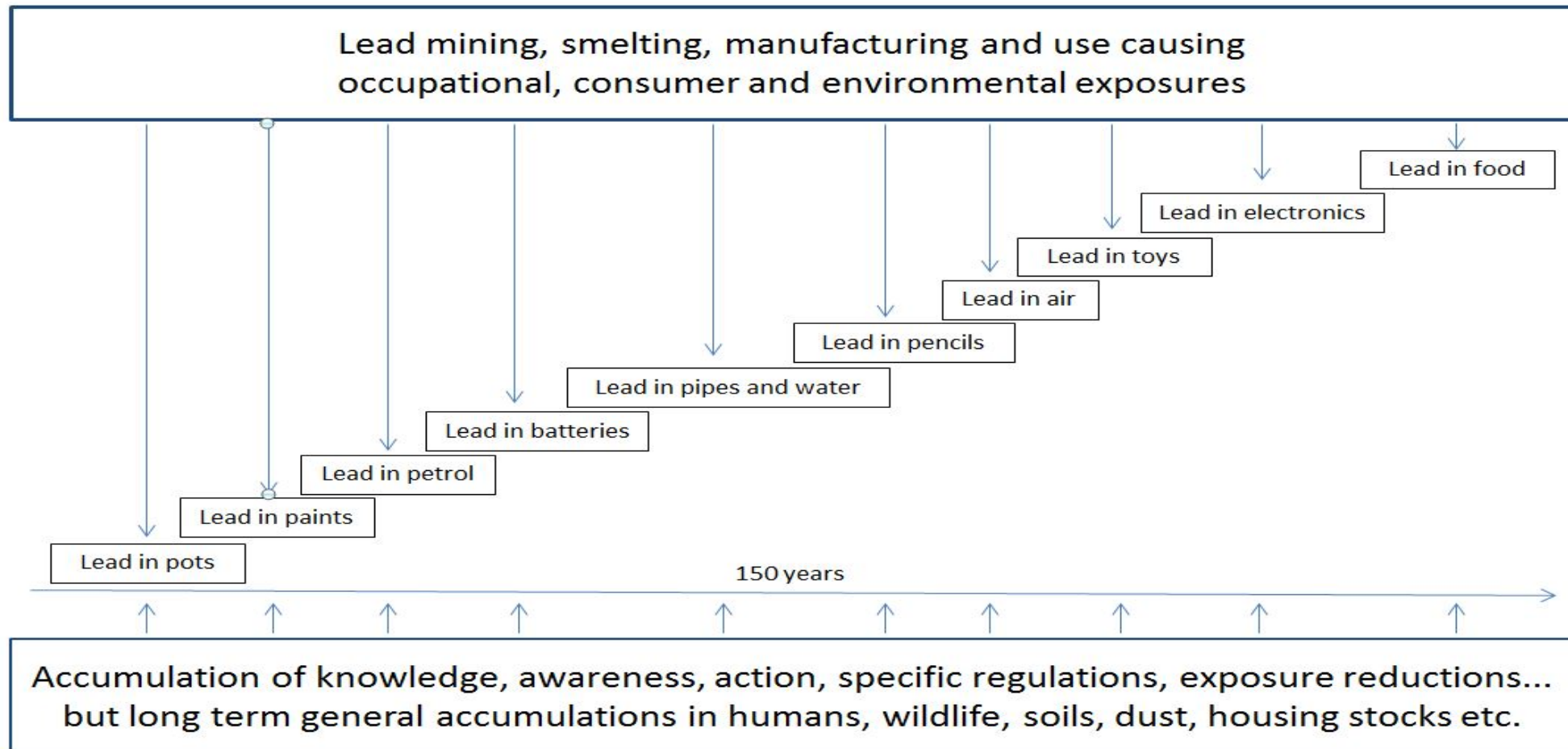
Group control via **Total Fume exposure limits/labels/ “Toxics Taxes”/phased bans: “sunset regs” etc**

“Control complexity by robust simplicity?”

From **“Fingers in the Dyke”** approach (1833-2020)

to **“Upstream Incentives and Innovation” 2020-2030?**

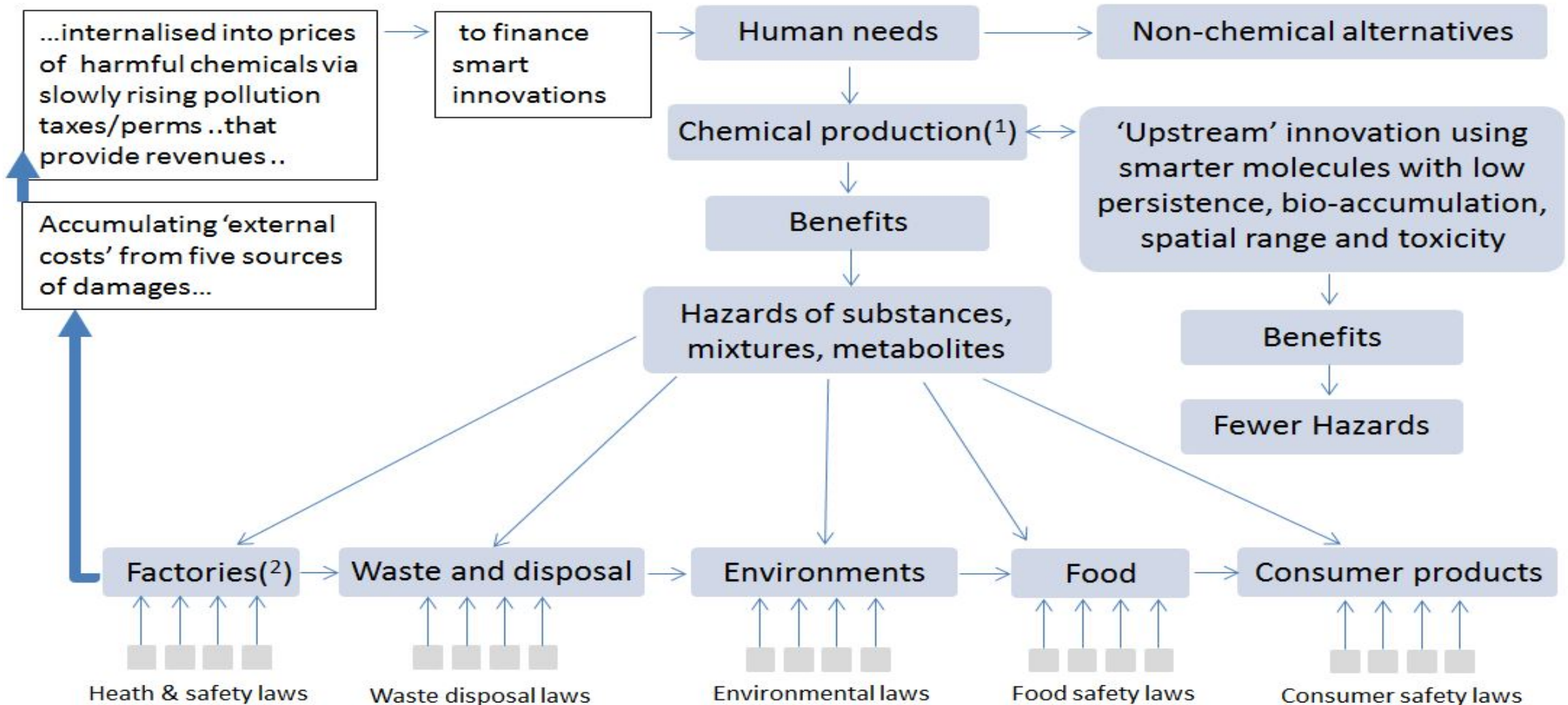
Lead production, flows, impacts, regulations, accumulations_over 150 years! "fingers in the dyke"



Would an upstream approach of limiting flows of lead through the economy be more effective and timely than regulations after specific harms occur? Is this a lesson for consumer chemicals now?

Upstream innovations via Toxics taxes?

Or continue with 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

The main “externalities” of chemicals

- costs of cancers, reproductive and other chronic health impacts;
- costs of acute health effects;
- public costs of fire & explosions;
- costs of pollution to air, crops, inland water, soil, sediments and seas;
- costs of damage to non-human species eg bees
- costs of damage to the stratospheric ozone layer;
- costs of registration, testing, assessing and classification *not* borne by companies;
- costs of permits, inspections & enforcements not borne by companies;
- cost of monitoring/sampling not borne by companies;
- cost of contamination clean up not borne by companies;
- losses of land value; fear; nuisance, smells in the vicinity of plants.

(EEA,1999, “*Chemicals In Europe: low doses, high stakes?*” Gee et al)

Some monetised costs of chemicals

- Health care costs and lost earnings linked to exposure to **endocrine disrupting chemicals** comes to an estimated **€157 billion each year (EU)**
- Use of **tributyltin (TBT)** as antifouling marine coatings caused population declines in shellfish, with an associated economic loss estimated in **€22 million per year to the UK** shellfish industry.
- Diphenyldichloroethene (**DDE from DDT**)-attributable **fibroids** and **phthalate**-attributable **endometriosis** affects some 56,700 and 145,000 women, respectively.
- This costs the **EU €163 million** (for attributable fibroids) and **€1.25 billion** (for endometriosis) per year.

These “externalities” are mainly paid by victims, Insurance Co’s, and taxpayers...

- Eg costs of harm, contamination, and safe treatment/removal etc. are **rarely internalised into the market prices.....**
- which means that **innovation on substitutes is stifled** by “cheap” chemicals
- and harm/research/treatment/removal **costs are paid mainly by victims, taxpayers, future generations,**
- a breach of the “**polluter pays**” principle

Internalise “external” health & environmental costs?

- Via ***Regs., taxes, tradable permits, anticipatory bonds*** (as in mining, oil, nuclear, banks) ...
- Introduced at the ***early warnings*** of possible/ probable harm..
- ...with taxes/permits ***rising predictably & gradually*** in line with ***expanding knowledge of harm...***
- With ***revenues used to fund innovations*** for better alternatives...

Eg taxes on ***CFCs (USA, 1980s); TURA, some pesticides & solvents; NOx; Carbon***

See “The effectiveness of environmental taxes”, EEA, 1996; and “Environmental tax reform in Europe: opportunities for eco-innovation”, EEA, 2011).

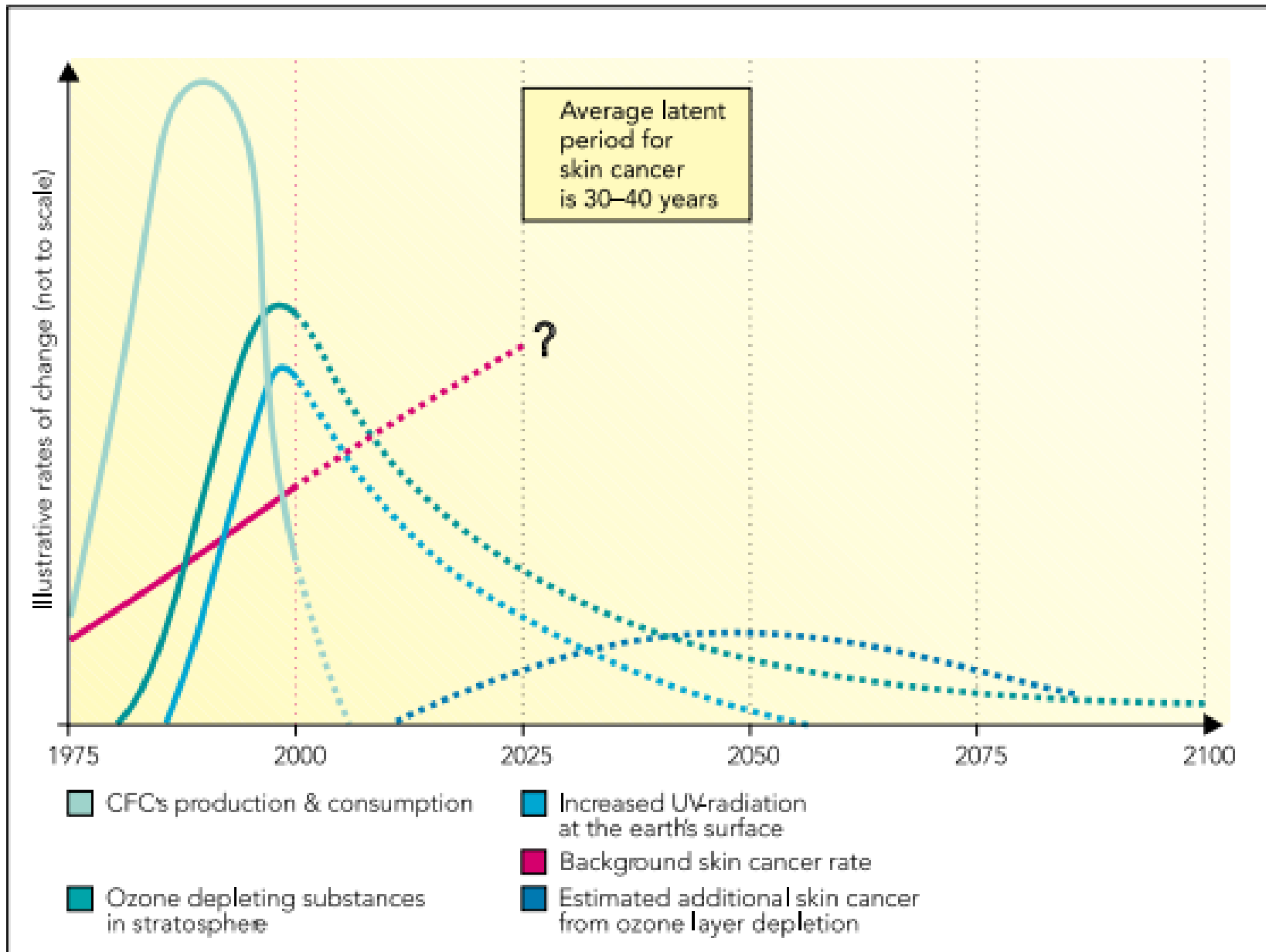
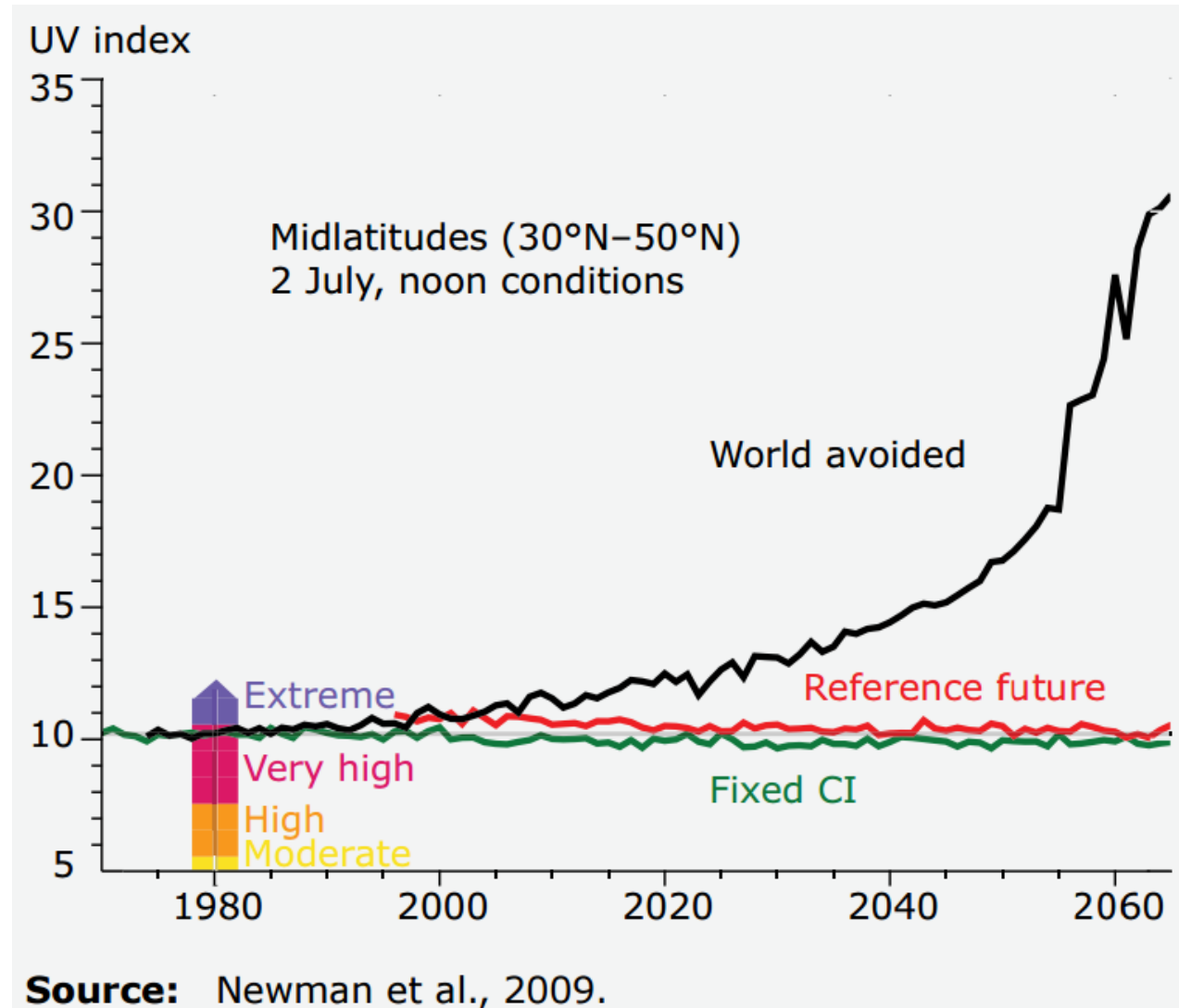


Figure 23.4 The 'world avoided' UV index as a result of international agreement



Well designed environmental taxes /investment incentives stimulate innovations

“Environmental tax reform (taxes on pollution & resources with reduced taxes on people +incentives for eco-innovation) can deliver:

- environmental objectives,***
- create additional jobs,***
- trigger eco-innovation***
- Save admin/enforcement costs***

Environmental tax reform in Europe: opportunities for eco-innovation”, EEA, 2011. And
“Taxation, innovation, and the environment”, OECD, 2010

The “*innovation principle*” is well supported by EU law & practice

- The EU “*shall promote scientific & technological advance*” (Art 3 (3) TFEU)
- “*the action of the EU & MS shall be aimed at fostering better exploitation of the industrial potential of policies of *innovation*, research and technological development*” (Art 173 TFEU)
- The “*promotion of alternatives*” (REACH)
- EU Action Plans on “*Eco-innovation*” & “*Innovation Deals*”
- Supported by *general entrepreneurship and market dynamics*

Use of the Precautionary Principle stimulates innovation by:

- **bringing forward by years /decades the innovations** that were stimulated by the late regulatory actions
- **saving billions in damage costs** that could have been spent on innovation.
- **stimulating debate & action** on wider technological & social options for meeting needs:
 - **GMOs or agro-ecology?**
 - ***“Demand side Management”* for energy, water, food, transport?**

The “foresight” (precautionary) principle

'The Irish Potato Famine and Precaution-1846

"Are you to hesitate in averting famine which may come, because it possibly may not come?"

"Is it not better to err on the side of precaution than to neglect it utterly?"

Sir Robert Peel, UK Parliament, 27 March 1846

Origins of the PP: German Clean Air Act 1974 & Report 1985

The **vorsorgeprinzip** (“foresight” or “precautionary principle”) is a “**principle of political action**” with elements of :

- **General reduction of environmental burdens** (limitations of the “assimilative capacity of the environment” ie **planetary boundaries**)
- Promotion of clean production & **innovation**
- **Anticipatory Research** & monitoring
- **Action** to reduce risks **before “specific hazards are encountered”**
- Costs of action not to be disproportionate to likely benefits: the **proportionality principle** now also in EU law.

The Bergen Ministerial Declaration, 1990

*“In order to achieve sustainable development **policies must be based on the precautionary principle***

*“Environmental measures must. **anticipate, prevent** and attack the causes of environmental degradation*

*Where there are threats of serious or irreversible damage **lack of full scientific certainty should not be used as a reason** for postponing measures to prevent environmental degradation”.*

The PP and the Marine Environment

*“huge amounts of **data** are available, but....we have reached a plateau in our **understanding** of what that information is for ..*

*This is what led to **the precautionary principle**”*

Marine Pollution Bulletin, 1997

The PP in the Treaty on the Functioning of the EU, 2007

“Union Policy on the environment....shall be based on the precautionary principle and on the principles that

- *preventive action should be taken, that*
- *environmental damage should as a priority be rectified at source, and that*
- *the polluter should pay”* Article 191(2), TFEU, 2007.

But no definition of the PP in the Treaty

An EU definition of the precautionary principle in Case law.

*“Where there is **uncertainty** as to the existence of or extent of risks to human health the institutions may take protective measures without having to wait until the reality and seriousness of those risks become **fully** apparent”*

ECJ, BSE, 1998, EEA, 2013, p649

The EU Communication on the PP, 2000

The PP can be applied :

*“where preliminary objective scientific evaluation, indicates that there are **reasonable grounds for concern***

*that the **potentially dangerous effects** on the environment, human, animal or plant health*

*may be inconsistent with the **high level of protection chosen** for the Community”*

The PP: a working definition from UNESCO

:

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

“The Precautionary Principle”, World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), UNESCO, 2005

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*”.

Gee, “More or less precaution?”, in Late Lessons, EEA, 2013.

Some Strengths of Scientific Evidence....

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

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

*Who benefits, and who gains, from **being wrong** in acting, or not acting, early enough to prevent harm?*

Short term, specific, economic interests?
Or the longer term health & wellbeing of people and their environments?

More Precaution with EDCs is needed because:

- fast **technological change** overtakes..
 - ..the **slow increase in scientific knowledge**
 - Complexity & multi-causality delays “sufficient” knowledge of harm...
 - **Plausible evidence** of delayed & serious impacts is available
 - **Justifying exposure reductions** on “low” strengths of evidence
-
- lessons from the past tragedies with EDCs eg **DES,TBT, PCBs, DBCP.**

Benefits of Regulatory Action expand over time with expanding knowledge...

- **CFCs**: from ozone “hole” benefits to Climate Change benefits
- **TBT**: from local to global benefits to sea snails and humans
- **PCBs**: from wildlife benefits to health benefits
- **Lead**: from children’s IQ benefits to adult heart disease benefits
- **Tobacco**: from lung cancer benefits to other cancers; heart disease; foetal toxicity benefits

Well-designed Environmental regulations stimulate innovation

- See Evidence from Ashford (MIT 1978-2012)
 - **Incremental innovation** from current firms, e.g., unleaded gasoline, leading to “ancillary benefits” and “first-mover” advantages.
 - 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
- From Porter et al (Harvard Business School 1995 & 2005)
 - Incumbent firms modernizing their operations leading to **“innovation offsets”** that balance off the costs of complying with regulatory demands and give **“first-mover” advantages**.

Stringent environmental regs do not harm productivity: OECD 2014

“the tightening environmental policies have had little effect on aggregate productivity, spurring primarily short term adjustments..”

“The indicator of Burdens on the Economy due to Environmental Policies (BEEP) shows that barriers to entry and competition.....vary notably across countries, but that this variation is not related to the stringency of policies”.

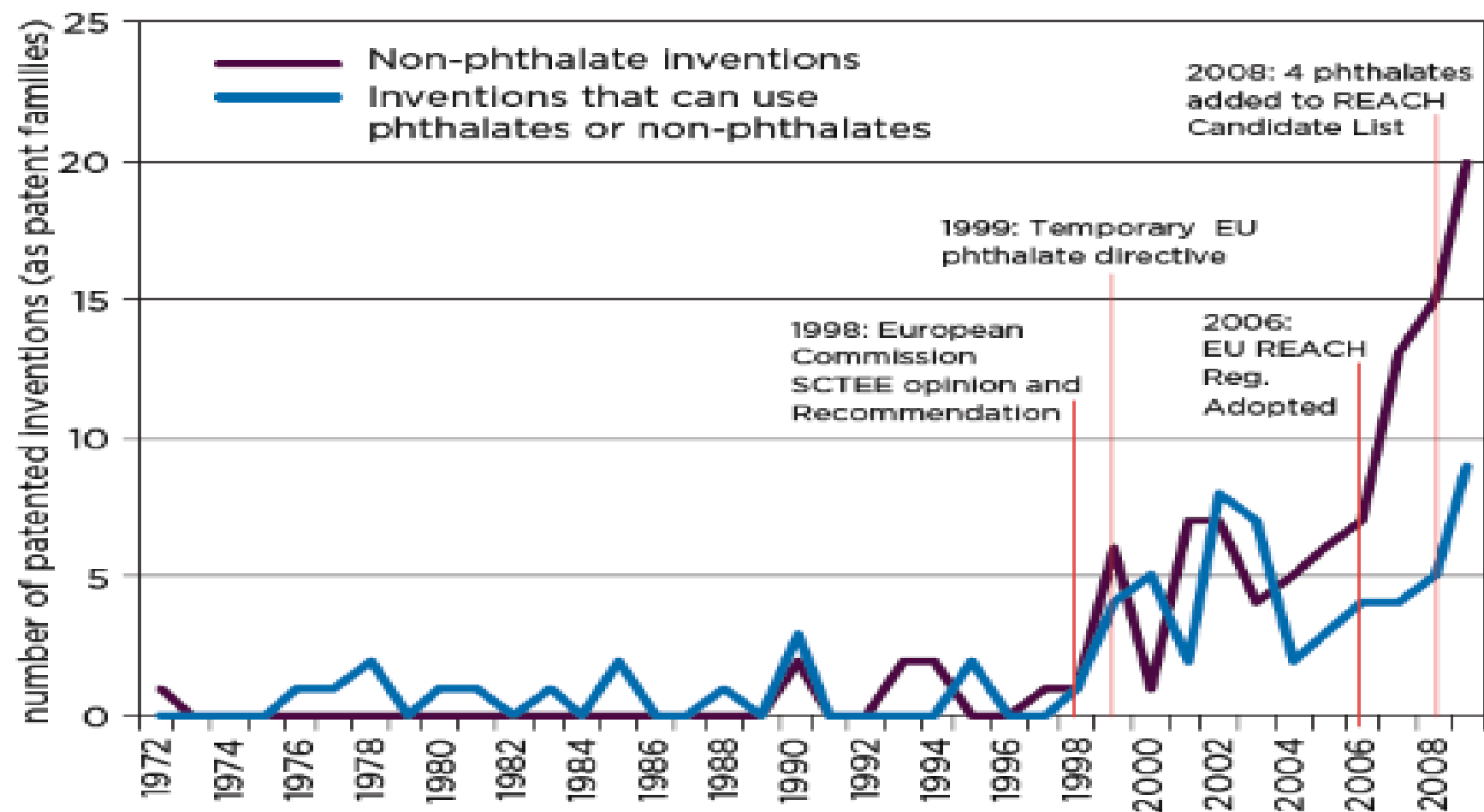
Productivity Growth?: Insights from New Cross-Country Measures of Environmental Policies”, Albrizio et al, OECD Economics Department Working Papers, No. 1176, OECD Publishing. 2014, <http://dx.doi.org/10.1787/5jxrjncjrcxp-en>

Stringent Environmental laws do not harm business overall.

“a tightening of environmental policies is followed byan overall improvement in production efficiency for a large share of the manufacturing industries”.

OECD,2014.

FIGURE 20.1
Spike In Patented Inventions Free of Hazardous Phthalates



Exponential growth in the number of patented inventions for phthalate alternatives beginning in 1999, coinciding with the adoption of stricter rules (as captured by the number of patent families for "non-phthalate" and "phthalate free" inventions)

The Green Chemistry & Commerce Council (USA)

“The Green Chemistry & Commerce Council (GC3) is a US multi-stakeholder collaborative that drives **the commercial adoption of green chemistry** by catalyzing and guiding action across all industries, sectors and supply chains”.

What is the Green Chemistry & Commerce Council?

- [GC3 members](#) are champions and innovators in the fields of **green chemistry, design for the environment**, and the production of **safer chemicals, materials and products**.
- Approximately 75% of GC3 members are **individual companies** and 25% are representatives from **non-governmental organizations, local, state and federal government agencies, and consulting firms**.
- All members agree to a set of [guidelines and policies](#).

The GC3 Technology Showcase-May 8, 2018, USA.

- 16 companies—including Apple, BASF, Johnson & Johnson, Levi Strauss & Co., L'Oréal, and Procter & Gamble—are seeking sustainable and bio-based chemistry solutions in a range of categories including:
- adhesives, coating technologies, flame retardants, monomers/polymers, ingredients for formulated consumer products (including personal care and household products), and recycling technologies...
- Stimulated by.....

GC3 Annual Innovators Roundtable

-a three-day forum that enables business leaders across supply chains and sectors to **exchange green chemistry strategies and network** to form new partnerships and collaborative projects.
- *“The GC3 Technology Showcase creates the setting for these conversations to take place so that innovators can bring green chemistry solutions to market much more quickly”*

Patrick Harmon, Industry Manager, BASF

Bio-based plastics.....

- [Cereplast, Inc.](#), manufacturer of proprietary bio-based, sustainable plastics, announced today that products made from Cereplast Compostables® resins meet new **federal procurement guidelines for bio-based content enacted June 13 2008** by the United States Department of Agriculture.
- All companies using Cereplast Compostables® resins can be listed on the USDA [“BioPreferred” web site](#).

Reduced exposure to chemicals brings big benefits.....

- Endocrine disrupting chemicals (EDCs) cost the EU €1.4bn per year
- Another study found costs savings of €1.59-1.87 billion for skin diseases and €250 million for asthma (2004-2013) thanks to reduced chemical exposure in Europe

The overall Benefits of EU Chemicals Regs.

- “the monetary value of all of these benefits over the last 50 years are likely in the *high tens of billion Euro per year*, perhaps more” eg
- “action taken *to protect the ozone layer* is cumulatively valued at *several hundred billion Euro*”.
- “nutrient recycling arising from tributyltin (**TBT**) regulations are estimated at upwards of *tens of millions of Euro*”
- “reductions in exposure to a group of **13 carcinogens** since 1995 (has led to) the *total number of cancer deaths avoided may be over 1 million deaths across Europe*.”
- “reduced exposure to just one carcinogen (**hexavalent chromium**) has avoided some 800 deaths from cancers, with a monetary valuation of some €4 billion”.
- “the **balance of evidence** indicates the known value of these benefits are *likely to increase, perhaps significantly*”

EU Study on the cumulative health and environmental benefits of EU chemical legislation. June 2017. Brunel, AMEC Foster Wheeler, EFTC (Economics for the Environment)

UK Chemicals Regs bring large benefits.....

- DEFRA (2011) estimates that the benefits for the UK arising from **REACH** regulation and **mercury** regulation are around **£17 million per annum**
- And that **the benefit-cost ratio** of chemicals regulation **is 38:1.**

*The Costs and Benefits of Defra's Regulatory Stock
Emerging Findings From Defra's Regulation Assessment
August 2011*