



DANGEROUS SUBSTANCES – LESSONS FROM THE PAST FOR THE FUTURE

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EU2019.FI



The European Environment Agency: Informing policy through science

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*Kosovo under UNSCR 1244/99

Keeping an eye on chemicals



- European Commission (2001): Global production of chemicals increased 50 times from 1950 to 400 M t in 2001 and is expected to triple again by 2050.
- Chemical industry is Europe's 3rd largest manufacturing industry.
- June 2015: Chemical Abstracts Service (CAS) assigned 100 Millionth CAS Registry Number®.
- Eurostat: about 33 M t of carcinogenic, mutagenic and reprotoxic chemicals produced in 2015 (~14% of EU28 chemical production)
- EEA estimated that 62% of the volume of chemicals consumed in Europe in 2016 were hazardous to health

Europe has REACH but....



- 2020, all known relevant SVHCs are identified, along with possible regulatory measures
- Authorisation and restriction process is seen as an effective driver for substituting SVHCs

but

- Compliance with the information requirements by registrants is considered insufficient
- Articles imported to the EU are exempt from the authorisation obligations

*COM/2018/0116 final: COMMUNICATION FROM THE COMMISSION:
Commission General Report on the operation of REACH and review of certain elements*



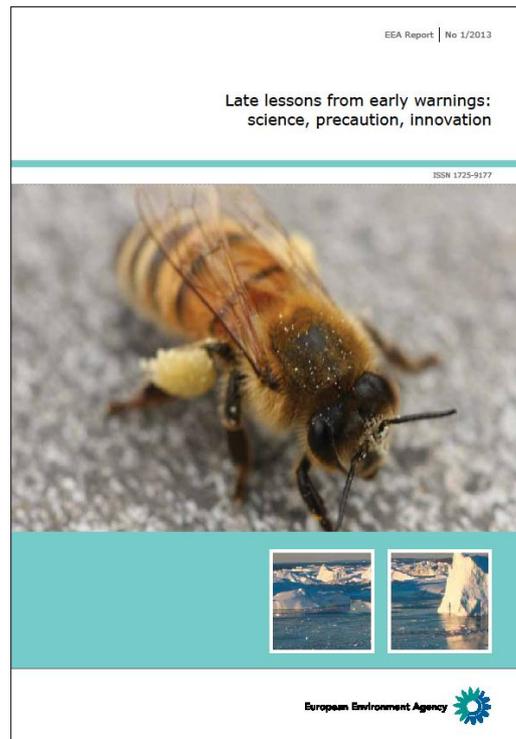
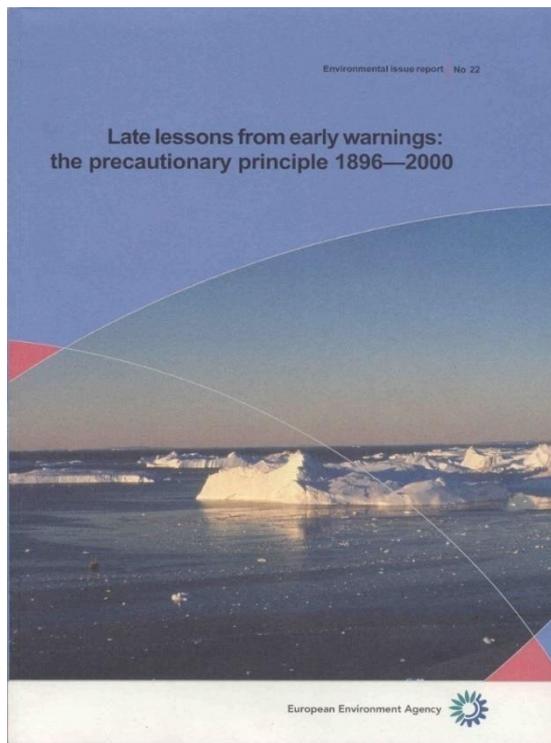
The Eurobarometer study (2016) of almost 28 000 people in 28 countries shows that 65 % are concerned about being exposed to hazardous chemicals, 26% were very concerned.





- The World Health Organization estimated the burden of disease from selected chemicals at 1.6 million lives in 2016 (this is likely to be an underestimate)
- Workplace pollution linked to 0.8 million deaths (*Lancet* Commission on Pollution and Health, Oct 2017)
- Carcinogens account for more than 100 000 work-related deaths (RIVM, 2016)
- Concern for neurotoxicants and substances with endocrine disrupting properties

Late lessons from early warnings : 2001 and 2013



Delays between early warning and actions

Asbestos: 1929 asbestosis; **1954** lung cancer; **1959** mesothelioma;

Major steps, workplaces and market restrictions

EU 1980 Work places: Protection of workers from the risks related to exposure to chemical, physical and biological agents at work: *'Exposure to workers to agents be avoided or kept as low a level as is reasonably practical'* (80/1107/EEC)

EU 1983 Work places: Directive on the protection of workers from the risks related to exposure to asbestos at work: Ban of certain types of spraying, OEL: 1 fibre/ cm³ introduced (83/477/EEC)

EU 1985 Market restriction: Ban of placing on the market and use of products of asbestos in several uses: toys, materials applied by spraying, retail products in powder form, smoking accessories, catalytic heaters, paints/ varnishes (85/610/EEC)

EU 1991 Work places: OEL reduced to 0.6 fibre/cm³ for white asbestos, chrysotile (91/382)

EU 1991 Market restriction: Banned of 5 types and 14 uses of asbestos, particularly in construction materials (91/659/EEC)

EU 1999 Market restriction: banned all uses of all asbestos types with few exceptions; transposition to MS latest **Jan 2005** (1999/77)

EU 2003 Work places: OEL set at 0.1 fibre/cm³ for chrysotile, detailed regulations for protection (2003/18/EC)

EU 2006 Market restriction: Ban of production and use (one exception), also for chrysotile (REACH Annex XVII)

EU 2009 Work places: Directive on the protection of workers from the risks related to exposure to asbestos at work. Latest regulation for workplaces, all uses prohibited, detailed regulations for removal and demolition work, OEL set at 0.1 fibre/cm³ etc. (2009/148/EC)

Delays between early warning and actions

Lead: early warnings in 1925, 1979 brain damage in children; 2012 heart disease in adults→

In Europe, the **Aarhus Protocol (UNECE, 1998)** initiated the phase-out of leaded petrol,
EU 2000 End-of-life-of-vehicles, sector specific lead restrictions
EU REACH 2006 (Annex XVII), manufacture and market restriction

Major steps, workplaces

EU 1980 Workplaces: Protection of workers from the risks related to exposure to chemical, physical and biological agents at work: 'Exposure to workers to agents be avoided or kept as low a level as is reasonably practical'.

Lead and compounds as substances with strongest protection measures (80/1107/EEC)

EU 1998 Workplaces: Risks related to chemical agents at work of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

Binding EU limit value for inorganic lead and compounds, 0,15 mg/m³ (Chemical Agents Directive, 98/24 EC)

OSH legislation nowadays

24 EU OSH Directives, among which:

- **Framework Directive (Directive 89/391/EC), sets out the principles**
- **Chemicals (Directive 98/24/EC)**
 - Sets out principles, e.g. workplace risk assessment
 - Hierarchy of control measures – elimination and substitution, technical and organisational measures and, as a last resort, personal protective measures
 - Health surveillance, information and participation of workers
- **Carcinogens and Mutagens (Directive 2004/37/EC)**
 - More stringent measures for carcinogens and mutagens (e.g. closed system, and delimitation of areas where they are used, etc.)
 - Directive (EU) 2017/2398, introduced 11+2 binding OELs
 - Directive (EU) 2019/130, introduced 6 binding OELs
 - Directive (EU) 2019/983, introduced 5 binding OELs



The infographic is divided into two main sections. The top section, titled 'Legislative framework on dangerous substances in workplaces', features a background image of a worker in a white protective suit. It includes a 'Key Points' box with text: 'There is a list of the European Union of work... The most... Agents... into national... Legislation... information... transport... Achieving a... following the... most effective...'. The bottom section, titled 'Carcinogens at work', features a background image of a worker in a blue uniform inside a large industrial machine. It includes a 'Key Points' box with text: 'A carcinogen is a substance that is capable of causing... regarding its potential cancer to humans or... animals. Some carcinogens can be inhaled, others... may enter through the skin or digestive... More detailed... are included in the... European... and national... Not every... will necessarily... lead to cancer... prolonged... while others... health and... exposure... There are... that workers... can be exposed to... carcinogens include asbestos, radon, certain... pesticides, arsenic and... Many of the... which workers are most... frequently... Examples include diesel exhaust, working... synthetic... Carcinogens... may also be present in... including... products or by... The effects of... may occur a long time after... Under EU... particularly... – in addition to those required for other... – must be taken by employers to prevent... where this is not... in a closed system, providing... and... information and... Any... of... are... It is therefore... that... of national... to...'. A 'Healthy Workplaces Manage Dangerous Substances' box at the bottom right states: 'The European Agency for Safety and Health at Work (EU-OSHA) runs a Europe-wide campaign during 2018 and 2019 to promote the prevention of risks from dangerous substances in workplaces. The aim is to reduce the presence of such exposure to dangerous substances in workplaces by raising awareness of the risks and of effective ways of preventing them.'

Delays between early warning and actions

- **PCBs: 1960s** bird reproduction; 2000s neurological harm in children, soil contamination→ **1996 EU directive to eliminate PCBs by 2010**
- **Mercury: 1950 neurological effects**; 1960s birth defects; 1990s children's IQs fall→ The **Minamata Convention entered into force in 2017**.

Reasons for the delays: lack of knowledge and ambiguity

Knowledge deficit:

Unknown effects: asbestos causing mesothelioma

Unknown exposure routes: methylmercury through fish consumption

Unanticipated consequences: persistent cyclic siloxanes are measured in arctic air samples

Microplastics ? Nanoforms ?

Ambiguity:

Dissent across disciplines: toxicologists versus epidemiologists and EDCs

Vested interests: tobacco, adding tetraethyl lead to petrol

Bisphenol A: risk assessments with different conclusions

Glyphosate: risk assessments from EFSA and IARC had different conclusions

Reasons for the delay: uncertainty

High strength of evidence required to establish scientific causality
High burden of proof needed for action ↔ precautionary principle?

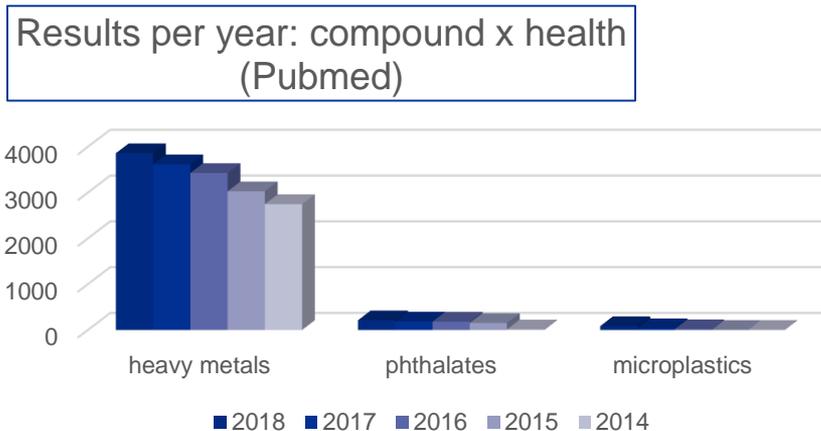


all scientific work is incomplete—where it be observational or experimental,’ noting that this uncertainty ‘does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time’

Bradford Hill, 1965

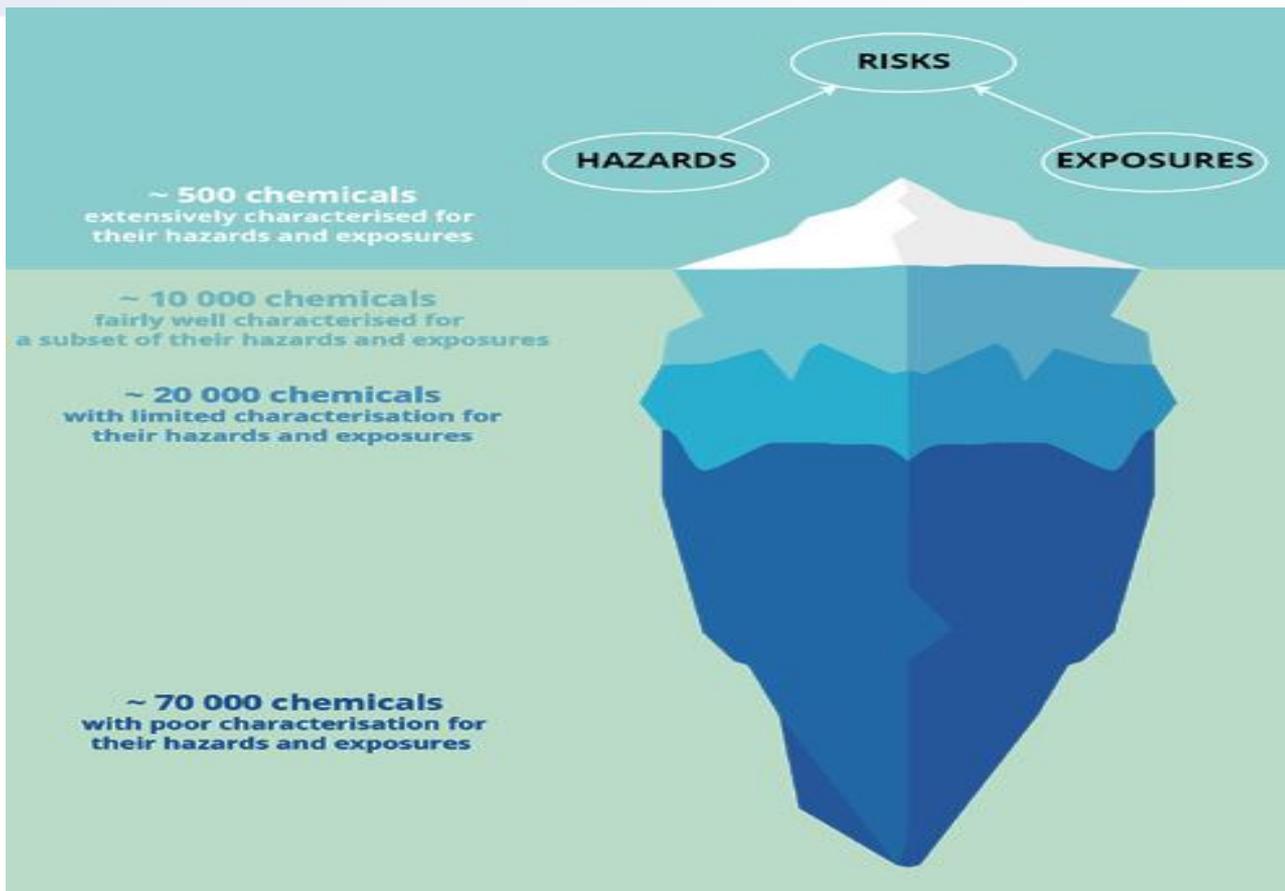
Reasons for the delay: inertia in science

Too many studies on too few chemicals: in depth research



Exploring new and emerging risks: horizon scanning

Monitoring for a wider variety of chemicals can provide earlier warnings



Research and governance are challenged by the speed of development



Per/polyfluorinated compounds (PFASs)

General population + firefighters, ski-waxers and workers in fluorochemical plants

First surveys (OECD) in 2004- only PFOS and PFOA
Now: more than 4700 known PFAS

1% of the total amount that EU Framework Programmes of Research and Development (2002-2013) allocated to developing products from nanotechnologies, biotechnologies and ICT was spent researching their potential hazards

<https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/productionandemissions/>

What are the effects of combined low exposures ?

Something from 'nothing' and 'a lot from a little'



Thrupp et al. *Sci Total Environ.* 2018 Apr 1;619-620:1482-1492. doi:10.1016/j.scitotenv.2017.11.081.

Complexity II: the hazards were shown over time to be more diverse and widespread than first anticipated



Same chemical

→ **Different effects**

→ **Different thresholds**

Same chemical, different exposure routes

Plastic toys

Food packaging and drink bottles

Indoor pollution

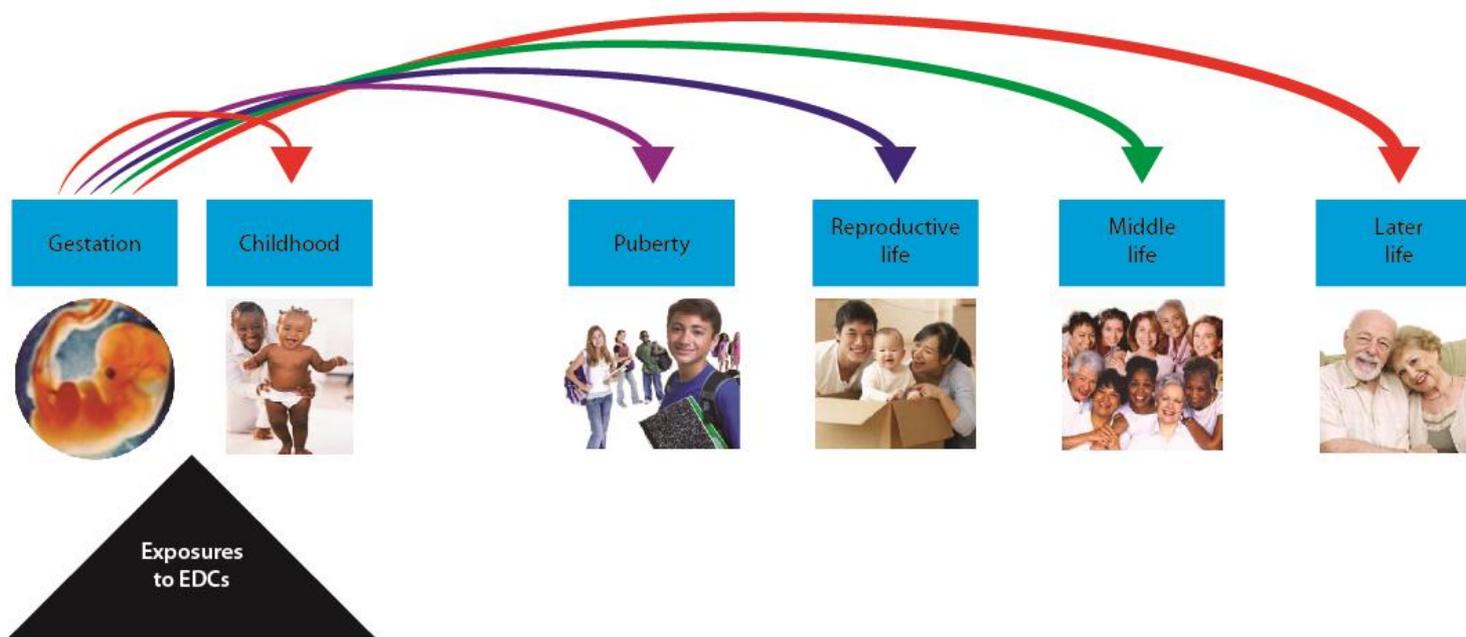
Soil contamination

Work places

→ **Exceeds one policy domain**

Complexity III: sensitive windows of exposures

Developmental exposures at the start of life may lead to adverse health effects later in life



Complexity IV: Transgenerational effects?



- Vinclozolin
- DES
- Methoxychlor
- Bisphenol A
- Dioxin
- Phytoestrogens
- Heavy metals
- Tributyltin
- Cigarette smoke

ENVIRONMENTAL



EPIGENETICS

Capturing the systemic dimensions of risks



EFSA's MUST-BEE Project:

The development of a holistic approach for the risk assessment on multiple stressors in bees

- Viruses
- Neonicotinoids
- Fragmentation of the habitat
- Climate change

Evolving environmental challenges: from specific to systemic

Characteristic	Process	examples
Specific 1970s/1980s (continuing today)	Single actor – single substance	Compliance with occupational exposure limits for single chemicals (OEL)
Diffuse 1980s/1990s (continuing today)	Cumulative causes Multiple sources Regional	Biomechanical, physical, and chemical hazards in agricultural workers Exposures of workers' families
Systemic 1990s/1990s (continuing today)	Interlinkages Global level	Exposures of workers in the circular economy



Changing the risk assessment paradigm

Reductionist approaches
Linear relationships
One chemical, one effect
Deterministic or probabilistic risk assessment



Combine data from different media

Monitor aggregated exposures

Grouping of chemicals to speed up and avoid regrettable substitution



Changing the risk assessment paradigm: early warnings

Use early warnings signals in different media from a wide variety of chemicals to inform risk framing

Prioritise and focus on critical parameters instead of gathering more general data)



Changing the risk governance: broaden the impact assessment

Include long-term impacts (late effects)

Include vulnerable populations

Consider distribution of costs and benefits within the society

Include externalities in pricing (damage across boundaries)

Search ... 



Changing the risk governance: *manage systemic risks*

World wide networking: fluid borders, global transport and economies:

Obtain non toxic material cycles

Reduce and minimize the use of hazardous che



Changing the risk governance: speeding up and innovate



Better use of information on hazards and persistency in the design phase of products

→ *“safe-and-circular-by-design”*

Better balance between innovation in chemicals with potential risks

Consider up-front future liability

More funding for alternatives

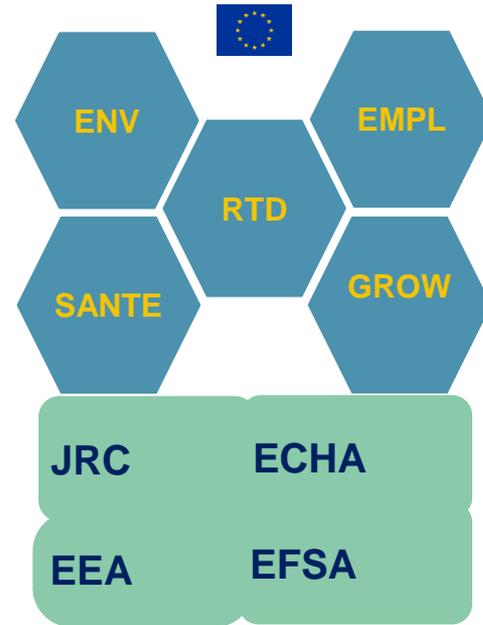
Current financial models benefit more short term profits than profits from innovation



Co-creation of knowledge

- Broaden the quality of the knowledge base
- Harmonise chemicals legislation across media, substances and their use
- Foster cross policy agendas

EU policy board



Changing the risk governance: create a visionary and inclusive stakeholder approach

- Co creation between industry, scientists and regulators to increase

→ Accountability

→ Trust

→ Transparency

→ Wide acceptance of risk management measures

- Include all available knowledge
- Include different perceptions and concerns
- Capture societal values to inform framing and trade of
 - Declare all vested interests
 - Document procedures and methods
 - Report uncertainties



- Better access to information, enhance public awareness of exposures

Conclusion:

In 2002 the EU agreed “to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment”

World Summit on Sustainable Development” 2002



2019: Ursula von der Leyen, President of the European Commission has promised a European Green Deal, including the ambition of moving towards zero-pollution.

Thank you!



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