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ANNEX 1: Presentations from OECD Workshop on the Best Practices in Assessing the Social Costs of Selected Chemicals

30-31 August 2017, Ottawa, Canada

Series on Risk Management
No. 42

This is an Annex to the workshop report that was prepared to summarise the key points of discussion at workshop held in Ottawa, Canada, 30-31 August 2017 as part of the SACAME project. It contains the presentations from the workshop. This document is available in PDF format only.

The workshop report is available under the cote ENV/JM/MONO(2018)22.

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Series on Risk Management
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IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2018

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Note from the secretariat

This is an Annex to the report on the workshop on Best Practices in Assessing the Social Costs of Selected Chemicals that was held in Ottawa, Canada on 30-31 August 2017. The workshop was organised in co-operation between the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology and the Working Party on Integrating Environment and Economic Policies, under the Environment Policy Committee, and was hosted by Health Canada.

The workshop report is available with the cote: ENV/JM/MONO(2018)22

The OECD gratefully acknowledges financial support for this project from the European Commission.

Assessing the social costs of chemicals

James K. Hammitt

Harvard University (Center for Risk Analysis)
Toulouse School of Economics (LERNA)

Motivation

- Chemicals can have adverse effects on human health and ecosystems
  - Under certain conditions
- Desire to manage risks
  - Compare social cost with social benefits
  - Optimize chemical use

- Problem: misperceptions, confusions, sloppy language, search for excessive simplicity
  - "Chemicals" is too inclusive
    - The material world is made of chemicals
  - Hazardous v. safe chemicals
    - Artificial/synthetic v. naturally occurring
    - Dose makes the poison
      - Quantity, timing, other exposures, susceptibility, ….

Social cost: consequentialist approach (conventional, economic)

- Social cost depends on probability & magnitude of possible harms
  - Cost increases with probabilities and magnitudes
  - Magnitude depends on severity and population affected
- Need to identify possible harms & characterize probabilities
  - Chemical, uses, exposures, endpoints
  - Often complicated impact pathways, multiple endpoints, & limited information →
    - Highly resource intensive (for thousands of chemicals …)
    - Much uncertainty !
- Need to value possible harms (& their probabilities)
  - Human health: reasonably clear in concept, but myriad endpoints, dependence on age & other characteristics
  - Ecosystems: how to measure quality, services v. existence, who decides?

Conventional economic approach: 2 steps

- Predict consequences of alternative policies
  - Positive question
  - Predict as accurately as possible, use descriptively accurate models
    - Departures from standard economic model may be appropriate
  - Goal is a probability distribution over possible consequences, incorporating uncertainty
- Value (uncertain) consequences of alternative policies
  - Normative question
  - Use citizens'/consumers' (reflective, informed) preferences
    - Consumers may be (efficiently) ill-informed
    - Departures from revealed preferences may be appropriate
    - May be optimal to delegate evaluation (e.g., QALYs)

Predicting consequences: health risks of chemicals

- Population risk = sum of individual risks
  - For each important consequence
- Change in individual risk (≡ probability of specified adverse effect) = product of
  - change in exposure
  - slope of exposure-response function
    - at individual's exposure
- Problem: we often do not know change in exposure or exposure-response function
  - Especially for new chemicals or new uses of existing chemicals
  - Need to assess exposure and exposure-response function for the chemical itself and any products that result, e.g., reactions in environment

Exposure

- Depends on
  - Use
    - Industrial, personal, in controlled facility, etc.
  - Quantity produced
- Assessment
  - Measurement, in practice or experiments
  - Modeling
    - Physical (e.g, environmental fate & transport)
    - Behavioral (e.g., demand for product, compliance with safety recommendations)
    - Knowledge of chemical properties may be useful (e.g., environmental persistence, bioaccumulative potential)

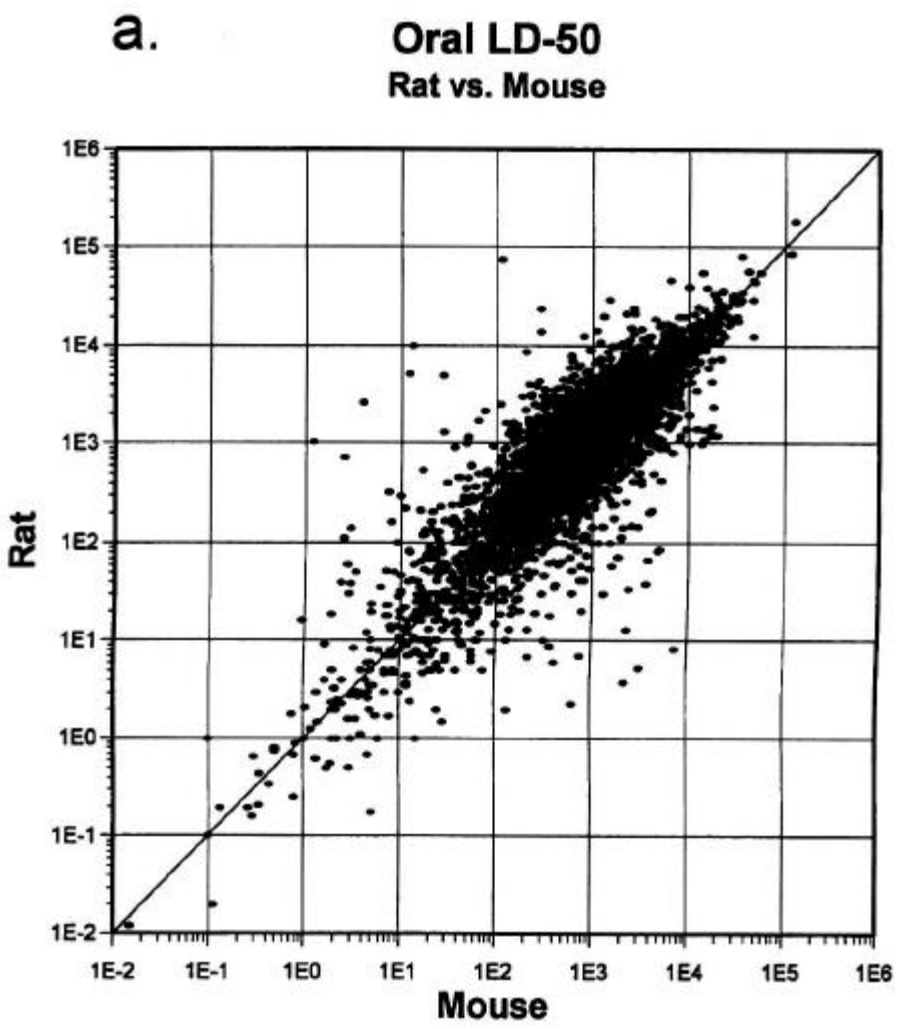
Exposure-response function

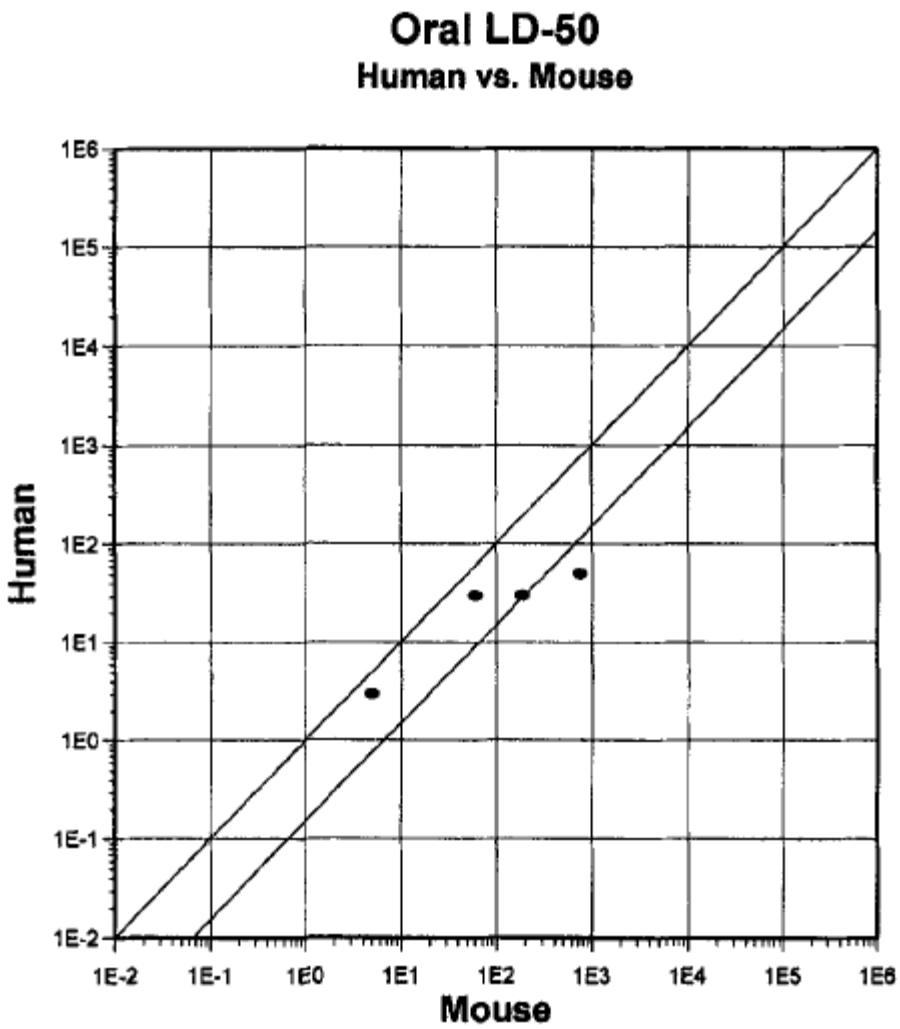
- Problem: we care about probabilities that are too small to measure
    - Human risks of 1 / 10,000 per lifetime or less
    - → 1 / 1 million per year
  - Requires sample size of millions or more?
- Alternative: create measurable risks & extrapolate
    - e.g., 1 / 100 or more
    - Increase exposure
    - Use super-sensitive test animals
  - Requires extrapolation: high- to low-dose, from super-sensitive animals to heterogenous humans
  - Extrapolation is model- (assumption-) dependent
    - Cannot validate
      - (because we cannot measure the risks)

Exposure-response function: information sources

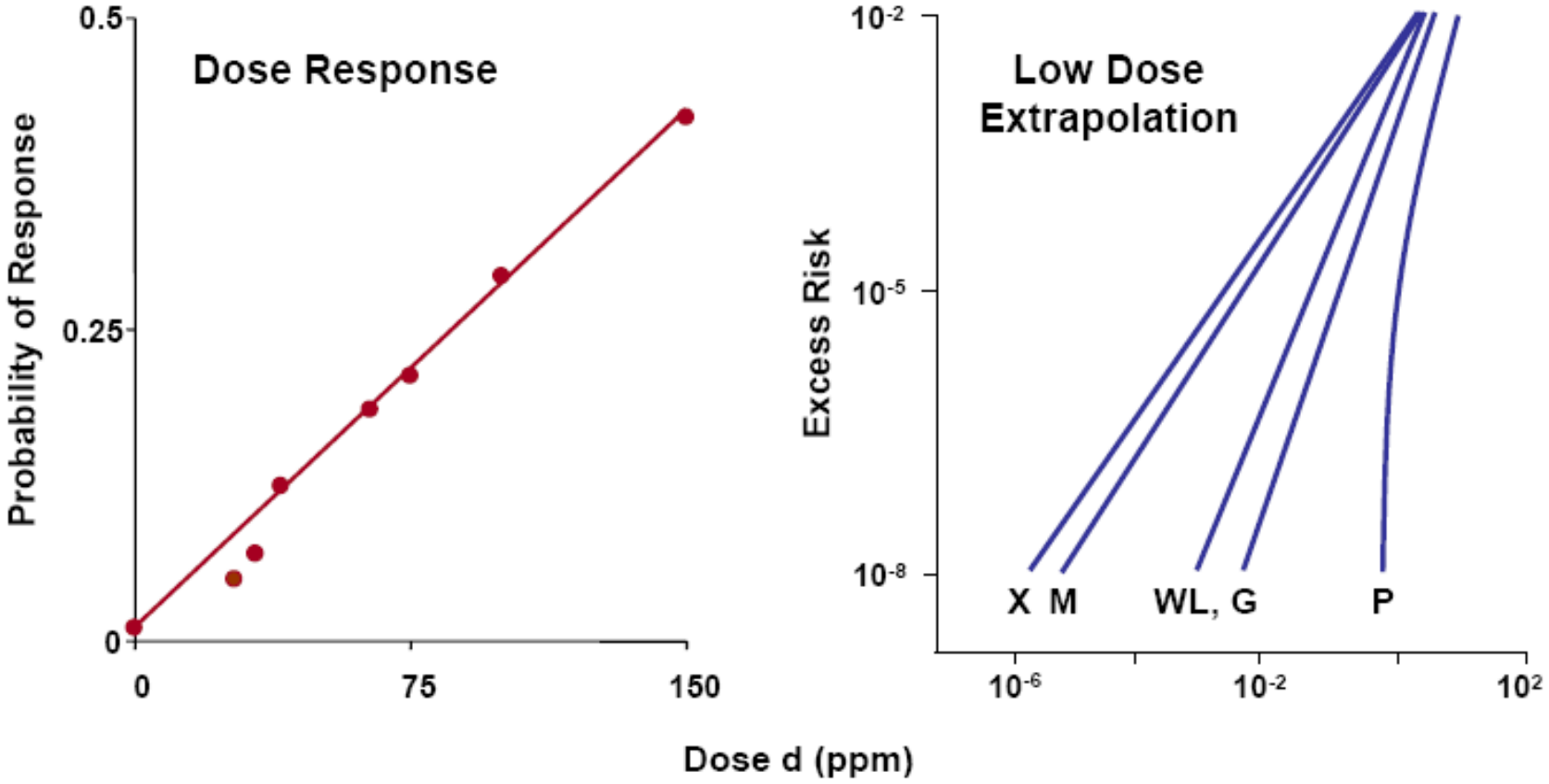
- Human experiments
  - Valuable but limited application
    - Severity of effects
    - Time period for follow-up
- Epidemiology
  - Exposures & other conditions may differ from policy context or be uncertain
    - Extrapolation (high- to low-dose, other conditions)
  - Omitted variables cannot be ruled out
    - Causation, slope/shape of function
  - Time period for follow-up may be limited
    - e.g., adult effects of childhood exposure
- Animal bioassays
  - Interspecies extrapolation
  - High- to low-dose extrapolation
- Models
  - Structure-activity relationships, synthetic biology, etc.
  - Informed by chemical properties (e.g., mutagenicity, carcinogenicity)

Uncertainty in interspecies extrapolation
(RTECS data; Rhomberg & Wolff 1998)





Uncertainty in high- to low-dose extrapolation



X – Linear Extrapolation
M – Multi-Stage Model
W – Weibull Model
L – Logit Model
G – Gamma Multi-Hit Model
P – Probit Model

Low-dose extrapolation for 2-acetylaminofluorene under several mathematical models.

Accommodating uncertainty

- Often great uncertainty about
  - Whether an effect is causally associated with exposure to the chemical
  - Shape & slope of exposure-response function (in humans)
- Uncertainty can be accommodated using probabilities

$$E[r(d)] = \sum p_i r_i(d)$$

  - E[r(d)] = expected response at dose d
  - $r_i(d)$ = response at dose d under exposure-response model i
  - p_i = probability that model i is accurate

Accommodating uncertainty

- Uncertainty about whether an effect is causal can be accommodated by including
  - p_0 = probability that exposure does not cause response
  - $r_0(d) = 0$ if exposure does not cause response

- Expected response often dominated by highest response
  - E.g.:
    - $r_1(d)$ is linear no-threshold
    - p is probability that linear no-threshold model is accurate
    - Alternative models have thresholds at doses higher than d*
  - Then

$$E[r(d^*)] = p \cdot r_1(d^*) + (1 - p) \cdot 0$$

    - Expected response is proportional to p

Interpretation of probabilities

- Probabilities are subjective
  - Quantitative measure of degree of belief
  - Can be elicited from subject-matter experts
  - Individuals can have different probabilities for same event
    - e.g., that an effect is causal
  - As evidence accumulates, experts should update their probabilities & ultimately converge
  - Before convergence, need some method to aggregate or choose among alternatives
- Probabilities are “objective” when everyone agrees
  - Overwhelming empirical evidence
  - Compelling theory (e.g., symmetry of 6-sided die)
  - Many “random” processes are not random but chaotic (e.g., coin toss, roulette wheel)
    - Deterministic nonlinear process
    - Sensitively dependent on initial conditions
    - Insufficient information about initial conditions

Monetary value of health risks

- Willingness to pay (WTP)
  - Maximum amount of money one would give up for the risk reduction
    - Compensating variation
  - Utility (baseline risk, wealth) = Utility (reduced risk, wealth - WTP)
- WTP should be roughly proportional to change in probability
  - (when WTP is small relative to budget constraint)
  - If satisfied, can summarize as value per statistical case
- WTP depends on health endpoint
  - Many studies about mortality risk
    - Uncertainty about dependence on age, life expectancy, health, cause of fatality
  - Studies about only a tiny share of non-fatal outcomes
    - Value often approximated as proportional to QALYs or alternative
      - Inconsistent with theory & evidence

Departures from standard model: errors or model inadequacies?

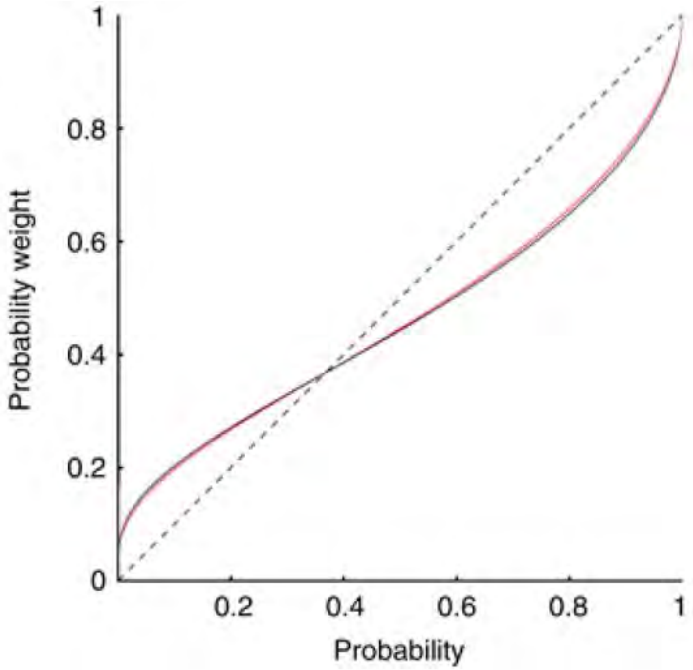
- Framing effects
  - Conflicting answers to logically equivalent descriptions
    - Loss aversion
  - Omission v. commission?
- Discounting
  - Hyperbolic v. exponential
    - Temporal inconsistency?
  - Discount rate
- Ambiguity aversion
  - Perils of prudence
- Disclosure and value of information
  - Fail to update prior beliefs correctly, overweight salient attributes
- Qualitative attributes of mortality risks
- Non-proportionality of WTP to risk reduction

Qualitative risk attributes

- Perception and tolerance of risk depend on
  - Dread
    - Uncontrollable, involuntary, catastrophic, inequitable distribution of benefits, affects future generations
  - Uncertainty
    - Unobservable, not understood scientifically, delayed consequences, newly recognized
  - Limited evidence that these affect WTP to reduce risk
    - Most good studies suggest modest effect (< 1.5 – 2 x)
- Other qualitative attributes
  - Natural v. artificial/synthetic chemicals
  - Genetic modification v. conventional breeding
    - More uncertain?

Non-proportionality of WTP to risk reduction

- WTP for (small) reductions in mortality risk should
  - Increase with magnitude of risk reduction
  - Be nearly proportional to magnitude of risk reduction (yield same VSL)
- Nonlinear response to probability



Empirical results often show sensitivity, not proportionality

WTP to reduce mortality risk (on foreign coach trip) from 8/100,000
(Jones-Lee, Hammerton & Philips, 1985)

Risk reduction	4/100,000	7/100,000
Mean WTP	£137	£155
VSL	£3.4 million	£2.2 million

Median WTP = £50 for each risk reduction

42% of respondents would pay same amount for each risk reduction

(8% would pay more for smaller risk reduction)

Non-proportionality of WTP to risk reduction

- Initial risk reduction is valuable, additional risk reduction is worth much less?
- Two actions that each reduce risk by Δr are valued more than one action that reduces risk by $2\Delta r + \varepsilon$
  - Value action or consequence?

- Value risk elimination more than risk reduction
  - Prefer to reduce :
    - Mortality risk A from 0.0001 to 0 ?
    - Mortality risk B from 0.010 to 0.009 ?
  - Is anxiety related to number of risks one faces?

Direct estimates by hazard attribute

- Often, regulators know little about a chemical but must decide how to manage
  - May have information about qualitative properties, but little or no quantitative information about slope of exposure-response function (or exposure)
- IEc stated-preference survey for Health Canada & Environment Canada (2016)
  - Elicited WTP to eliminate chemicals with specified attributes from a basket of frequently purchased products
  - Internet survey, nationwide sample
  - Careful development, focus groups, pre-test, etc.

Direct estimates by hazard attribute

- Respondents chose between (monthly baskets of) household products that differ in attributes and cost

Personal care products (e.g. shampoo and cosmetics)
Cleaners (e.g. detergents, bleach, and dry cleaning chemicals)
Paper products (e.g. paper, toilet paper and napkins)
Plastic products (e.g. bottles)
Batteries
Lights (e.g. bulbs, fluorescent tubes)
Electronics (e.g. radios, computers and music players)
Fertilizers and pesticides
Automotive products (e.g. gasoline, motor oil, antifreeze and tires)
Construction materials (e.g. paint and insulation)

Attribute levels (qualitative, binary)

ATTRIBUTE	LEVELS
Persistence	Not Persistent Persistent
Bioaccumulation	Does Not Bioaccumulate Bioaccumulates
Environmental Impacts	No Impacts Impacts Water Quality Impacts Air Quality Impacts Soil Quality
Toxic to Non-Human Organisms	No Effects Toxic to Non-Human Organisms
Carcinogenic to Humans	Not Carcinogenic Carcinogenic
Other Potential Health Effects on Humans	No Effects Respiratory/Cardiovascular Effects Reproductive Effects Developmental Effects
Additional Cost Per Month	$0, $5, $30, $60, $90, $120, $150

Please consider the current and alternative products options and indicate which option you would purchase. Please keep in mind that the options are identical in all other aspects except potential environmental and health risks and monthly cost to your household.

	Current Products with Chemical A ▼	Alternative Products Option ▼
Persistence	*Persistent*	*Not Persistent*
Bioaccumulation	*Does Not Bioaccumulate*	*Does Not Bioaccumulate*
Environmental Impacts	*No Impacts*	*No Impacts*
Toxic to Non-Human Organisms	*Toxic to Non-Human Organisms*	*No Effects*
Carcinogenic to Humans	*Not Carcinogenic*	*Not Carcinogenic*
Other Potential Health Effects on Humans	*Developmental Effects*	*No Effects*
Additional Cost Each Month	*$0*	*$25*

Which option would you purchase?

☐ would continue to purchase currently available products

☐ would purchase alternative products

Results (WTP by attribute)

Attribute	WTP ($ CAN / month)
Chemical properties	
Persistence	29
Bioaccumulation	26
Environmental effects	
Water quality	37
Air quality	36
Soil quality	37
Toxic to non humans	41
Human health effects	
Carcinogenic	49
Respiratory/cardiovascular	27
Reproductive	24
Developmental	18

Alternatives to conventional approach

- Consequentialist approach is resource-intensive, time consuming
  - Not feasible for tens of thousands of chemicals in commerce, plus newly developed compounds?
  - Tradeoffs (valuation & prediction) often hard to quantify
    - Many alternatives seek to avoid confronting tradeoffs
- Alternative approaches – all are unsatisfactory
  - Technology standards
  - One-factor approaches
    - Negligible risk
    - Worst-case analysis
  - Precautionary principle

Conclusions

- Conventional model for social cost based on individuals' preferences
  - Normative preferences (informed, reflective)
- Requires information on (multiple) risk changes
  - Magnitude (change in probability)
  - Consequence (fatal, cause of death, etc.)
  - Other characteristics relevant to individual
- Many challenges!
  - Predicting changes in risks
    - Too small to measure or verify
  - Eliciting preferences
    - Distinguishing normative from non-normative preferences
- Implications
  - Seek approximate estimates for most important quantities
  - Refine if needed & feasible
  - Politically feasible?

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Canada

Mercury Containing Compounds Case Study by Canada

Experiences and Challenges

Best Practices in Assessing the Social Costs of Selected Chemicals

OECD Workshop: August 30, 2017, Ottawa, Canada

Joe Devlin, Policy Manager, Economic Analysis Directorate, ECCC

Case Study: Canada's Products Containing Mercury Regulations

In the next few minutes, I will try to explain to you:

1. What did the regulations target, and why?
2. What was our experience in conducting the associated cost-benefit analysis (a.k.a. socio-economic analysis), and
3. What were the challenges; what are the lessons?

Chemical Management Plan (CMP)

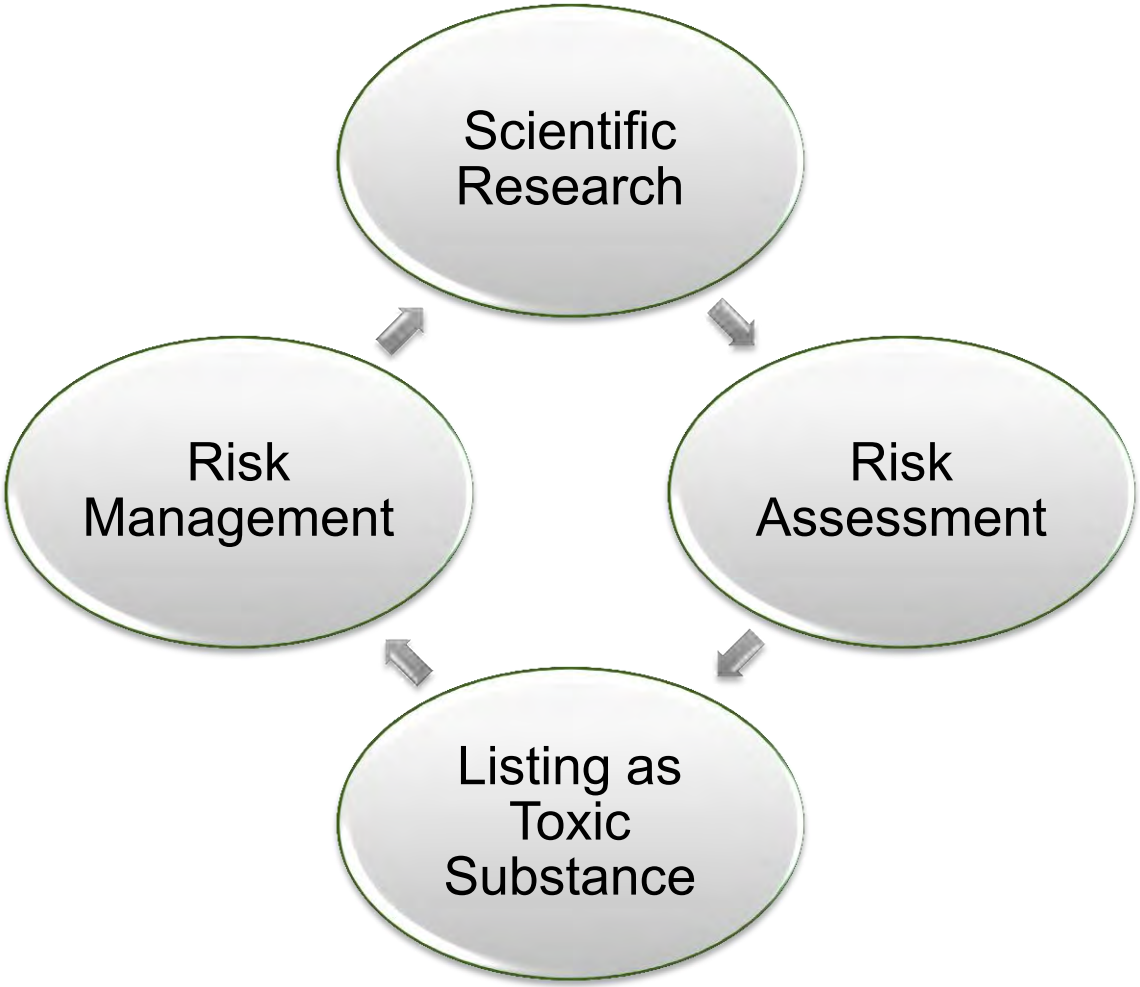
Since the launch of the CMP in 2006, Canada has:

- Prioritized action on 3,200 chemicals
- Found over 420 substances to be harmful
- Implemented over 80 risk management actions

CMP and the Mercury Regulations

- 2010: CMP Risk Assessment recognizes methylmercury as a threat
- 2012: Mercury compounds added to our list of toxic substances
- 2013: Canada signs global Minamata Convention on Mercury
- 2015: *Products Containing Mercury Regulations* are implemented
- 2016: New Canadian Mercury Science Assessment released
- 2017: Canada ratifies global Minamata Convention on Mercury

CMP Regulatory Framework



2010 Risk Assessment: Trends

- Since the 1970s, Canada has reduced domestic sources of anthropogenic mercury by approximately 90%
- Transboundary flows of mercury emissions account for over 95% of mercury deposits in Canada
- The Arctic acts as a sink that traps many pollutants like mercury, and it is downwind from growing sources of mercury emissions in Asia and Eurasia

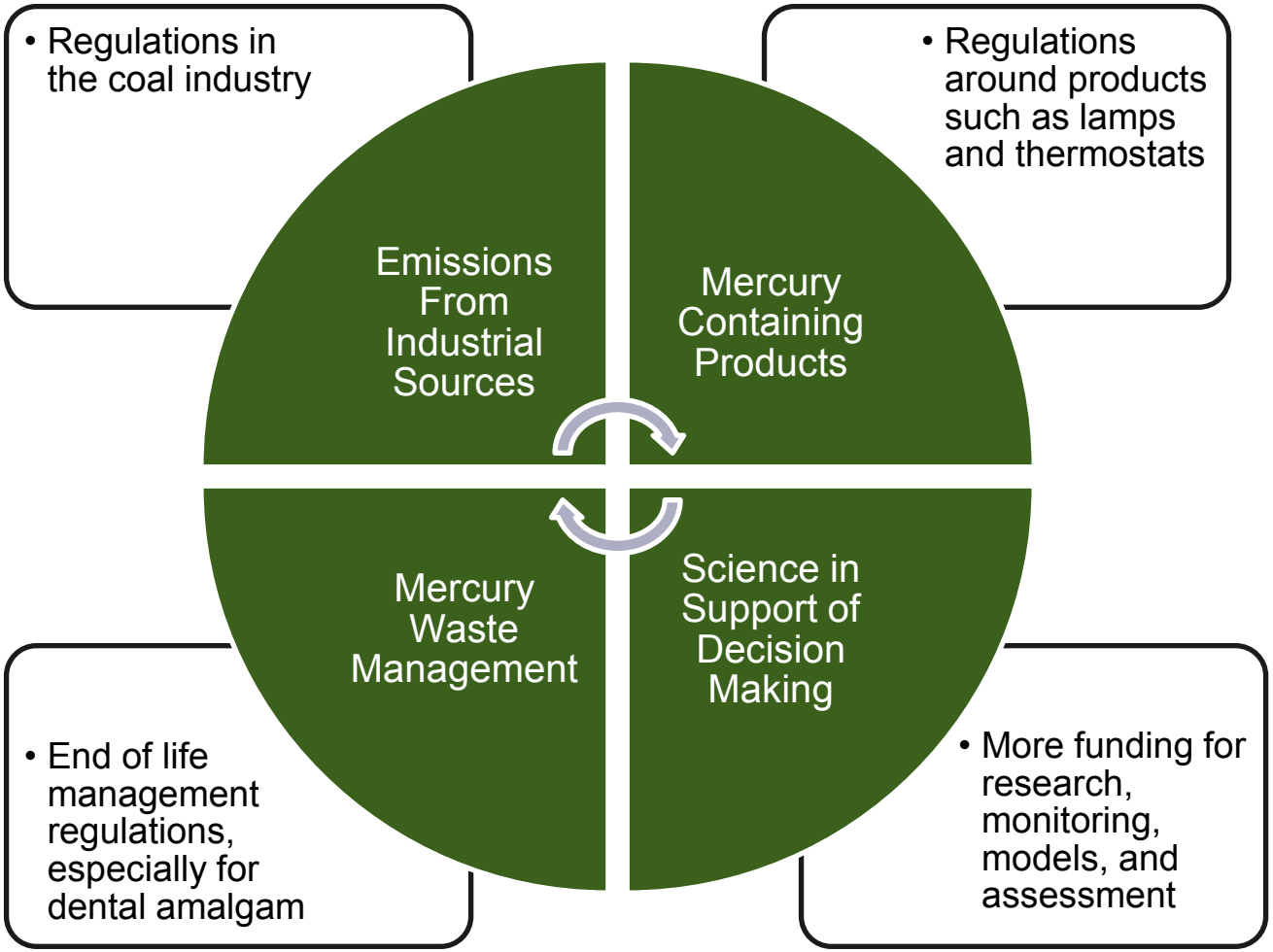
2010 Risk Assessment: Environment

- In the environment, mercury can convert to methylmercury, the form to which humans are most exposed
- Methylmercury is bio-accumulative: high levels in fish eating predators (loons and larger fish)
- Effects on fish and wildlife include:
  - slower growth,
  - reproductive failure,
  - development of abnormal behaviours that can affect survival

2010 Risk Assessment: Health

- Methylmercury is a potent neurotoxin that is readily absorbed and passed through the blood-brain barrier
- Primary health risk: impaired brain development, especially in fetuses, infants and young children
- Primary source: diets high in fish and marine mammals
- Low risk to the general population; advisories work well
- Higher risk to:
  - northern populations and Indigenous Peoples who may consume higher levels of large fish species
  - pregnant and lactating women; developing fetuses and infants

2010 Domestic Risk Management Plan



Products Containing Mercury Regulations (Mercury Regulations)

- One of several mercury risk management actions identified in our 2010 Risk Assessment
- These Regulations came into force in 2015, and they:
  - Prohibit the manufacture and import of most products containing mercury or its compounds (e.g. thermometers and batteries)
  - Add labelling and reporting provisions for exempted products (e.g. dental amalgam and research-related uses)
  - Set limits for the mercury allowed in lamps (to complement energy efficiency regulations that prohibit incandescent lamps)

Typical Cost-Benefit Analysis (CBA)

Level of costs corresponds to level of required analysis:

< $10 million	→ low impact	→ no CBA needed
> $10 million	→ medium impact	→ CBA if possible
> $100 million	→ high impact	→ CBA required

Mercury CBA: Costs of Regulations

Total costs: $9 Million CAD (2014 to 2032)

- Substitution Costs $5.5 M
- Government Admin Costs $2.1 M
- Industry Admin Costs $1.4 M

$9 million CAD ≈ €6 million ≈ $7.2 million USD

Mercury CBA: Reductions & Exposure

Between 2015 to 2032. the Regulations are expected to:

Reduce mercury releases by **21,000 kg**

- → Releases to land: 16,822 kg (80%)
- → Releases to air: 4,102 kg (19%)
- → Releases to water: 182 kg (1%)

Mercury emitted into the air can cycle through the atmosphere and deposit into aquatic and terrestrial ecosystems.

Typical CBA Health Benefit Methods

For these Regulations, we did not have the typical health endpoints that allow us to easily monetize health impacts:

- No annual mortality risk reduction estimates
  (so we couldn't use the Value of a Statistical Life)
- No illness endpoints like the number of hospitalizations
  (so we couldn't calculate any costs of illness)
- No illness endpoints like the number of sick days
  (so we couldn't calculate productivity losses)

Mercury CBA: Value of Health Damages

Monetized Health Benefits: **$18 million**

Assuming that there is no lower threshold with respect to the negative impacts of mercury on brain development, we can estimate benefits of **$10,000 to $11,000 per kg of mercury air emissions avoided** (Rice and Hammitt, 2005)

Used as a proxy (benefit transfer)

Mercury CBA: Environment Benefits

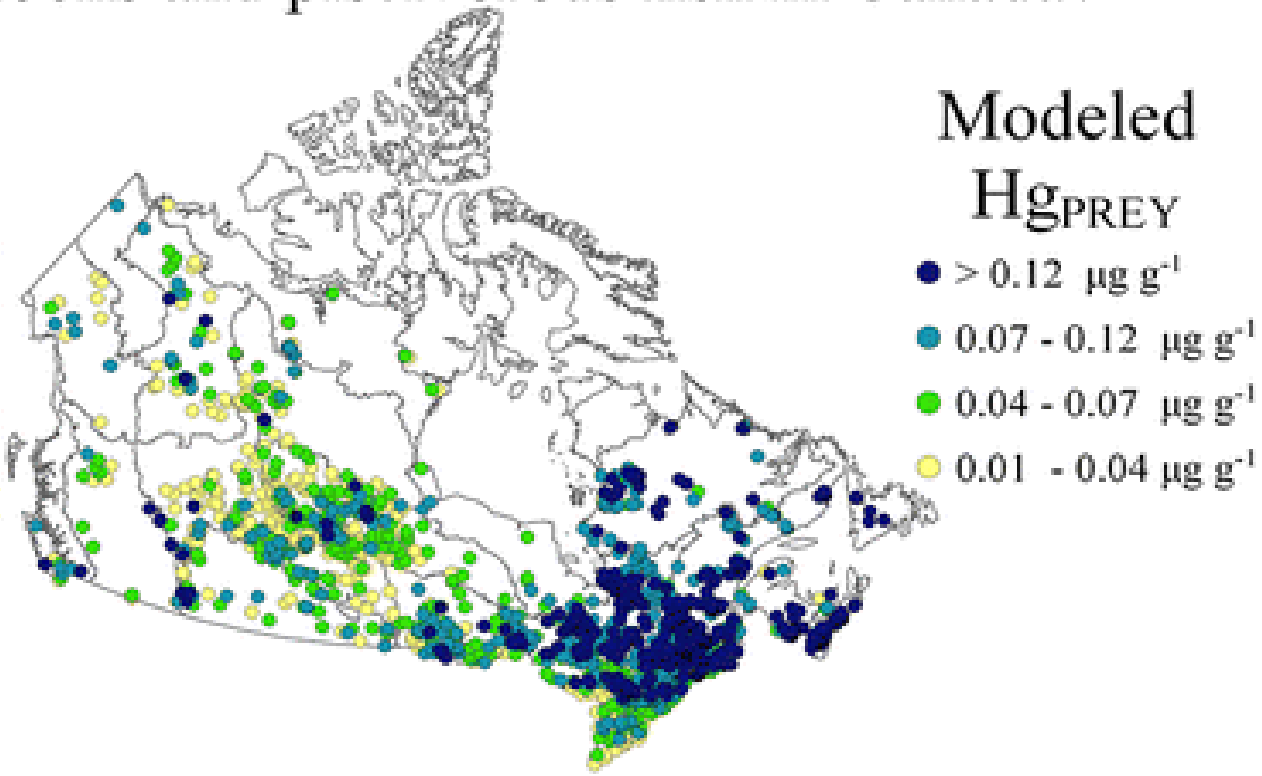
Unquantified Environmental Benefits

The environmental benefits associated with the Regulations are discussed qualitatively as the parameters of interest have yet to be studied and quantified in a manner that is suitable for a cost-benefit analysis.

Typical of what we say for CMP regulatory analyses

2016 Mercury Science Assessment: New Environmental Information

What is the extent of MeHg risk to common loons and piscivorous fish in Canada?



Mercury in Context of CMP CBA

Regulations	Triage	Costs ($)	Reduction (Q)	Risks (Q)	Benefits ($)
PCB	High	✓	✓	✓	✓
2-BE	Medium	✓	✓		
Chromium	Medium	✓	✓	✓	✓
Prohibition	Medium	✓	✓		
Mercury	Medium	✓	✓	✓	✓
Prohibition Amendments (2-ME)	Low	✓	✓	✓	✓
PFOS	Low	✓	✓	✓	✓
PBDE	Low	✓			
Phosphorus Amendments	Low	✓	✓		
PCB Amendments	Low	✓	✓		
Prohibition Amendments (HBCD)	Low	✓	✓		

Conclusions

- This case study is typical of our CMP CBA work:
  - Estimates of both costs and quantities of chemical reductions
  - Incomplete risk and valuation information to permit full CBA
  - Enough monetized benefits to justify the monetized costs
- Better information may be possible regarding the willingness-to-pay (WTP) for risk reductions
- However, even when WTP estimates are available, there may not be enough risk information on incremental exposure in order to apply WTP within a CBA context

Thank you; merci beaucoup!

Additional questions and comments are welcome during the panel discussion, workshop breaks or via email: **joe.devlin@canada.ca**

2016 Mercury Science Assessment: Health Knowledge Gaps

- Lack of data on methylmercury exposure to Canadian children, especially Indigenous Peoples
- Lack of info on connection between methylmercury exposure and other diseases
- Unable to calculate how many deaths may be prevented by regulating mercury

2016 Mercury Science Assessment: Environmental Knowledge Gaps

- Lack of information on impact of mercury contamination in vulnerable ecosystems (e.g. Arctic, coastal regions)
- Inability to monetize exposure of methylmercury for wildlife, changes in land use and climate change
- Inability to monetize economic benefits to fisherman from decreased mercury warnings, as well as cultural benefits to Indigenous Peoples and coastal communities

European experience in restricting mercury

OECD Workshop

Best Practices in Assessing the Social Costs of Selected Chemicals

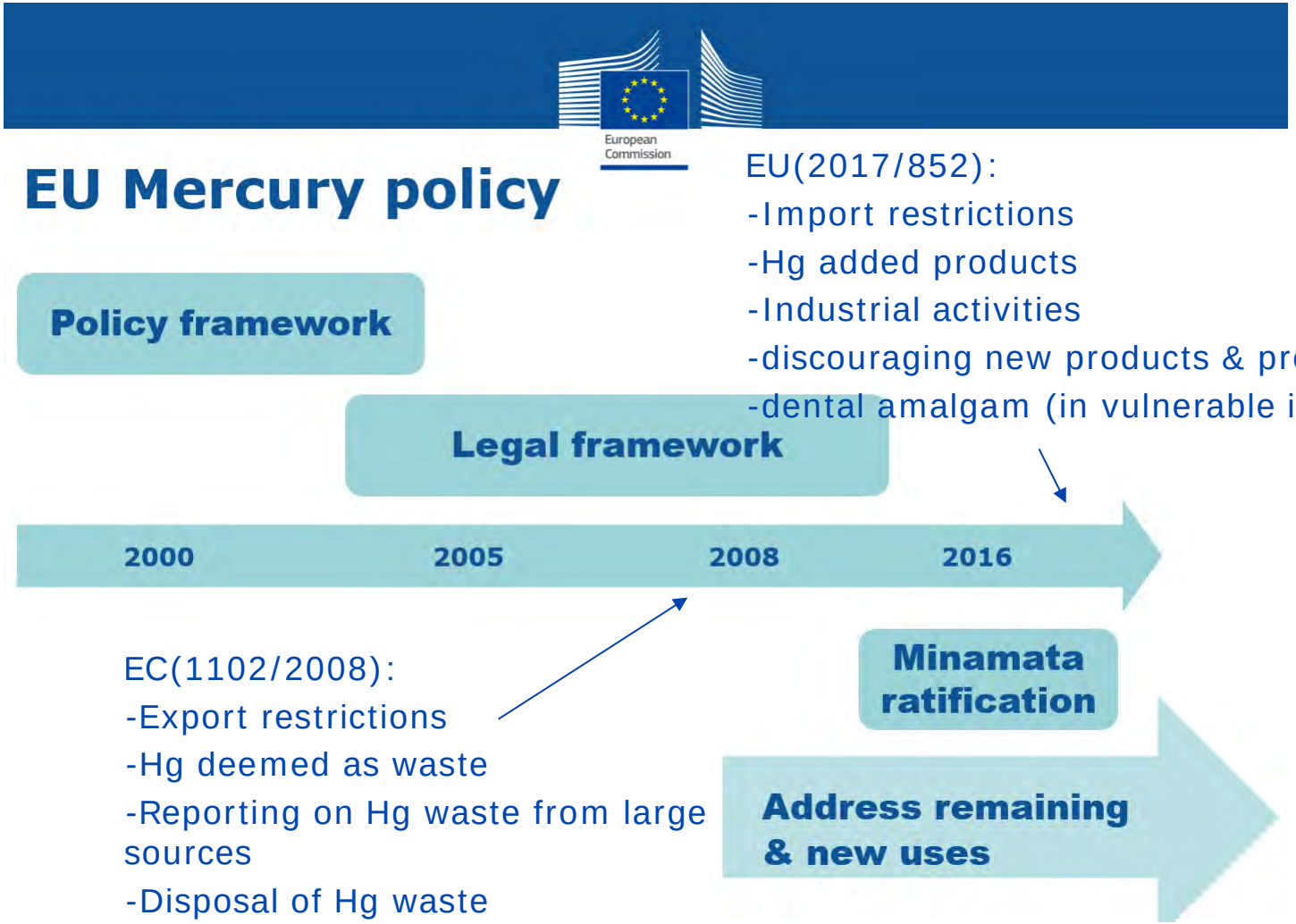
Ottawa, Canada
30-31 August 2017

Christoph Rheinberger
Risk Management Implementation
European Chemicals Agency

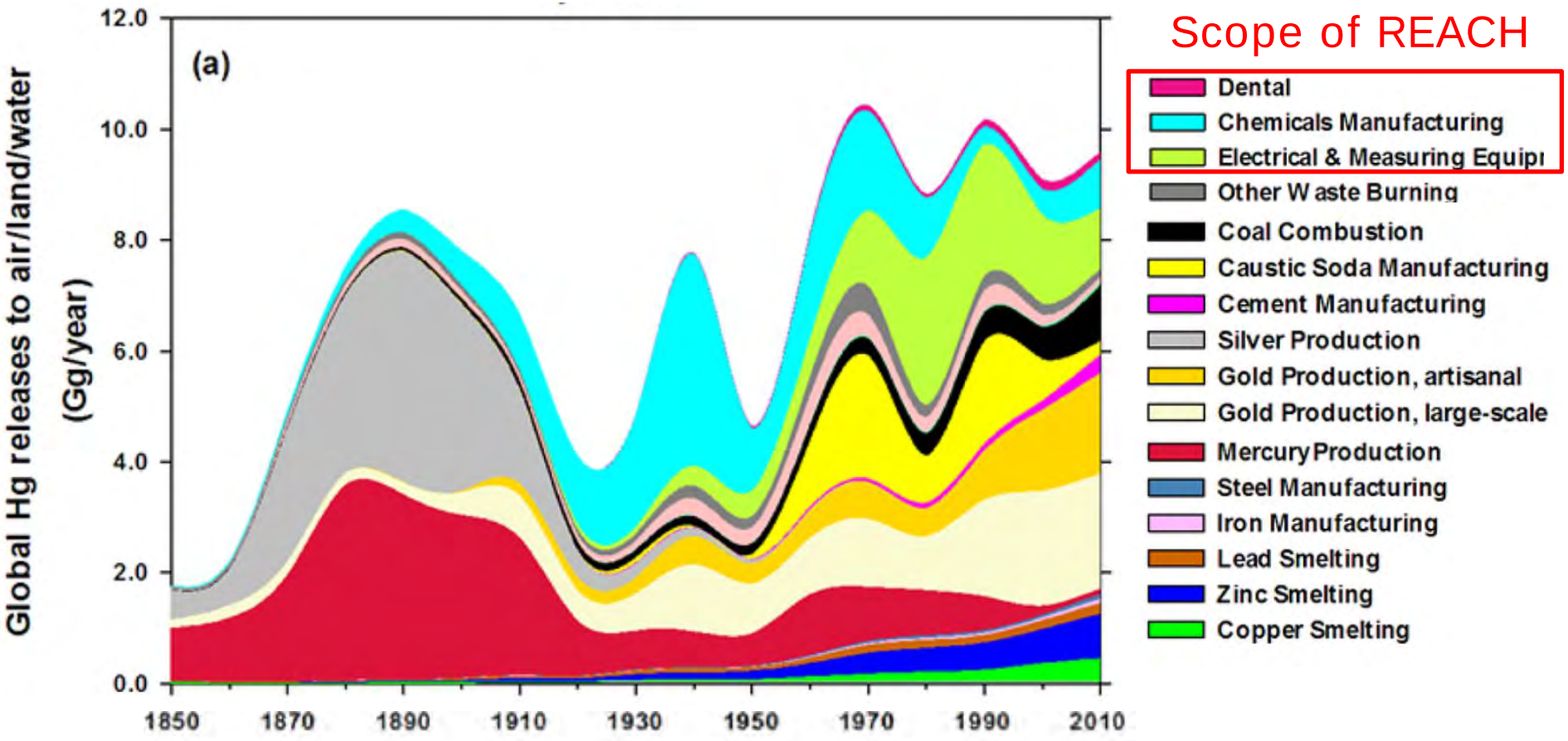
Presentation in a nutshell

- EU regulatory actions on mercury
- Experiences in regulating mercury under REACH
- Challenges in the conduct of socio-economic assessment for Hg (and other heavy metals)

EU regulatory actions on mercury



Anthropogenic Hg releases by sector



Source: Streets et al. (2017) *ES&T* 51: 5969-5977

Existing REACH restrictions (1)

- Two restrictions made under REACH on:
  i. phenylmercury compounds in catalysts
  ii. mercury in measuring devices
- Central estimate of social costs of restrictions:
  i. €1.0m p.a. over a time horizon of 10 yrs
  ii. €12.3m p.a. over a time horizon of 20 yrs
- Central estimate of Hg emissions avoided:
  i. 1.6 tonnes p.a. over a time horizon of 10 yrs
  ii. 3.0 tonnes p.a. over a time horizon of 20 yrs

Existing REACH restrictions (2)

- Benefits not quantified but assumed to be in the range of €5-20k per kg of Hg emission avoided
- Assumptions based on Rice & Hammitt (2005) of how exposure to 1kg would translate into:
  - IQ point loss in (unborn) children
  - Cardiovascular events in adults
- Compare to central estimates of cost-effectiveness:

  i. €650 per kg of Hg emission avoided

  ii. €4,000 per kg of Hg emission avoided

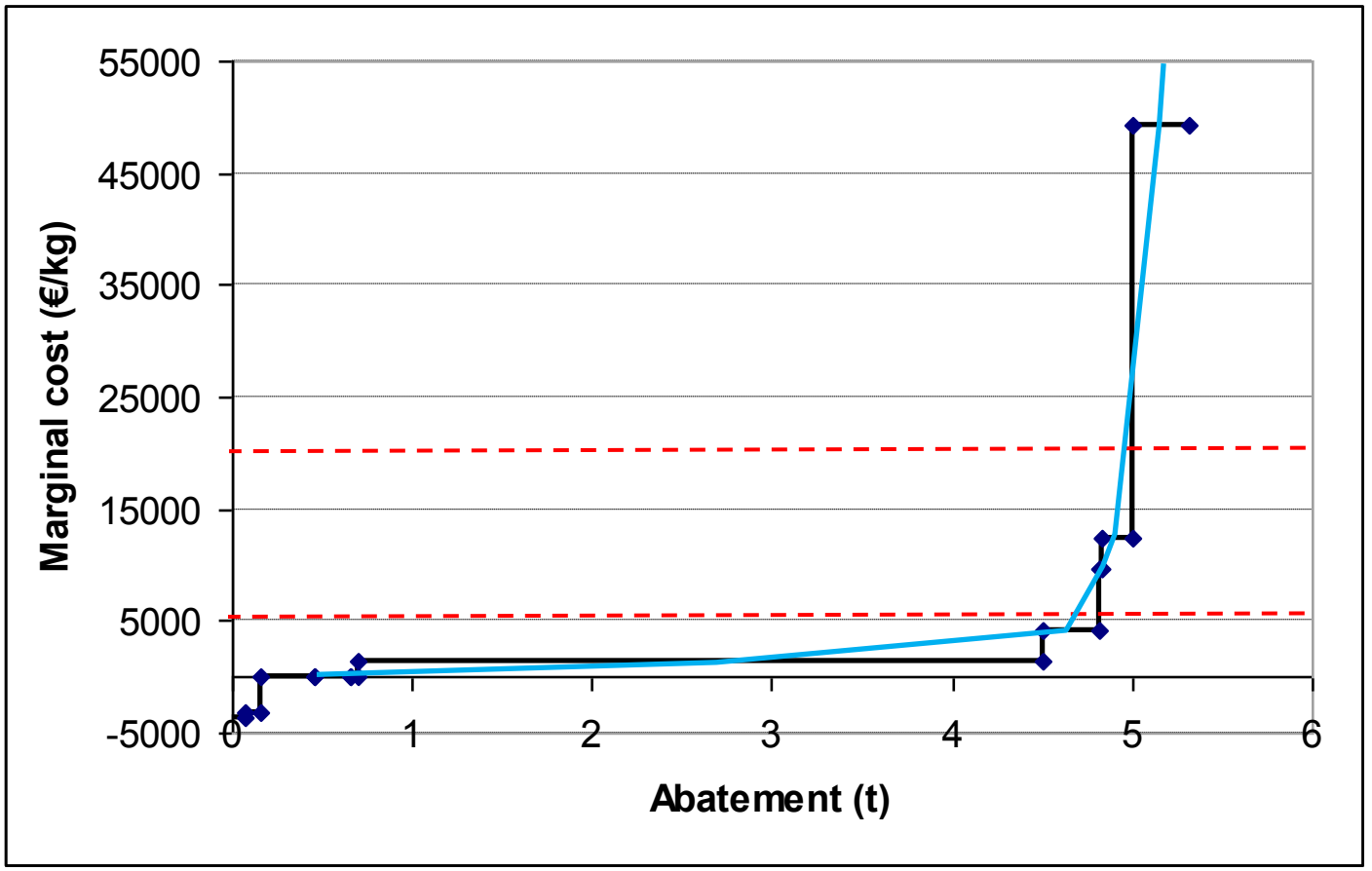
  → both restrictions are likely to pass B-C test

Potential future REACH restrictions

- New restriction on mercury in dental amalgam
- Not yet decided which scope, how (different legal possibilities) and when to be developed

Challenges in SEA of Hg restrictions (1)

- Where to optimally cut-off abatement cost curve?



Challenges in SEA of Hg restrictions (2)

- Where to optimally cut-off abatement cost curve?

Note: the red and green areas do not relate to actual cases and are for illustrative purposes only.

Figure 8 *Graphical representation of the principle of establishing an 'orders-of-magnitude' zone where the costs of PBT measures (in EUR/kg) may (green) or may not (red) be acceptable for cost-effectiveness reasons*

Oosterhuis & Brouwer (2015) Benchmark development for the proportionality assessment of PBT and vPvB substances, available at: https://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

Challenges in SEA of Hg restrictions (3)

- Marginality debate on neurodevelopmental impacts:
  - Does marginally small exposure result in marginal IQ loss (non-threshold assumption)?
  - Can marginal IQ loss be linked to marginal reduction in lifetime earnings?
  - Does baseline IQ matter? Does baseline exposure matter?
  - Do distributional aspects matter? (10 IQ points lost among 100 individuals vs 10 IQ points lost among 100,000 individuals)

Conclusions

- Restrictions on mercury have so far not used a benefit-cost analysis in the strict sense
- Major reason: too many uncertainties in the emission—exposure—endpoint—value chain
- Instead, cost-effectiveness approach used. Has own shortcomings but allows comparison of different regulatory actions (at least for same substance)

Thank you!

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The Economics Interface

Existing approaches to the socio-economic analysis of the impacts of mercury

Richard Dubourg

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OECD Workshop: Best Practices in Assessing the Social Costs of Selected Chemicals

Ottawa, 30-31 August 2017

Outline

- Mercury impact pathways
- Types of mercury study
- Quantified outcomes
- Dose-response relationships
- Valuation approaches
- Geographical coverage
- Pathway assumptions
- Values
- Gaps and ‘issues’

Mercury impact pathways

- Direct inhalation of mercury vapour (ASGM)
- Ingestion of methylmercury through fish consumption
  - Emission of different forms of mercury (elemental, particulate, oxidised)
  - Nearby or distant deposition to ground, lakes and rivers, and oceans
  - Bioaccumulation in (wild) fish at different rates and concentrations
  - Variation in fish consumption across countries, populations, individuals, (species)
  - Variation in exposure of pregnant women and the foetus, and of men/general population

Types of mercury study

- Impact pathway studies of coal-fired power station emissions
- Damage assessments of current exposure to (methyl) mercury
- Mercury exposure in ASGM
- Single study of willingness-to-pay for mercury emission reductions
- Regulatory impact assessments
- (Fishing advisories)

Quantified outcomes

- IQ decrements from pre-natal maternal fish consumption
- 'Mental retardation' (IQ < 70)
- Cardiovascular disease and mortality
- Chronic mercury intoxication (ASGM)
- 'All impacts' of coal-fired power station mercury emissions

Dose-response relationships

- IQ – Faroe Islands, Seychelles and New Zealand epidemiology studies
  - 500 – 1 000 subjects
  - Various measures of exposure (maternal hair, cord blood)
  - Followed through early childhood (c. 7 years)
  - Various measures of intellectual development
  - Threshold/non-threshold, functional forms, individual/integrated
- 'Mental retardation' – assumed
- Cardiovascular effects – epidemiology studies of fish-eating Finnish men

Valuation approaches

- Impact of IQ on market wages (Salkever study)
  - Years of education
  - Labour market participation
  - Hourly wage rates
- Value of statistical life
- Costs of health and educational services
- QALYs/DALYs used for chronic poisoning, IQ-related 'morbidity', non-fatal heart attacks
- Willingness-to-pay for reductions in mercury emissions
- Cost-effectiveness analysis

Geographical coverage

- Impact pathway studies – United States, Taiwan
- Small number of 'global' studies
  - Spadaro and Rabl (2008)
  - Giang and Selin (2016)
- Country-specific damage assessments (US, EU)
- 'National' RIAs in the EU, Canada, Australia (Minamata)
- ASGM in countries in Africa, East Asia, South America

Pathway assumptions

- Mercury emissions – deposition – fish concentrations – mercury consumption – IQ (etc)
- Speciation – no assumption *to* explicit modelling
- Deposition – no pathway *to* identified waterbodies
- Fish concentrations – no assumptions *to* proportional changes
- Ecosystem lags – zero to 50+ years
- Consumption – 100% *to* modelled self-caught fishing behaviour
- Disease latency – discounted cardiovascular risk and salary losses

Values

- Significant variation in values depending on context and assumptions
- US EPA (2005) USD 719 -1 258 per kg, USD 175 - 266 per kg
- Trasande (2005) USD 26 400 per kg (imputed)
- Rice and Hammitt (2005) USD 4 400 – 191 000 per kg (IQ only, IQ and cardio)
- Spadaro and Rabl (2008) USD 1 500 - 3 400 (threshold-no threshold, global mean)
- Shih and Tseng (2013) USD 0.325 - 1.87 million per kg mercury (IQ only, cardio, Taiwan)
- Giang and Selin (2016) USD 150 000 – 1.1 million per kg (Minimata, MATS), USD 6 400 – 61 800 per kg (Minimata, MATS, corrected)

Gaps and 'issues'

- Most gaps are in the scientific evidence base
  - IQ impacts – three small (individually insignificant) studies of highly exposed populations up to age 7; no evidence of effects in adulthood; variation in functional form, effect sizes etc
  - Cardiovascular effects – no consensus
  - Ecosystem impacts (e.g. animal populations) - anecdotal
  - Ecosystem lags – ignored (mostly)
- Cardiovascular effects dominate economic values if included
- IQ-based values assume effects from marginal (sub-clinical) impacts
- Most studies ignore important environmental factors (lags, speciation)
- Values transferred without considering comparability of contexts
- Mercury as a global, persistent pollutant

The Economics Interface

Thank you

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OECD Workshop: Best Practices in Assessing the Social Costs of Selected Chemicals

Ottawa, 30-31 August 2017

Mercury-containing compounds: discussion

James K. Hammitt

Harvard University (Center for Risk Analysis)
Toulouse School of Economics (LERNA)

Observations

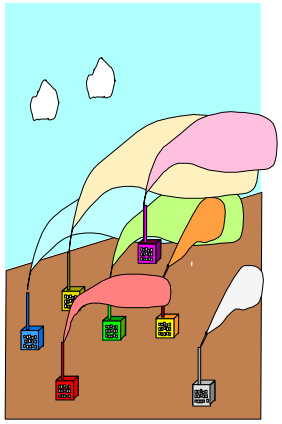
- Impact pathways differ between uses
- Multiple endpoints must be considered
  - Different degrees of uncertainty
- Epidemiology difficult because of confounding
- Valuation of cognitive effects
  - Earnings estimates may be biased upward
  - Stated-preference estimates may be biased downward
- Temporal aspects & sensitivity to discounting
  - Time lags differ across impact pathways
  - Increased environmental concentrations may persist for decades

Impact pathway

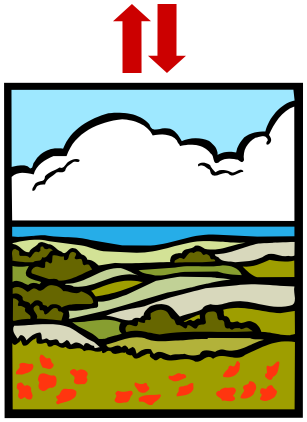
- Existing literature mostly about Hg emissions from coal-fired electricity-generating plants, but policy interest is on other products
  - Pathway from chemical use to human exposure may be very different
  - Effects of exposure to MeHg through dietary fish consumption may remain relevant, but effects of policies on MeHg concentrations by fish species may differ
  - Exposure to other forms of Hg may have different effects
    - Absorption of elemental Hg
      - Inhalation of gas: 70%
      - Dermal contact with liquid: 0.01%
    - Absorption of MeHg (fish consumption): 90%

Mercury from power plants

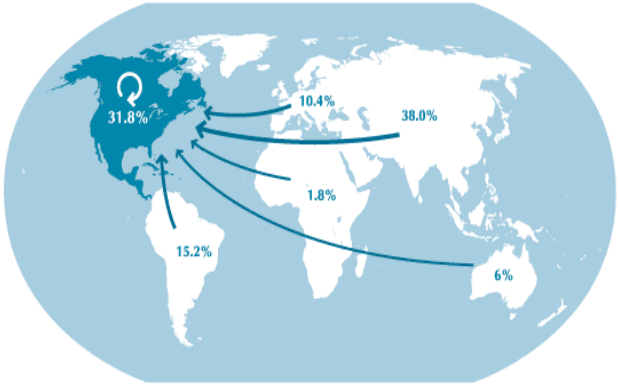
Emissions



Deposition



Fate & Bioaccumulation



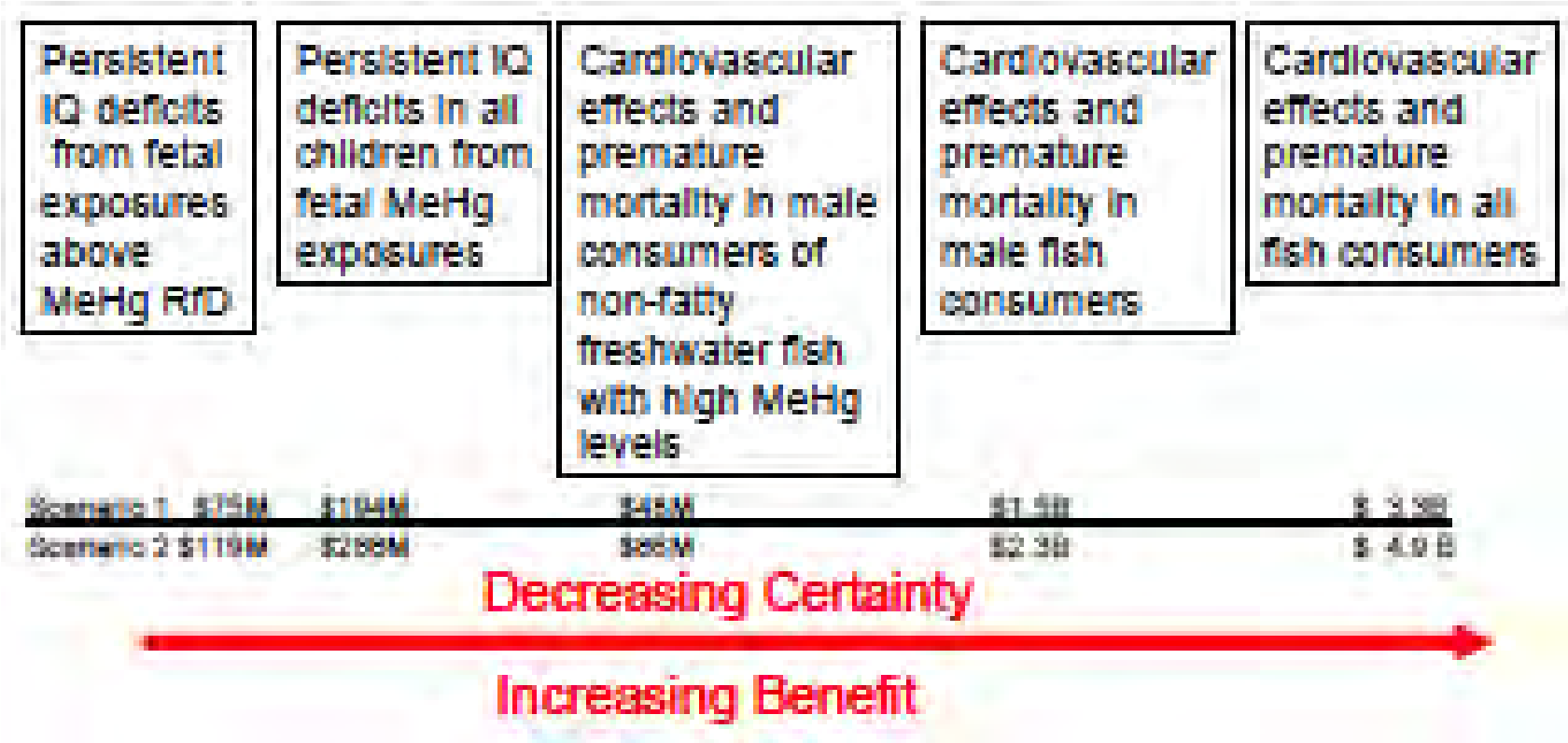
Exposure

IQ loss?
Heart attack?

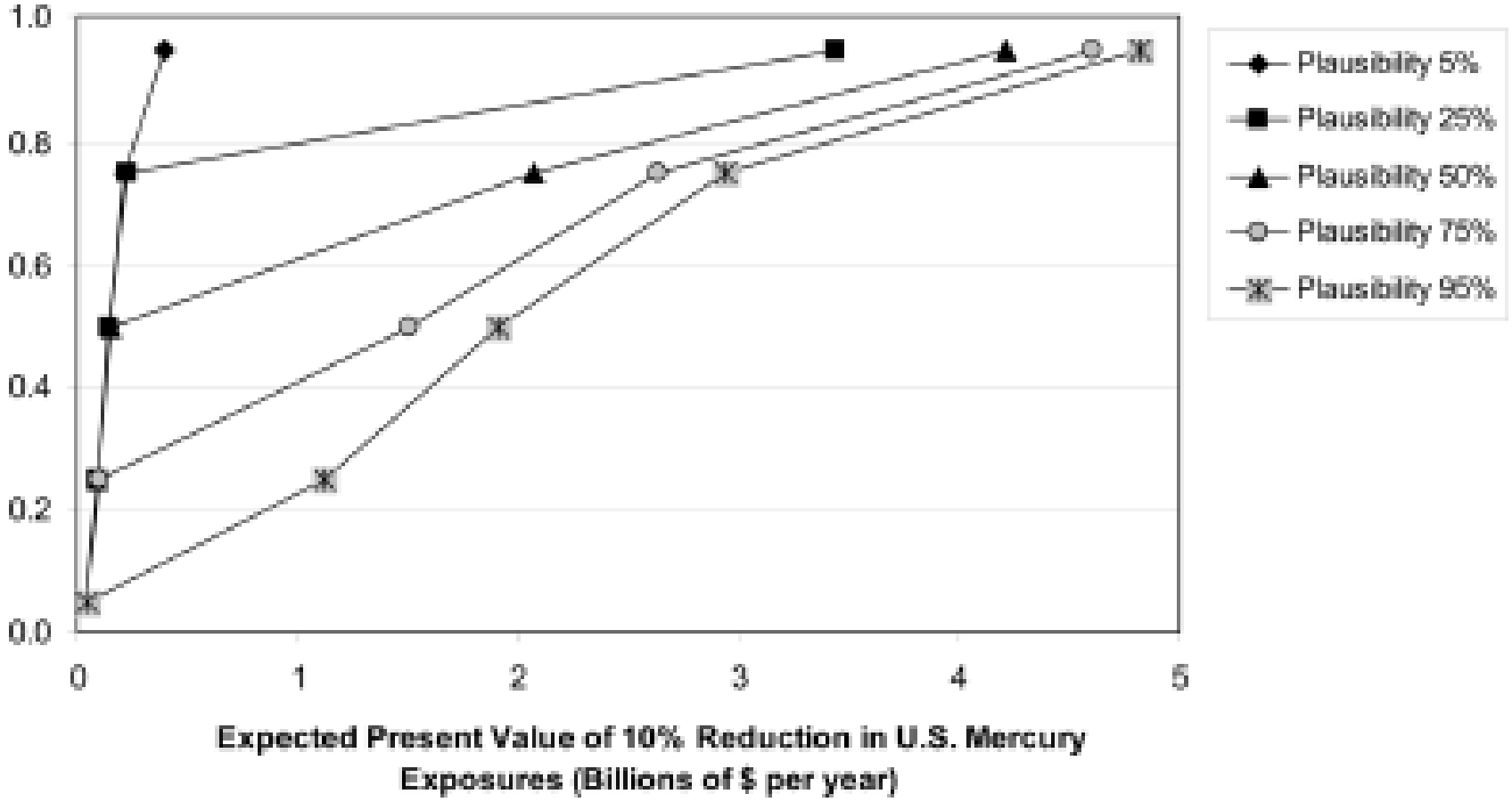
Multiple endpoints

- Multiple endpoints to consider, with different strength of evidence for causality
  - Heart-attack risk seems to dominate developmental cognitive effect, if it is real
    - With probability of causaility ≈ 1/10, heart-attack and cognitive effects are comparable
  - Developmental neurocognitive effects
    - Limited temporal follow-up; assumed to persist through lifetime
    - Diverse & different tests used in epidemiological studies, extrapolated to IQ

"Spectrum of health-effect certainty"
(Rice & Hammitt 2005)



Benefits & prob(causal effect on heart attack)
(Rice et al. 2010)



Epidemiology difficult because of confounding

- Most exposure to MeHg is through dietary fish consumption
  - Fish consumption is protective against heart attacks
  - Fish consumption by pregnant women is beneficial for offspring's neurocognitive development

Valuation of cognitive effects

- Usually estimated as incremental lifetime earnings (proxy for productivity)
- Do relative and absolute IQ affect earnings differently?
  - Studies estimate effect of relative position: increase in IQ shifts individual up in the distribution
  - Effect of population intervention depends on absolute position: upward shift in IQ distribution increases everyone's productivity
  - Are these equivalent?
    - If earnings = marginal product, yes
    - If earnings determined by tournament, perhaps not

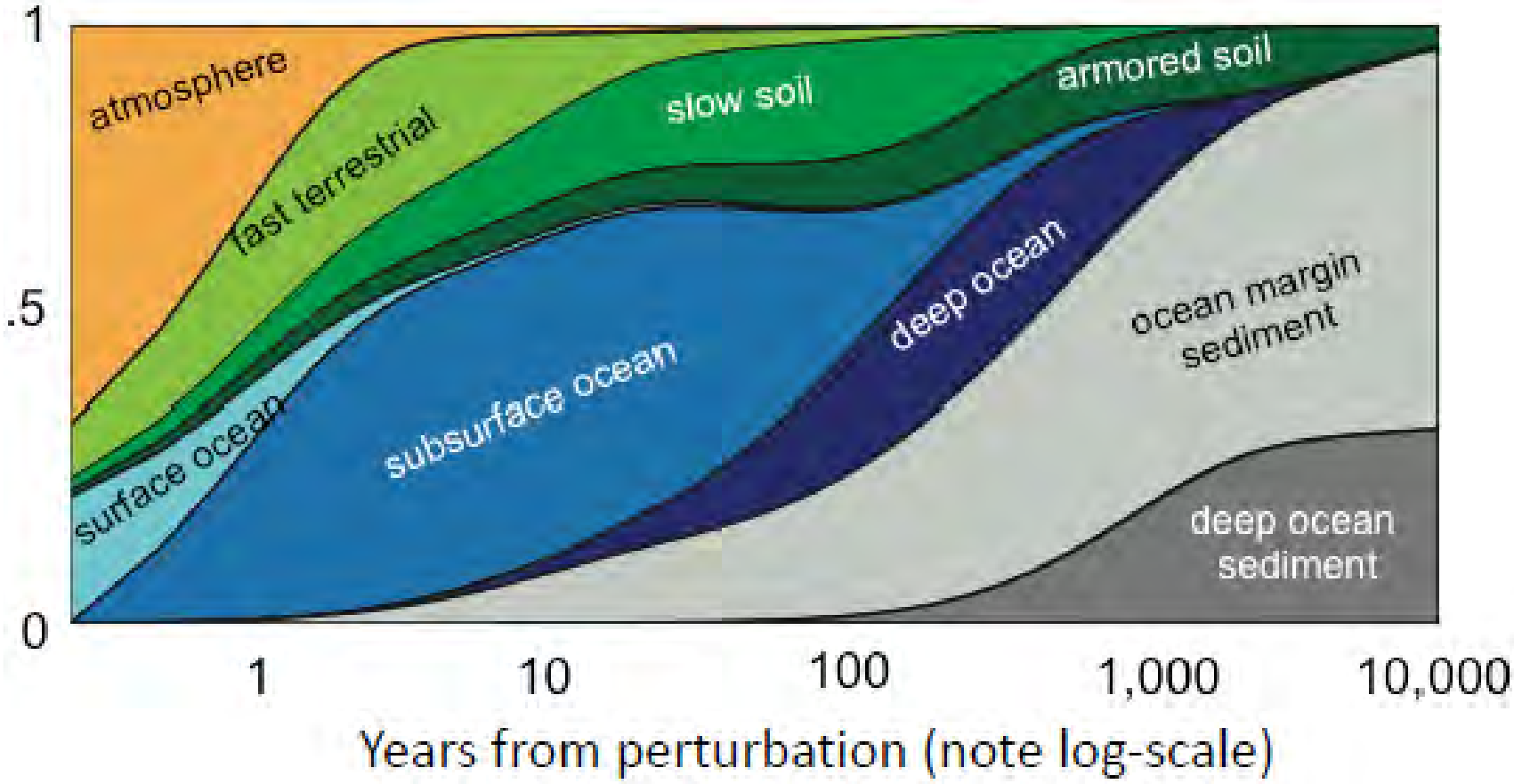
Stated-preference estimates underestimate value of cognitive effects?

- Parents' WTP to reduce risk of a 6 point IQ loss to offspring (from PCB exposure)
  - $500 / IQ point
  - QALY weight for 6 point IQ deficit = 0.99
    - 0.01 x $100,000/QALY / 6 IQ points = $170 / IQ point
    - Von Stackelberg and Hammitt 2009
- Dyslexic individuals' WTP to improve in reading & speaking-aloud skills to "very good"
  - Average WTP = $3000 but annual earnings deficit compared with nondyslexic individuals = $8000
    - Herrera et al. 2017

Temporal aspects

- Time from environmental release to transport to aquatic ecosystem, methylation, bioconcentration in food chain and human consumption can be decades
  - Environmental Hg may be sequestered in soil or other reservoirs & re-emitted later, producing long tail of exposure ("legacy emissions")
  - Effects of emissions may persist for decades
- Minimal time lag for direct exposure
  - E.g., artisanal scale gold mining, dental amalgams
- Effects of prenatal exposure may persist over lifetime
- → results sensitive to discounting

Environmental fate of atmospheric release
(Amos et al. 2013)



Comments on: Socioeconomic analysis of the impacts of mercury

Vic Adamowicz
University of Alberta

UNIVERSITY OF ALBERTA

Department of Resource Economics and Environmental Sociology
Faculty of Agricultural, Life and Environmental Sciences

Impacts of Mercury

- Policy Question
- Ecological impacts / pathways
  - Ecological lags
  - Ecosystem impacts
  - Bio-accumulation
- Human impacts / pathways
  - Health
    - Averting behavior / diet
    - Unintended consequences
    - Valuation
  - Recreation
  - Ecological impacts
    - Passive Use Values - Valuation
  - “Extent of the market”
  - Distribution of impacts
    - Indigenous people

Canadian Mercury Science Assessment (2016)

- Ecological Impacts:
  - 15 year assessment of impacts on fish and wildlife populations:
    - Increased in 31%
    - Decreased in 21%
    - Remained stable in 48%
  - Much slower decline in mercury in wildlife than decline in emissions.
- Human Impacts
  - “1.6% of Canadian children and youth and women of childbearing age combined have mercury levels exceeding the guidance level”
  - Nunavut (2005 – 2007 study) 20% of mothers exceed guidance levels.
  - But downward trends over time
  - North to south trend

Canadian Mercury Science Assessment (2016, pg 13)

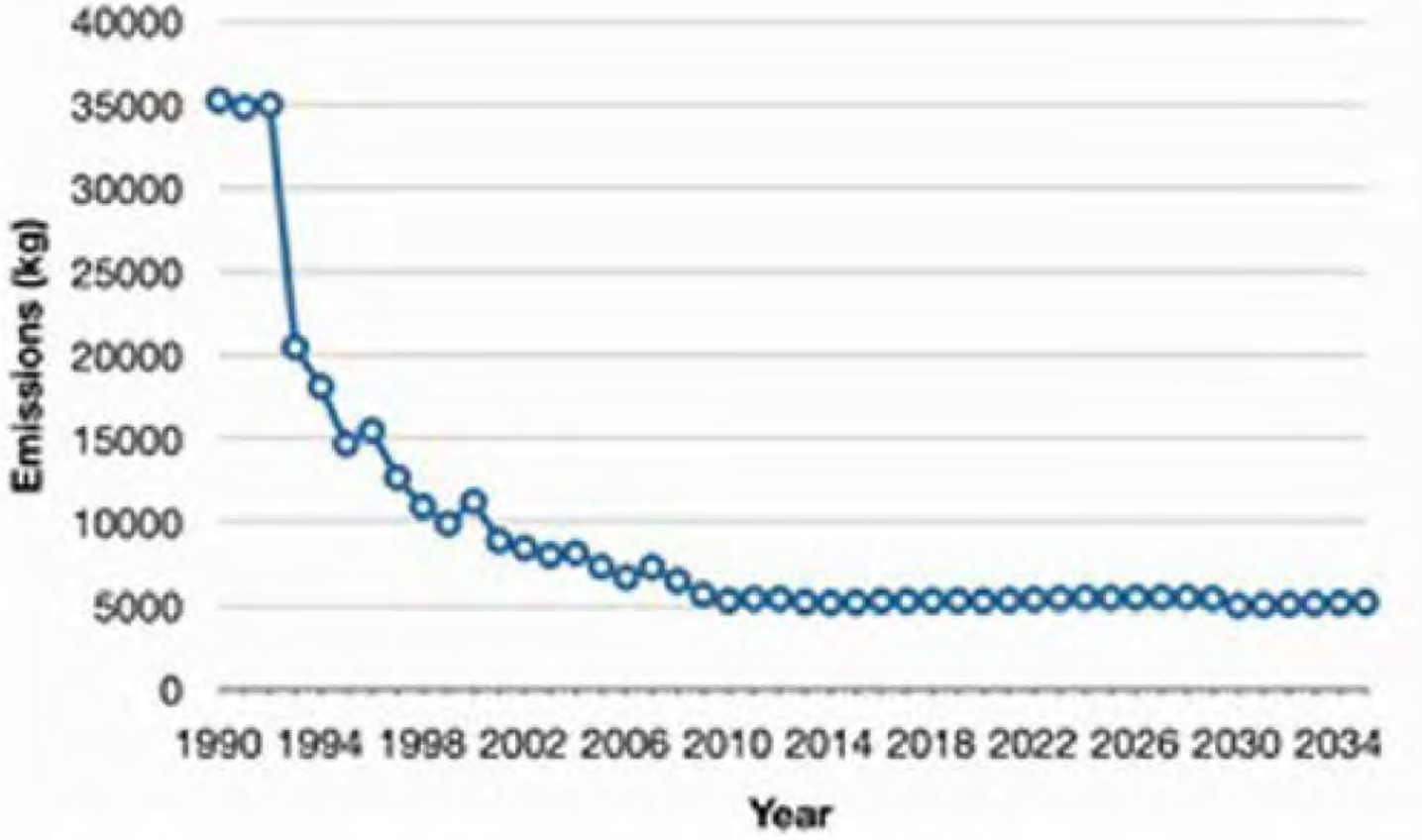


Figure 7: Historical and projected Canadian mercury emissions trends in air using the Energy, Emissions, and Economic Model for Canada (E3MC) model.

Canadian Mercury Science Assessment (2016, Pg 15)

by natural emissions as well as re-emissions of anthropogenically released mercury.

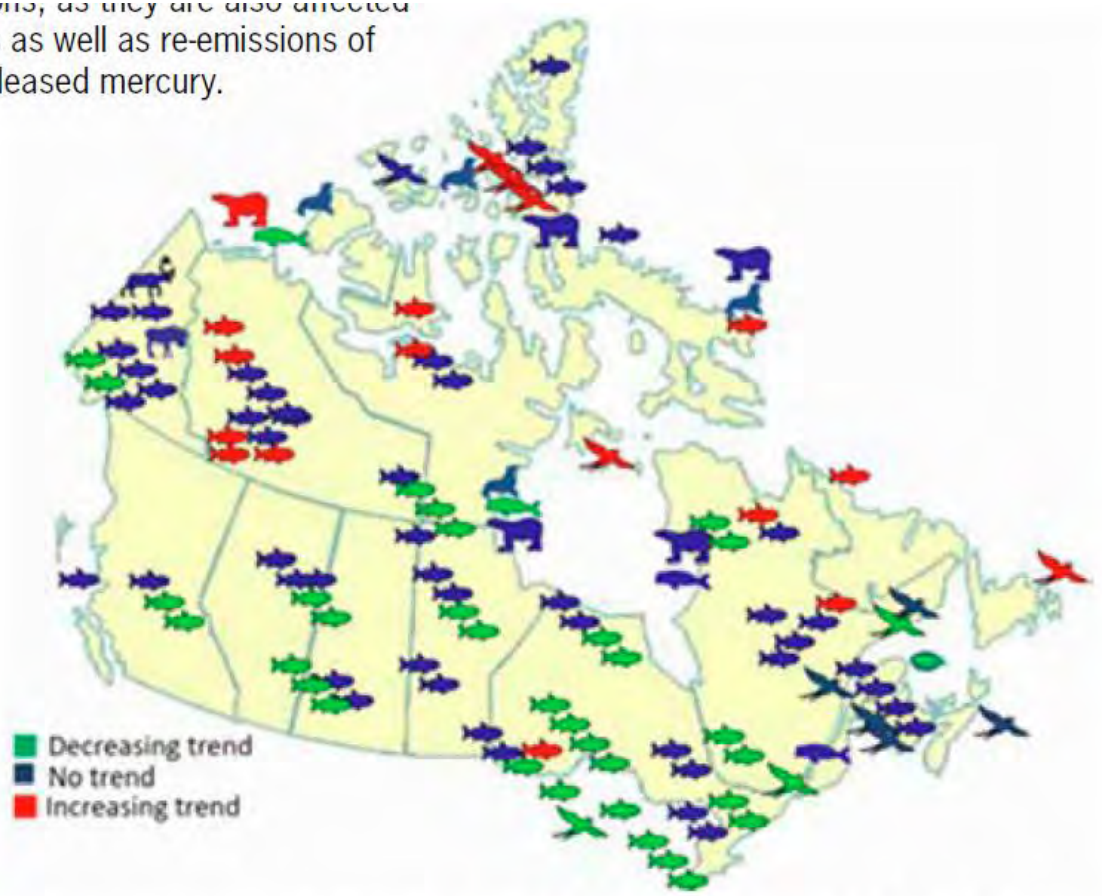


Figure 9: Overall trends in mercury concentrations in Canadian terrestrial mammals, fish, polar bears, beluga whales, seals, seabirds, and mussels (1967–2012).

Mercury: What are the key factors?

- Valuing policy options
  - Given ecological lags and latency, policy option benefits may be “small”
- Valuation endpoint?
  - Human health
    - Mothers, children, anglers, etc.
      - Diet, averting behavior, unintended consequences
    - IQ points / cognitive skills / thresholds
    - Morbidity / Mortality?
      - Cardiovascular
      - Other? (IQ – mortality links)
  - Ecosystem?
    - Wildlife – recreation? (declining license sales; days)
    - Passive use values? (lakes, marine mammals?)

McAuley and Knopper *Environmental Health* 2011, **10**:55
http://www.ehjournal.net/content/10/1/55

ENVIRONMENTAL HEALTH

COMMENTARY Open Access

Impacts of traditional food consumption advisories: Compliance, changes in diet and loss of confidence in traditional foods

Claire McAuley[1] and Loren D Knopper[2*]

Current Agriculture, Food & Resource Issues
A Journal of the Canadian Agricultural Economics Society

Indirect Effects of Pesticide Regulation and the Food Quality Protection Act

Sean B. Cash
Assistant Professor, Department of Rural Economy, University of Alberta

Table 2 Cases of Coronary Heart Disease and Ischemic Stroke Induced in the U.S. Population by a 1 Percent Increase in the Price of All Fruits, All Vegetables, or All Fruits and Vegetables

Disease	All fruits	All vegetables	All fruits and vegetables
Coronary heart disease	1,442	2,951	6,903
Ischemic stroke	744	1,482	3,022
Total	2,186	4,433	9,925

Source: Cash (2003).

Results reported are the simulation means from a series of Monte Carlo trials (n=100,000).

thebmj

BMJ 2017;357:j2932 doi: 10.1136/bmj.j2932 (Published 2017 June 28)

EDITORIALS

Check for updates

Higher IQ in childhood is linked to a longer life

OPEN ACCESS

New data on cause of death suggest the link is mediated by risk factors such as smoking

RESEARCH

CrossMark

Childhood intelligence in relation to major causes of death in 68 year follow-up: prospective population study

OPEN ACCESS

Catherine M Calvin *postdoctoral research assistant*[1 2 3], G David Batty *reader in epidemiology*[2 4], Geoff Der *senior research fellow*[2 5], Caroline E Brett *lecturer in health psychology*[2 6], Adele Taylor *research assistant*[1], Alison Pattie *research associate*[1], Iva Čukić *postdoctoral research assistant*[1 2], Ian J Deary *professor of differential psychology*[1 2]

Mercury: What are the key factors?

- Valuation approach?
  - IQ points
    - Earnings versus WTP?
    - Recent Canadian study: $4,000 / IQ point WTP (2013 CAN$) (Edwards 2015); $10-$20K other literature using earnings
    - New Lin at al (2016) results on IQ points and earnings ($8K - $13K assuming 3% discount – 2016: See Hafstead and Lutter, 2016.)
    - Why the difference?
      - Research topic….. Endogeneity, Marginal Costs, Discounting, Perceptions / Information?
  - Cardiovascular impacts (mortality / morbidity)
    - VSL, variants
  - Recreational fishing impacts?
  - Private goods versus public goods?
    - Hagen et al. SP study
    - Passive use and use value
    - Altruism

Lin et al, 2016. Pg. 42

Table 7: Cognitive Performance Effects on Lifetime Labor Income through Age 65

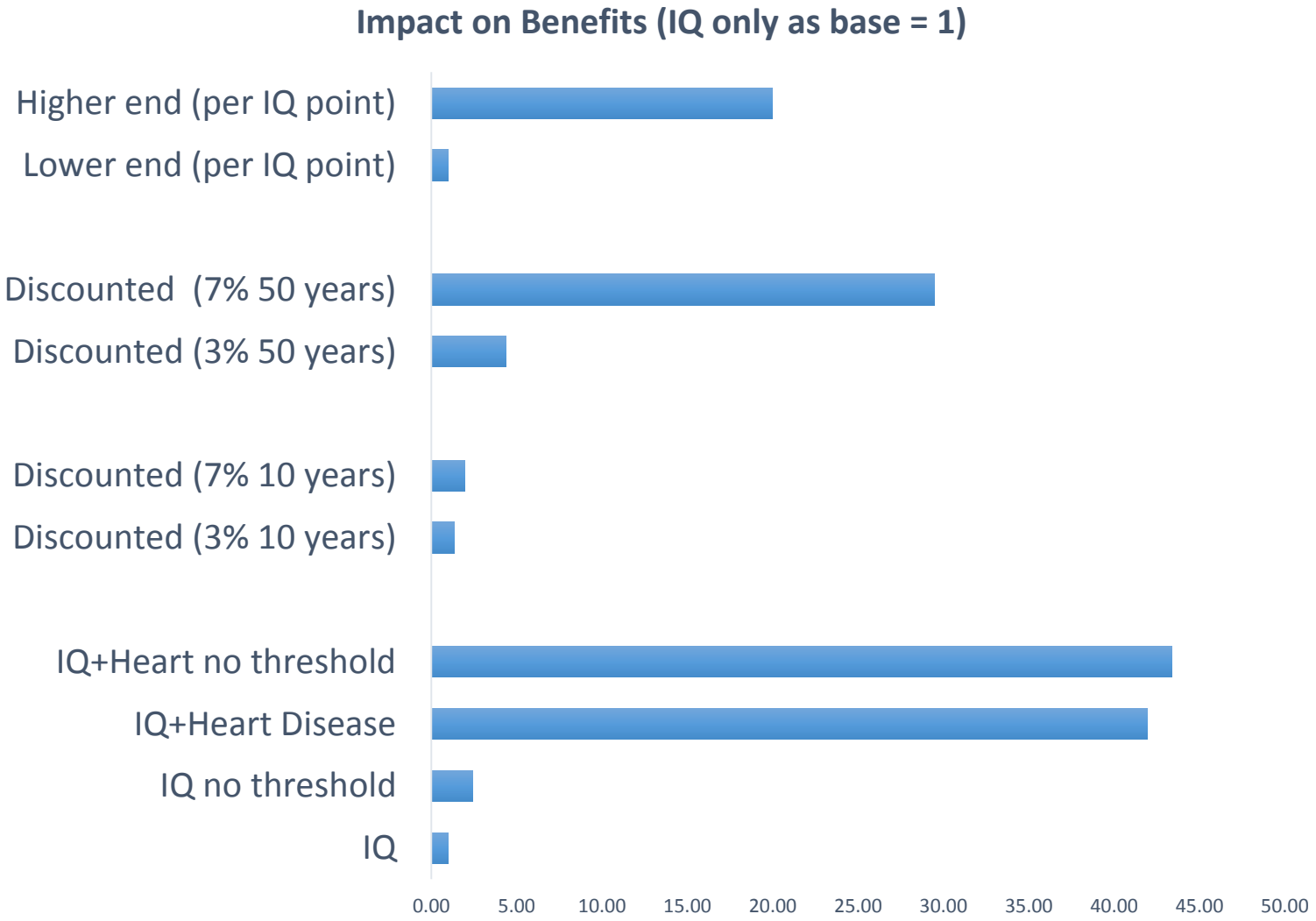
	All	Men	Women	Non-Hispanic White	Non-Hispanic Black	Hispanic
Percentage Change	2.15% (0.16%)	1.71% (0.21%)	2.62% (0.24%)	1.92% (0.17%)	3.59% (0.28%)	3.13% (0.31%)
Lifetime Incomes NLSY79 Cohort	$11,846 (886)	$12,560 (1489)	$10,168 (905)	$11,294 (1004)	$13,107 (1027)	$14,010 (1361)
Lifetime Incomes 2014 Births	$19,545	$20,724	$16,778	$18,635	$21,626	$23,117
N	3,950	1,860	2,090	3,206	1,892	1,177

Note: See notes on Tables 2, 5 and 6. Table shows estimated effects of a 0.1 standard deviation increase in AFQT score for the representative NLSY79 sample as a percentage or dollar amount change on the net present value of the sum of annual labor income from age 20 through age 65 for the specified population group. Incomes are discounted to the birth year using an annual real discount rate of three percent and are expressed in 2014-year dollars. For Americans born in 2014, the estimates are inflated by the growth in real earnings occurring from 1961 to 2014. For all individuals, men and women, data are from the nationally representative NLSY79 sample. The race/ethnicity estimates use the full sample, including the supplementary samples of blacks and Hispanics. "Whites" refer to non-black non-Hispanics. In addition to AFQT scores, the models control for background, age-varying, and non-cognitive characteristics and survey year fixed-effects. Robust standard errors are shown in parentheses.

Mercury: What are the key factors?

- Discount rate
  - Ecological lags
  - Latency
- Distributional impacts
  - Indigenous people

Very rough “Sensitivity Analysis Factors”



Conclusions

- Dubourg provides an excellent review
- There is “reasonable” knowledge of pathways and impacts
  - Thin dose- response – but at least something!
- Key questions
  - BCA context
  - Uncertainties re morbidity / mortality
  - Lags / discounting
  - Valuation puzzles / challenges
    - Validity of RP, SP and Earnings studies
    - New studies – focus on cognitive impacts?
    - Can we get away from lost earnings and IQ points…..?
    - Passive use values
  - Extensions
    - Climate change, changing “preferences”, distributional effects

References

- Canadian Mercury Science Assessment. 2016. Environment and Climate Change Canada. Cat. No.: En84-130/2-2016F-PDF
- Edwards, B. 2015. Valuation of neurological impacts from childhood lead exposure. Presented at Working Meeting on Best Practices in Economic Analysis to Support Chemicals Management. February 16-17, 2015. Ottawa, Canada
- Lin, D., R. Lutter and C. Rehm. 2016. Cognitive performance and labor market outcomes. NBER Working paper 22470.
- Halfstad, M. and R. Lutter. 2016. What is the economic value of improved labor market outcomes from infant nutrition. Resources for the Future discussion paper DP 16-29.

U.S. Experience with Socio-Economic Analysis: Formaldehyde Standards for Composite Wood Products

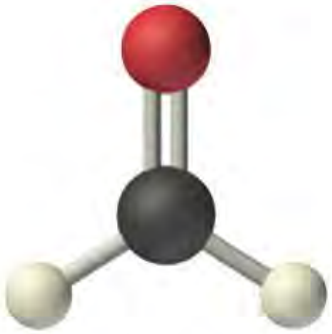
OECD Workshop on Best Practices in Assessing the Social Costs of Selected Chemicals

August 30, 2017

BACKGROUND

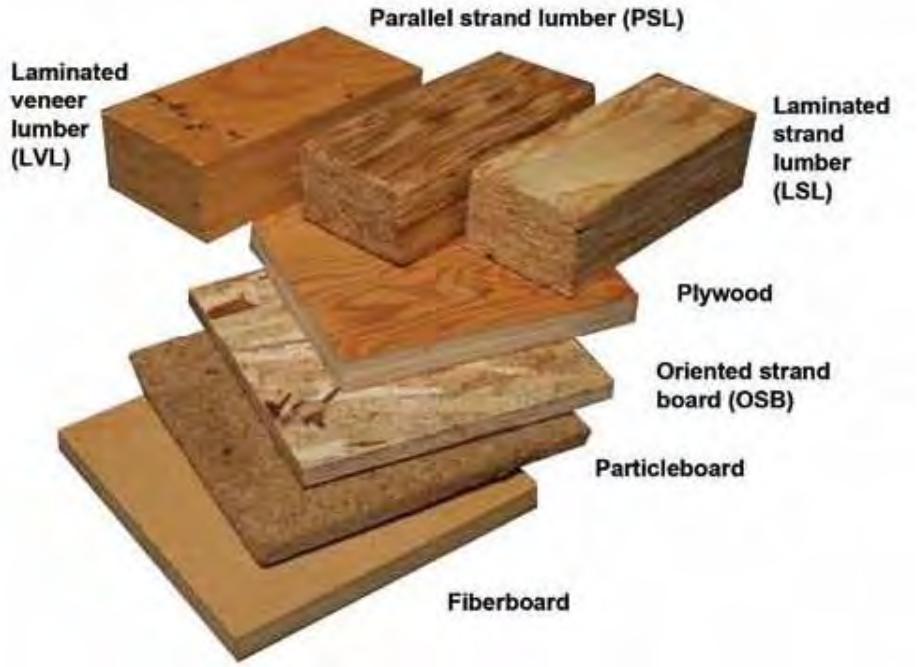
Formaldehyde in consumer products

- Formaldehyde is a known human carcinogen. It can also cause eye, nose, and throat irritation, as well as cause respiratory symptoms.
- Many household products emit formaldehyde. These include glues, permanent press fabrics, carpets, antiseptics, medicines, cosmetics, dishwashing liquids, fabric softeners, shoe care agents, lacquers, plastics and paper product coatings.
- Formaldehyde-based resins are often used as glues in making wood-based composites.
  - These resins can continue to emit formaldehyde long after the products have been manufactured, leading to concerns about consumer exposures and health effects.



Formaldehyde, CH_2O

Some examples of wood-based composites



Hardwood plywood, **medium density fiberboard**, and **particleboard** are used in cabinets for electronics; door components; flooring; household furniture; kitchen & bath cabinets, vanities, and countertops; millwork; moulding; office furniture; paneling; shelving; store fixtures; and various other applications.

Urea formaldehyde (UF) resins are often used as glue in these products.

California Formaldehyde Rule

- In 2008, California established formaldehyde emission limits for 3 types of “composite wood products” – panels of hardwood plywood, particleboard or medium-density fiberboard.
- Panel manufacturers must demonstrate compliance through emissions testing and third-party certification.
- Finished goods sold in California must be made from compliant panels.
- Applies to products sold in California whether they are produced there, elsewhere in the U.S., or outside the U.S.

California Formaldehyde Rule

- Chain of custody requirements for panels and finished goods apply to panel manufacturers, distributors, importers, fabricators, and retailers. Requirements include product labeling and recordkeeping.
- Due to the size of the affected market, the California rule became a *de facto* national standard in the U.S., and affected production throughout the world.

This product contains composite wood that complies with Phase 2 of CA ATCM 93120 for formaldehyde

Federal Regulation of Formaldehyde by U.S. EPA

- In 2010, the U.S. Congress passed legislation amending the federal Toxic Substances Control Act (TSCA).
- The statute directed EPA to implement regulations establishing a national formaldehyde program to ensure compliance with emission standards identical to those in the California rule.
- EPA published a proposed rule for public comments in 2013 and a final rule in 2016.
- EPA has subsequently proposed minor amendments and technical corrections to the rule.

Some Challenges in EPA's Economic Analysis of the Formaldehyde in Composite Wood Products rule

1) Concentration-response functions for health endpoints;

2) Benefits of labeling, notification, chain-of-custody, recordkeeping, and other administrative requirements; and

3) Impact of compliance date on rule costs.

CONCENTRATION-RESPONSE FUNCTIONS TO ESTIMATE HEALTH BENEFITS FOR ECONOMIC ANALYSIS

Health endpoints and economic analysis

- EPA identified 8 health endpoints as being associated with formaldehyde exposure.
- EPA initially determined that 4 endpoints had sufficient data for quantitative concentration-response modeling in support of the benefits assessment:
  - nasopharyngeal cancer,
  - asthma,
  - eye irritation, and
  - reduced fertility

Formaldehyde exposure and asthma

- Research suggests that exposure to asthma can influence a variety of respiratory related effects. This includes two impacts on asthma:
  - **Exacerbation** – bad asthma day in existing asthmatics;
  - **Occurrence** – new cases of asthma in children who had not been asthmatic.
- EPA determined that a statistical relationship between formaldehyde exposure and asthma exacerbation has not yet been sufficiently well established to develop a concentration-response function.
- After peer review of a methodology to estimate asthma benefits from reducing children's exposure to formaldehyde, EPA initially concluded that there was sufficient evidence to include asthma occurrence in the Economic Analysis.

Benefits of reducing risk of asthma in children

The monetized benefit of reducing asthma risk was estimated as

$$\mathbf{Benefits} = \mathbf{WTP} * \mathbf{POPC} * \mathbf{IncAa} * \left(1 - \left(e^{(\ln(\mathbf{OR}) \times (\mathbf{AIDC_p} - \mathbf{AIDC_b})}\right)\right)$$

where

WTP = willingness-to-pay to avoid statistical case of asthma

POPC = population of children exposed to formaldehyde from composite wood

IncAa = annual baseline asthma incidence rate

OR = odds ratio for asthma derived from McGwin et al (2010) meta-analysis

$AIDC_p$ = average indoor daily concentration of formaldehyde for the policy scenario

$AIDC_b$ = average indoor daily concentration of formaldehyde for the baseline scenario

Willingness-to-pay (WTP)

- **WTP to avoid asthma estimated at $35k to $66k (USD 2010).**

- This lifetime WTP is the present discounted value of the stream of annual WTPs to avoid a year of asthma. Based on average of estimates of annual WTP to avoid asthma of $2,268 per year (1996$) in Blumenschein and Johannesson (1998); and $1,200/year (1990$) in O'Conor and Blomquist (1997); adjusted for age of child, life-expectancy, and fraction of asthmatic children who become asymptomatic at some point as adults.

- The monetized benefits were estimated based on studies of willingness-to-pay to avoid asthma in adults. While there is evidence that parents are willing to pay more to avoid adverse health effects in their children than they are to avoid the same adverse health effects in themselves, EPA did not account for this.

Population of exposed children (POPC)

- Populations were estimated from U.S. Census data.
- Separate cohorts were calculated based on:
  - Age of the child (less than age 2; 3 to 15; or 16 to 17 years old).
    There are different activity patterns and exposures for different age groups.
  - Residence type (single family attached, single family detached, apartment, manufactured housing, or trailer/camper/recreational vehicle).
    This affects the amount of composite wood products used and the volume of air in the residence.
  - Whether the source of composite wood products was new construction or renovation.
    This affects the quantity of composite wood products used.
  - How long since the residence was built or renovated.
    Formaldehyde can off-gas from composite wood products for over 10 years, at a declining rate.
  - The climate zone.
    Temperature and humidity affect the rate of formaldehyde releases from composite wood.

Baseline asthma incidence rate (IncAa)

- **The estimated annual baseline asthma incidence rate is 0.83% for each age of child.**
- Based on data from the U.S. Centers for Disease Control and Prevention that 8.3% of children in the 5-14 age range have been diagnosed with asthma, and assuming that new asthma cases are uniformly distributed over the 10 ages in that age range.
- Applied to all ages through 17 (assumes that children do not outgrow asthma before age 17).
- The baseline rate of asthma in children under age 6 is uncertain because conducting lung function testing on young children is difficult so doctors may rely on symptoms instead, resulting in misdiagnoses.
  - EPA calculated an estimate of higher-end benefits based on children ages 2 to 17, and a lower-end estimate based on children ages 6 through 17.

Odds Ratio (OR)

- **EPA calculated an odds ratio of 1.027 per ppb increase in formaldehyde exposure, with a 95% confidence interval of 1.008-1.047 per ppb.**
- Based on McGwin et al (2010) meta-analysis of several studies of formaldehyde and asthma in children.
- The studies included in the McGwin et al. measured individuals' exposure to formaldehyde at a single point in time; almost all of the studies related that single formaldehyde measurement to asthma *prevalence* rather than *incidence*.
  - A **prevalence** study relates the number of asthma cases at a given point in time to the formaldehyde levels at that time.
  - An **incidence** study associates new cases of asthma with formaldehyde exposure over some period of time.

Odds Ratio (OR)

- To estimate the benefits of reducing formaldehyde levels, the economic analysis must estimate the change in asthma **incidence**. Using McGwin results in benefits analysis requires assuming that

  1) The formaldehyde exposure measurements in the underlying studies reflect typical or average exposure levels of the individuals in the study; and

  2) Asthma prevalence in an age group can be considered cumulative incidence up to that age.

Formaldehyde Indoor Air Model

- AIDCs were modeled by EPA using its Formaldehyde Indoor Air Model - Pressed Wood Products, Version 2.0 (FIAM-pwp v2.0). The model was designed to estimate the steady-state formaldehyde concentration indoors due to emission sources such as composite wood products.

- The initial, “steady-state” indoor concentration estimated by the model is assumed to decrease over time as the reservoir of formaldehyde in various sources is gradually depleted; the gradual decrease is assumed to follow a first-order exponential process.

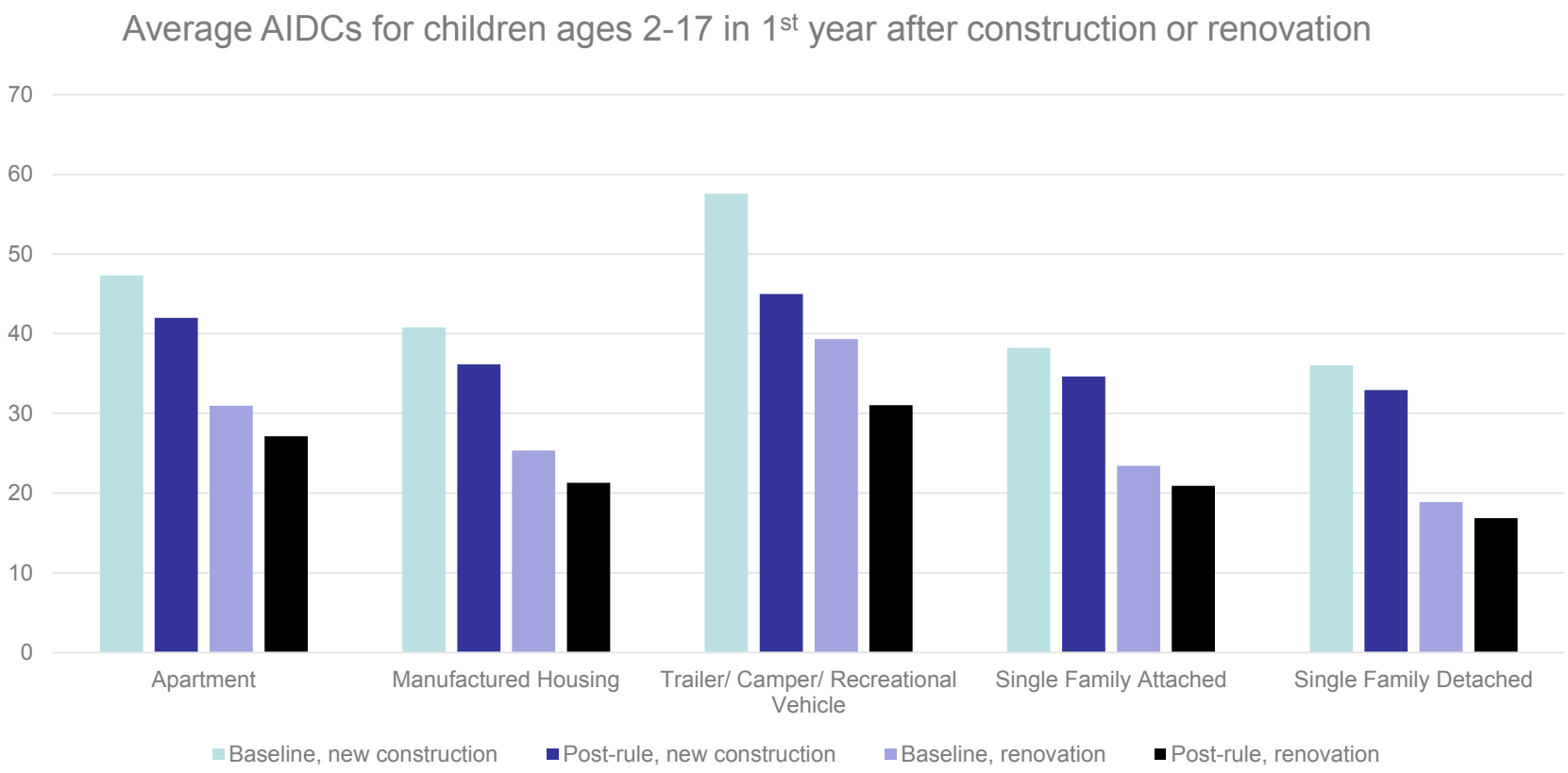
- Inputs to the FIAM-pwp model include the formaldehyde background concentration, building air volumes and airflows, indoor temperature and humidity, the types and amounts of PWPs installed in the structure and their emission rates, and age specific exposure factors and activity patterns for the occupants (such as time spent in/out of the residence).

Average indoor daily concentration (AIDCs)

- **In the analysis of the proposed rule, average AIDCs for children ages 2-17 in 1st year after construction or renovation ranged from 19 to 58 ppb in the baseline, depending on the housing type. Comparable post-rule values ranged from 17 to 45 ppb.**

- Separate AIDCs were calculated using FIAM-pwp for each of the populations described earlier (based on age of the child, residence type, new construction or renovation, time since construction or renovation, and climate zone).

Average indoor daily concentration (AIDCs)



Initial Economic analysis for proposed rule option

Annualized Quantified Benefits (millions 2010$)

	3% Discount Rate	7% Discount Rate
Cancer	$20 to $43	$9 to $19
Eye irritation	$1 to $5	$1 to $4
Asthma	$162 to $229	$81 to $113
Reduced Fertility	$2	$1
Total	**$184 to $278**	**$91 to $137**

Initial Economic analysis for proposed rule option

Annualized Quantified Net Benefits (millions 2010$)

	3% Discount Rate	7% Discount Rate
Costs	$72 to $81	$81 to $89
Benefits	$184 to $278	$91 to $137
Net Benefits	**$103 to $206**	**$2 to $57**

Quantitative estimates of avoided asthma were removed from the analysis

- After inter-agency review EPA removed the quantitative benefits estimates for asthma occurrence and reduced fertility, due to uncertainty regarding how best to quantify formaldehyde exposure's effect on these endpoints. The economic analysis substituted a qualitative discussion of the evidence about the relationship between formaldehyde and these health effects.

- Avoided cases of asthma accounted for the majority of quantified benefits in EPA's initial analysis of the proposed rule. Removing the asthma estimates substantially decreased the quantified benefits estimates, and changed the sign of the quantified net benefits of the proposal from positive to negative.

- The estimates of costs and benefits changed at the final rule stage, although the benefits from avoiding asthma were still discussed qualitatively.

Revised Economic analysis for proposed rule option

Annualized Quantified Benefits (millions 2010$)

	3% Discount Rate	7% Discount Rate
Cancer	$20 to $43	$9 to $19
Eye irritation	$1 to $4	$1 to $4
Asthma		
Reduced Fertility		
Total	**$20 to $48 + B**	**$9 to $23 + B**
"B" represents the unquantified benefits		

Revised Economic analysis for proposed rule option

Annualized Quantified Net Benefits (millions 2010$)

	3% Discount Rate	7% Discount Rate
Costs	$72 to $81	$80 to $89
Benefits	$20+B to $48+B	$9+B to $23+B
Net Benefits	**($60)+B to ($24)+B**	**($79)+B to ($57)+B**
"B" represents the unquantified benefits		

Evolution of estimates and rule

Annualized Quantified Net Benefits (3% discount rate, millions 2010$)

	Proposed rule stage		Final rule stage	
	Initial analysis for proposed rule option	**Revised analysis for proposed rule option**	**Reanalysis of proposed rule option**	**Final rule**
Costs	$72 to $81	$72 to $81	$155 to $297	$38 to $83
Benefits	$184 to $278	$20+B to $48+B	$77+B to $226+B	$64+B to $186+B
Net Benefits	**$103 to $206**	**($60)+B to ($24)+B**	**($220)+B to $71+B**	**($19)+B to $148+B**
"B" represents the unquantified benefits				

Evolution of estimates and rule

Annualized Quantified Net Benefits (7% discount rate, millions 2010$)

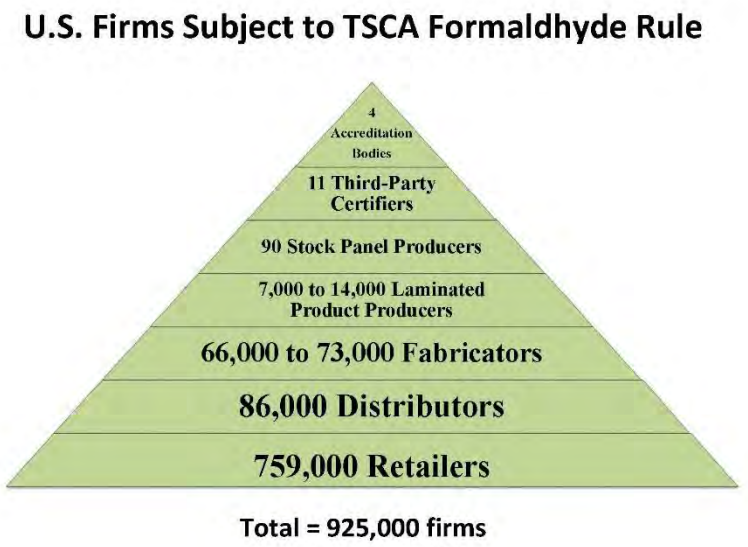
	Proposed rule stage		Final rule stage	
	Initial analysis for proposed rule option	**Revised analysis for proposed rule option**	**Reanalysis of proposed rule option**	**Final rule**
Costs	$81 to $89	$80 to $89	$167 to $301	$43 to $78
Benefits	$91 to $137	$9+B to $23+B	$34+B to $105+B	$26+B to $79+B
Net Benefits	**$2 to $57**	**($79)+B to ($57)+B**	**($268)+B to ($62)+B**	**($53)+B to $36+B**
"B" represents the unquantified benefits				

ADDRESSING CONTRIBUTION OF ADMINISTRATIVE REQUIREMENTS TO RULE EFFECTIVENESS

Labeling, notification, recordkeeping, and other administrative requirements in formaldehyde rule

- In addition to setting emission standards, the statute directs EPA to include provisions relating to emissions testing, third-party certification, product labeling, chain of custody documentation, recordkeeping, and other administrative requirements for the supply chain.

- The California rule has many similar or identical provisions.



Administrative requirements in California rule

- Under the California rule, fabricators, importers, distributors, wholesalers, and retailers are required to take "reasonable precautions" to ensure that the composite wood products and finished goods they acquire are in compliance with the applicable emission standards.
  - This includes instructing each supplier that the product supplied must comply with applicable emissions standards, and obtaining written documentation confirming that.
- In addition, these firms must keep records showing the date of purchase, the supplier, as well as all precautions taken to ensure that the product meets emissions standards.
- Some industry commenters opposed California's chain of custody requirements (claiming they were duplicative with labeling) and wanted California to rely on existing paperwork instead. California disagreed.

Inability to quantify effectiveness of administrative requirements

- Enforcement staff typically support including multiple administrative requirements in order to promote compliance.
- Information is generally not available to quantify how such administrative requirements contribute to regulatory compliance, or reduces agency enforcement costs.
- EPA's Economic Analysis for the formaldehyde rule considered the costs of different options for these requirements, but not their impact on rule effectiveness. So the analysis makes it appear that scaling back such requirements reduces costs without affecting benefits.

Evolution of requirements in EPA's rule

Key differences in requirements		California Rule	EPA Proposed Rule	EPA Final Rule
Panel Producer and Laminators	Written communication with supplier requesting compliant material	✓		
	Keep additional records	✓	✓	✓
Fabricators	Written communication with supplier requesting compliant material	✓		
	Keep additional records	✓	✓	Ordinary business records*
Distributors (Wholesalers)	Written communication with supplier requesting compliant material	✓		
	Keep additional records	✓	Ordinary business records*	Ordinary business records*
Retailers	Written communication with supplier requesting compliant material	✓		
	Keep additional records	✓	Ordinary business records*	Ordinary business records*

* Must take reasonable precaution to ensure their composite wood products are compliant by maintaining invoices, bills of lading, or comparable documents that include a written statement of compliance from the supplier. Importers (which are classified as manufacturers under TSCA) must also have the ability to produce records identifying the panel producer and the date of production; and records identifying the supplier, if different, and the date the composite wood products, component parts, or finished goods were purchased.

Observations about quantifying administrative requirements

- When there are many firms subject to a rule, total costs of administrative requirements can be substantial, even if unit costs are low. Such requirements would have accounted for a large share of the total costs of the formaldehyde rule if EPA had not reduced recordkeeping requirements.

- Changes to recordkeeping requirements decreased the EPA rule's estimated cost by $85 million to $98 million per year compared to an option consistent with California's rule.

- The inability to quantify the effectiveness of these requirements limits the usefulness of the analysis in informing decisions about which alternatives to adopt.

EFFECT OF COMPLIANCE PERIOD ON COSTS

Laminated Products

- "Laminated products" are generally finished goods or component parts made by fabricators who affix wood veneer to composite wood platforms to produce items such as cabinets, doors, or furniture.
- California's rule does not require emissions testing or third-party certification for laminated products.
- EPA's rule applies emissions limits and third-party certification requirements to laminated products unless they are made with no-added formaldehyde (NAF) resins or phenol formaldehyde (PF) resins, which have low releases.

Compliance Period for Laminate Emissions Testing

- In the baseline, most laminators were not conducting emissions testing on their products or being certified by a third-party. Some of their products may exceed the emission limit.
- Many of the provisions in EPA's rule become mandatory one year after the effective date of the rule. Laminators may need extra time to either switch to a NAF or PF resin or work with a third-party to become certified.
- How would different options for the length of time for laminators to comply with testing and certification affect the costs and benefits of the rule?

Laminator Costs for Switching Resins

- A firm switching to a NAF or PF resin may incur the following costs:

  1) **Initial costs** to use a different resin system (e.g. R&D or new capital equipment);
  2) **Transition costs** while switching to a new resin system (e.g. trial and error or suboptimal production while learning to use a different adhesive); and
  3) **Recurring costs** of using a different resin system (e.g. increased resin costs or product reject rate, or lower productivity if the new resin has a longer press time or slower curing rate).

- Presumably, allowing more time to comply could affect the magnitude of transition costs, and could even impact initial and recurring costs (if a very short deadline and hasty decisions could result in poor choices about which technology or equipment to adopt).

Analysis of Compliance Date Options for Laminator Emissions Testing and Certification

- EPA was unable to find literature about the interaction between compliance periods and the efficiency of investments in technology, in order to estimate how different compliance date options would determine the magnitude or timing of compliance costs.
  - It is unclear how many companies will use an extended compliance period to find and adopt more efficient technologies, versus waiting until just before the deadline to act (merely delaying when they adopt a given technology).
- EPA's analysis did not account for how different options for the compliance date for laminator emissions testing and certification would affect the magnitude of costs.
  - The length of the delay period only affected the estimated annualized costs (and benefits) of different options for the compliance date due to the impact of discounting.

Compliance Date for Laminate Emissions Standard in EPA's Rule

- EPA ultimately allowed laminators 7 years after the rule takes effect to comply with these provisions, to allow sufficient time to either
  - Fully evaluate alternative resins and adopt a NAF or PF resin (qualifying for an exemption from testing and certification); or
  - Comply with the emission standard and the testing and certification provisions;

  or

  - Design and conduct studies supporting exemptions for additional product categories, and allow EPA to create such exemptions through rulemaking.

For more information on formaldehyde rule

The formaldehyde rulemaking docket (contains the proposed rulemaking, technical support documents, public comments, etc.) is available at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2012-0018.

- EPA's methodology for assessing benefits of avoided asthma cases is discussed in https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0472 and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0470
- The original draft Economic Analysis for the proposed rule is at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0495
- The revised Economic Analysis for the proposed rule is at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0484
- The Economic Analysis for the final rule is at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0461-0037

More information on the rule is available at https://www.epa.gov/formaldehyde

Questions or Comments?

Thanks!

Economic Valuation in Formaldehyde Regulation

Alistair Hunt & Nick Dale
University of Bath, UK

Ottawa, 30 August, 2017

OECD Workshop on Best Practices in Assessing the Social Costs of Selected Chemicals

Outline of Talk - Formaldehyde

- Summary of uses targeted by risk management activity
- Summary of the main endpoints of concern
- Use of assessments in informing regulatory decision-making?
- Costs in Formaldehyde economic assessments

- Valuation of endpoints of concern in economic assessments to date
- Data & methodological gaps in assessments;
- Key differences in endpoints & valuation methods between studies
- Scope for improving economic valuation

Formaldehyde: Summary of uses targeted by risk management activity

- Important chemical building block in varied applications
- Colourless gas, commercialised in liquid form as formalin

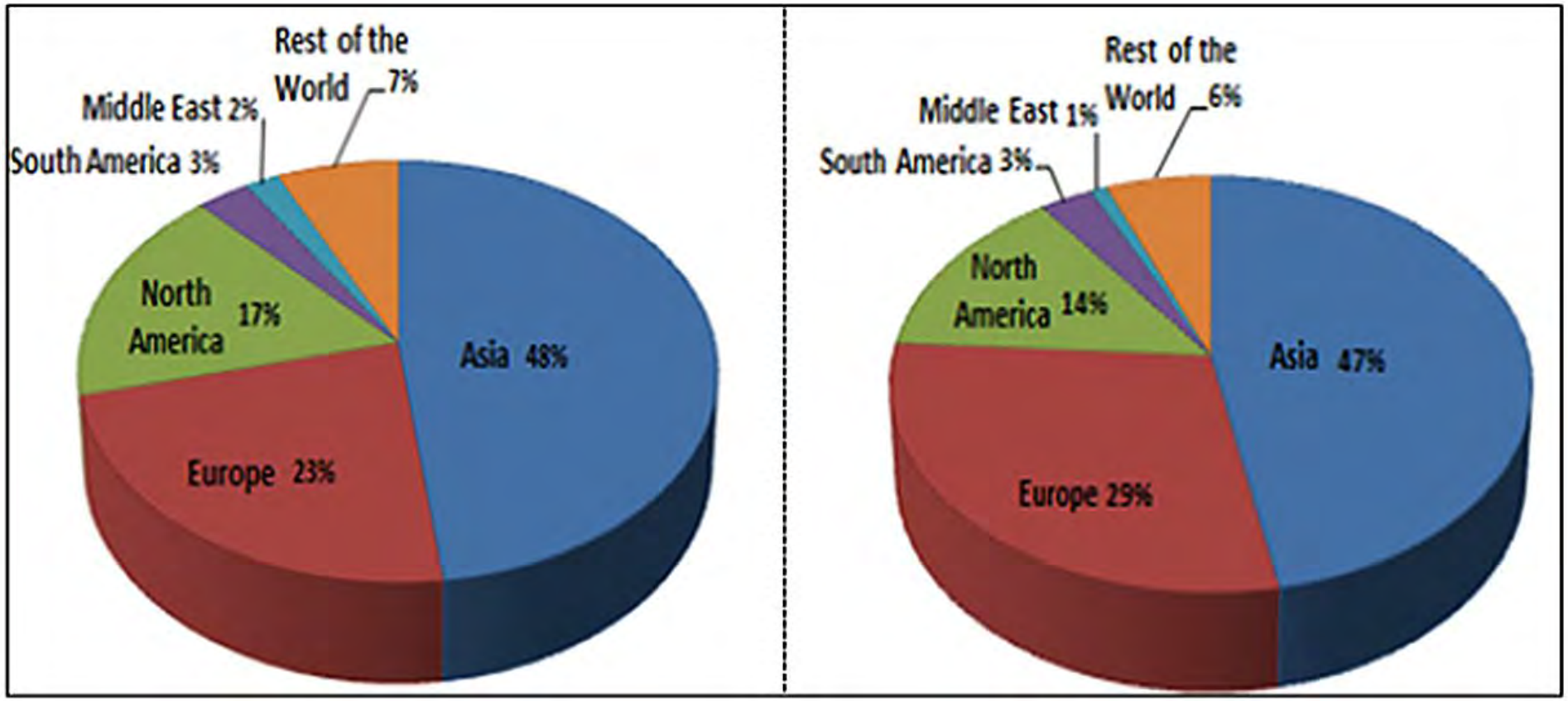
Used in, inter alia:

- Manufacture of resins for wooden furniture, construction, transport (65%)
- Disinfectant & fixative in cosmetics
- Preservative in vaccines and foods

Market Size

- Global Formaldehyde market value - > $15 billion (2015)
- Global production -50 million tonnes (2016)
- Continued expected growth, from demand in Construction, Food & Healthcare

Production



Consumption

Formaldeyde: Summary of the main health endpoints of concern

Type of health effect	Specific conditions
Acute health effects	Severe irritation of skin and eyes, with possible eye damage (O, C) Irritation of nose, mouth and throat; Inhaling can irritate lungs, causing coughing or shortness of breath (O, C) Asthma attacks (O, C)
Chronic health effects	Cancer hazard: cancer of the nasopharynx and leukaemia (O) Reproductive hazard: damage to female fertility (O)
	Bronchitis from repeated exposure, with cough, phlegm and shortness of breath (O) Skin allergy, leading to serious skin rash and itching (O, C)

O = Occupational exposure; C = Consumer exposure

Formaldehyde: Summary of the main endpoints of concern Environment

- Evidence: Typical releases of formaldehyde quickly removed from air by reaction in the atmosphere and broken down in water and soil.

→ unlikely to affect plants and wildlife (Liteplo et. al. (2002)

- Environment Canada (2001) “based on the information available… formaldehyde is not entering the Canadian environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity”.

State of Formaldehyde Risk Management

- EU REACH:
  - DNEL exposure (Derived No-Effect Level) for workers of 0.4 ppm.
  - For consumers, DNEL = 0.1 mg per m^3
  - Registrants requested to provide further information on consumer exposure scenarios – Oct 2017
  - Investigating formaldehyde releasers – include in restriction dossier?

- Number of EU nations have regs on products – e.g. composite wood emissions
  - Netherlands has legislation on Chipboard ("Warenwet", 1987) and textiles ("Warenwet", 2001; Schuur et al., 2008) and there is a ban on use in cosmetics in Sweden.

- USA: National & State level regulation
  - Formaldehyde Standards for Composite Wood Products Act (2010) for various products
  - State-specific restrictions on specific uses of formaldehyde.

- Japan: ban on formaldehyde use in cosmetics & regulation of emissions from wood panelling.

Use of economic assessments in informing regulatory decision-making?

- US EPA (2013; 2016) - closely considered in development of the US Composite Wood Products Act (See US EPA 2013, 2015 and 2016)

- EU: likely that data collected by consultancies - TNO/RPA (2013) - for ECHA, considered in on-going regulatory development

  - TNO/RPA (2013) states: “The data generated under the present study is intended to inform the work of the authorities within the Substance Evaluation Procedure.”

Costs in Formaldehyde economic assessments to date

- EU: 2 core sets of studies (TNO/RPA 2013 and ICF 2013)
  - Wood-based panels: compliance costs of regulatory options re occupational & consumer exposures – economic impacts on producers & consumers
  - Costs based on industry surveys of manufacturers
  - No discounting
  - No consideration of market loss, impacts on R&D, admin burdens

- USA: 2 studies (US EPA, 2013 & 2016)
  - Compliance costs analysis for use of UF resins in laminated product industry
  - Supply chain approach plus regulatory costs
  - Uncertainty analysis only included numbers of entities affected, not cost derivation

Valuation of endpoints of concern – EU Studies

Study & Risk	Impact	Metric/Valuation	Methodology
TNO/RPA (2013) Assessment of alternative regulation scenarios in EU: **Occupational health**	Respiratory conditions	Metric: number of people – 25% to 80% of factory operators estimated to be potentially at risk	Authors' judgement.
TNO/RPA (2013) Assessment of alternative regulation scenarios in EU: **Consumer products**	Nasal irritation Skin sensitisation Eye irritation	No EU estimates. Study of incidence in French female population (Perouel, 2011) Metric: Disability-adjusted life year (DALY). Improvement of 560 DALYs following regulation	Quantitative, based on authors' modelling of detergent, incense, shower gel exposure

Social costs of Health

Treatment costs (e.g. hospital costs, medicines)

+

Opportunity costs (lost work & leisure time)

+

Disutility costs (pain and suffering)

=

Total Social costs (Willingness to Pay)

Valuation of endpoints of concern: US Studies

Study & Risk	Metric/Valuation	Methodology
US EPA (2013); (2016) Economic analysis of options for implementing the Formaldehyde Standards for Composite Wood Products Act 40 year benefit assessment period	Nasopharyngeal cancer – fatal: WTP USD 9.77 million.	WTP derived from Weibull-mean of wide sample of VSL estimates from wage-risk and contingent valuation studies made in 1974-1991, in US EPA (2014).
	Nasopharyngeal cancer non-fatal: COI approach (2013 version) USD 114,327	Treatment costs derived from two surveys of costs associated with component parts of treatment processes. Opportunity costs derived for: value of work - wages plus employment benefits leisure time - wages Estimates from mean national wage levels.
	Nasopharyngeal cancer non-fatal: WTP (2016 version) USD 820,000 (CB) USD 4.38 million (Lymph)	Range derived from: Viscusi et al. (1991) WTP to avoid chronic bronchitis Magat et al. (1996) WTP to avoid curable lymphoma, and;
	Eye irritation: WTP	From IEc (1993), derived from Tolley (1986) and Weitzel (1990), quoted in US EPA (2016), WTP estimates of minor respiratory restricted activity days.

Acknowledgement of leukaemia, respiratory effects & fertility impacts but not valued

Data & methodological gaps (I)

Possible Health Impacts	EU Studies	US Studies
Irritations		
Skin	✓ (DALY, French females)	
Eyes	✓ (DALY, French females)	✓ (WTP)
Nose	✓ (DALY, French females)	
Mouth		
Throat		
Skin allergy		
Asthma		
Cancers		
Nasopharynx		✓ (COI; WTP)
Leukaemia		
Reproductive		
Female fertility		
Developmental limits		

Low confidence in epidemiological evidence has limited quantification/monetisation to date

Data & methodological gaps (II)

- EU experience – no full quantification & monetisation
- US experience
  - Limited treatment of uncertainties
    - Transfers of unit values from:
      - One health end-point to another
      - One study context to another
      - One time period to another
  - Incomplete coverage of treatment and opportunity costs & disutility value components
  - Reliance on older studies - methodologically dated?

Scope for improving economic valuation (I)

- Cancer (fatal)
  - Up-date VSL meta-analyses for:

a) More recent VSL studies (and re-weight towards those with sound methodologies?)

b) Recognition of cancer premia (if exist for specific context/type of cancer)

  - Note: More recent EPA guidance recognises these issues
  - Undertake primary valuation work on specific types of cancer – Nasopharynx & Leukaemia

Scope for improving economic valuation (II)

- Cancer (non-fatal)
  - Undertake up-date of Magat et. al. lymphoma study – ensure COI components fully incorporated in survey design
  - Value specific cancer types using a value of a statistical case (VSCC) metric (see e.g. Adamowicz, 2011; Alberini & Scasny, 2014)

- Eye irritation
  - Replace MRAD unit value with eye irritation value (e.g. up-date Berger et al., 1987)
- Skin irritation
  - Meta analysis of available values (see ECHA, 2016, for review)
  - Primary study – context specific

Scope for improving economic valuation (III)

- Lack of epidemiological evidence limits scope for quantification for some end-points – new epi studies?

- Values exist for transfer:
  - Female fertility, (ECHA, 2016)
  - Bronchitis, (e.g. Bloyd et al. (1996) in US; Maca et. al. (2011) in Europe),
  - Skin allergy (ECHA, 2016)
  - Asthma attacks (e.g. Dickie & Messman (2004))

- Need for primary studies (esp. in Asia)
  - Immune function effects
  - Neurological & behavioural conditions
  - Environmental impacts (if any?)

Conclusions/discussion points

- Lack of comprehensive coverage of benefits suggests potential for under-regulation if based on CBA
- Since values often exist for transfer, even when no epidemiology, maybe useful to test “what-if” break-even scenarios in assessments
- Given difficulties in valuing more severe end-points, maybe focus on less severe, more frequently occurring end-points

EVALUATING THE BENEFITS OF FORMALDEHYDE REGULATIONS

Maureen L. Cropper
University of Maryland and RFF

OECD Workshop, Ottawa
August 30, 2017

Overview

- Comments focus on USEPA's (2016) analysis of benefits of formaldehyde standards for composite wood products
- EPA benefits focuses on eye irritation, nasopharyngeal cancer (NPC)
  - Annualized benefits associated with NPC ($62-$171 million) much greater than for eye irritation ($2-$15 million)
- Monetized benefits > costs for the Final Rule
  - But not for the Proposed Rule
- Would quantification of other cancer benefits have caused benefits > costs for Proposed Rule?

Annualized Benefits and Costs of EPA's Formaldehyde Rule (3% Discount Rate)

Analytical Options	Cancer		Eye Irritation		Costs	
	Low	High	Low	High	Low	High
Proposed Rule	$74	$208	$3	$18	$155	$297
Final Rule	$62	$171	$2	$15	$38	$83

Questions Addressed

- Does the analysis adequately characterize uncertainty in estimated cancer benefits?
  - Uncertainty in dose-response
  - Uncertainty in valuation
- Should the analysis make use of epidemiological evidence relating formaldehyde exposure to cancer?
- What are the issues in measuring cancer risks to consumers from worker studies?
- How should fatal and non-fatal cancers be valued?
  - How was this done by EPA?
  - How to categorize cancers from a valuation standpoint?

Treatment of Cancer Risks in 2016 RIA

- Risk of NPC based on EPA's 1991 IRIS document
- Relies on animal studies
  - EPA extrapolates results from "mouse to man" and from high to low doses
  - Unit risk presented as excess lifetime cancer risk per µg/m3
  - Unit risk based on upper bound of 95% CI of dose response function
  - Additional risk multiplier added for possible mutagenicity
  - No mean estimates presented or confidence intervals
- Issues for benefits analysis
  - Would like expected value of slope of dose response and confidence interval
  - Would prefer studies based on human populations

Epidemiological Literature

- Case-controlled and cohort studies of workers
  - NCI worker cohort studies (Hauptmann et al. 2003, 2004; Beane-Freeman et al. 2009)
  - OSHA textile worker study (Pinkerton et al. 2004)
  - NCI case-controlled study of funeral workers (Hauptmann et al. 2009)
- NCI studies find significant mortality effects associated with peak exposures for
  - Myeloid leukemia (Hauptmann et al. 2003)
  - LHP and Hodgkin's lymphoma (Beane-Freeman et al. 2009)
  - NPC (Hauptmann et al. 2004)
- Results are weaker for cumulative exposure, except for NPC

Possible Use of NCI Cohort Studies

- 2010 IRIS revision uses NCI studies to estimate impact of lifetime exposure on lifetime cancer risk
  - For NPC, Hodgkin lymphoma and leukemia
  - Unit risk factors based on upper bound of 95% confidence interval from NCI worker cohort studies
- NRC (2011) review raises question about mechanism of action for leukemia and lymphoma
  - But does not dismiss NCI studies
- Using 2010 IRIS would reverse results from 2016 RIA
- Would prefer mean estimates and confidence intervals for a benefits analysis

Lifetime Unit Risk Factors for Formaldehyde (IRIS 2010)

	Lifetime Risk (per µg/m3)	US Incidence (Cases per year)	5-Year Survival Rate
NPC Incidence	1.1 x 10-5	3,200 cases	72% (Stage I) 64% (Stage II)
Hodgkin Lymphoma Incidence	1.7 x 10-5	8,300	86%
Leukemia Incidence	5.7 x 10-5	21,000 (AML) 8,200 (CML)	27% (AML) 90% (CML)

EPA (2016) Valuation of Reduced Cancer Risk for NPC

- Fatal cancer risks are valued using the agency's VSL ($9.77 million 2013$)
  - Analysis accounts for time pattern of mortality, using a 3% discount rate
- Non-fatal cancer risks are valued using:
  - Median WTP to avoid chronic bronchitis ($820,000 2013$) as a low estimate (based on Viscusi, Magat & Huber1991)
  - WTP to avoid non-fatal lymphoma (Magat & Viscusi 1996) as a high estimate
    - WTP to avoid non-fatal lymphoma = .583 x VSL = $5.69 million
    - Multiply this by ratio of NPC/lymphoma treatment costs (0.77)
    - High estimate = $4.38 million
- Use of chronic bronchitis seems strange to me, as does the 0.77 adjustment factor

Valuation of Reduced Cancer Risk

- Would like to value reduction in risk of cancer incidence and also risk of cancer mortality
- Alberini and Scasny (2017) do this using a stated preference study in 4 countries
- Respondents value risk of getting cancer, given 5-year survival probability, as well as risk of mortality, conditional on having cancer
- WTP to reduce risk of getting cancer depends on 5-year survival rate
- Big issue is how to characterize cancer:
  - For non-fatal cancer is what matters the nature/duration of treatment?
  - Is there a premium for cancer mortality per se?

Concluding Comments

- Dose-response is key in this benefits evaluation
  - Using EPA's 2010 IRIS update of risk factors for NPC, myeloid leukemia and Hodgkin's lymphoma would have caused benefits > costs
- Estimation of cancer risks subject to great uncertainties which should be incorporated into the analysis
  - Don't rely on upper bound of 95% confidence interval
  - Provide confidence intervals rather than "low" and "high" sensitivity analyses
- Valuation of fatal and non-fatal cancers
  - All cancers are not the same (e.g., acute myeloid leukemia (AML) v. chronic myeloid leukemia (CML))
  - What are key characteristics of cancer that should drive valuation?

Presentation to OECD workshop,
"Best practices in assessing the social costs of selected chemicals"
Hosted by Health Canada
Ottawa, 30-31 July 2017

Formaldehyde Case Study: Comments on the paper by Alistair Hunt and Nick Dale, "Economic Valuation in Formaldehyde Regulation"

by

Dr. Rana Roy

Consulting Economist

Introduction

- The structure of this commentary follows the structure of the paper: Background on formaldehyde; Overview of economic assessments; Analysis of findings of economic assessments of formaldehyde; Conclusion.

- As per my commentary on Anna Alberini's paper in Helsinki, the focus here is not on the excellence of the paper nor my very many points of agreement with it but rather on the potential scope for strengthening it.

Background on formaldehyde

- First, a word on the excellence of the Background – on the production, use and disposal of formaldehyde, its risks, and its risk management status – if only as a guide to the ideal standard of completeness.

- At 6 pages, it is succinct. But it succeeds in providing a full bird's-eye of the subject, incl. its quantitative dimensions. And it is unafraid to make judgements in highlighting landmarks (e.g., the IARC classification).

Background on formaldehyde (continued)

- One point which may be worth expanding on is the non-trivial difference between the DNEL (Derived No-Effect Level) applying to consumers and the DNEL applying to workers, its rationale and its implications.

- A second point that arguably merits fuller treatment – especially in the light of Figure 1 and the final Para 49 – is the risk management status of formaldehyde across both OECD- and non-OECD Asian countries.

Overview of economic assessments

- Turning to the Overview of economic assessments (bottom of p. 12 to top of p. 16), there are no errors or points of disagreement that I can detect. But I do find this section, at just over 3 pages, too compressed.

- Perhaps in consequence, the Overview is, I think, somewhat less than complete and lacking in that highlighting of landmarks that helps to give the reader, and the decision-maker, a sense of what is at stake.

Overview of economic assessments (continued)

- Example 1. Yes, there is a range of valuation methods in use. But there is also best practice versus others. And the quantitative difference can be very large.

- Hence, as shown in multiple OECD studies following OECD (2012), the quantitative importance of using WTP-derived VSLs as a measure of avoided-mortality benefits – and of including WTP-derived disutility costs within the sum of avoided-morbidity benefits.

Overview of economic assessments (continued)

- Example 2. Yes, there is a range of discount rates in use. But there is also best practice versus others. And the quantitative difference can be very large.

- Cf. the US EPA findings on benefits cited on p.15: USD 64-128 million with a 3% discount rate vs. USD 26-79 million with a 7% discount rate. The point here is that best practice is indeed circa 3%, not circa 7% (cf. Spackman, 2001; HM Treasury, 2003; Roy, 2008).

Analysis of findings of economic assessments of formaldehyde

- The Analysis section shows clearly that studies in this field are few in number, incomplete in coverage, and “rather dated”. It also suggests that we may be under-estimating the potential benefits of regulation.

- I agree. But the claim could be strengthened if it were to build on an expanded preceding section, showing how departures from best practice, incl. esp. on the discount rate, can deliver such an under-estimation.

Analysis of findings (continued)

- On the calculation of costs, the statement of the claim in Para 34 of “a risk of bias towards over-estimation”, arising from “an incentive to exaggerate” on the part of survey respondents, is a little too compressed to be persuasive.

- And how to resolve this? Repeating the survey? An arbitrarily imposed deflator? A deflator drawn from the literature on hidden information/hidden action? A deflator drawn from expert assessments of available techniques?

Conclusion

- The incomplete state of the economic evidence base (Paras 45-47), when coupled with the continuing use of economic analysis in the regulation of formaldehyde (Para 48), clearly justifies the authors' call for research.

- I suggest that any such new research needs to include inter alia: an expanded list of end-points as per Para 46; the recently rebased and updated OECD VSL estimates (Roy and Braathen, 2017); an economically justified discount rate; one or more Asian countries in its scope.

Risk Management of Four Phthalates under REACH

OECD Workshop

Best Practices in Assessing the Social Costs of Selected Chemicals

Ottawa, Canada
30-31 August 2017

Evgenia Stoyanova
Risk Management Implementation
European Chemicals Agency

Presentation scope

- Case study: Risk management of DEHP/DBP/DIBP/BBP under REACH
  - Introduction
  - What did the restrictions target and why
  - Experience
  - Challenges and lessons learnt

Background

Restriction on DEHP/DBP/DIBP/BBP in articles

- Submitted in 2016
- Scope
- Recent agreement in RAC & SEAC
- Commission decision expected in early 2018
- Entry into effect in 2021

Events leading to recent restriction proposal

- Restriction measures:
  - on toys and childcare articles
  - other articles (not adopted)
- REACH Authorisation: Identification
  - Past
  - During dossier development
- REACH Authorisation: Applications
  - Virgin use
  - Recyclate
  - Industrial uses

=> REACH requirement to assess risks in imported articles of substances whose sunset date has passed

Restriction on 4Phthaltes in articles

Proportionality: proposal

- Cost-effectiveness and comparison to cost-effectiveness of previous restriction measure on toys and childcare articles
- Affordability & market trends
- Beak-even analysis: infertility

Proportionality: proposal

- Supporting information for cost-benefit comparison in appendixes:
  - Cryptorchidism
  - Hypospadias
- Proposal prepared on the basis of threshold effects on reproduction & development
  - Endocrine disrupting properties in uncertainties

Approach

- Health effects:
  - 17 discussed qualitatively
  - Strength of the relationship between exposure estimates and human health impacts (≈likelihood or probability for human health impacts)
    - "strong" - both the evidence from animal studies and the evidence based on exposure considerations are strong
    - "moderate" - (1) the evidence from animal studies is strong, but exposure considerations are moderate or weak; or (2) the evidence of both animal studies and exposure considerations are moderate
    - "weak" – in other cases where some evidence for effects from animal studies or epidemiology exists

Approach

- Reviewed a number of recent studies:
  - Norden, HEAL, Applications for Authorisation, Trasande & co-authors
- Aetiological fraction
  - Incidence
  - Reduced by hereditary cases and all known non-chemical related factors (e.g., injury, surgery, etc.)
  - Assumed share of incidence attributable to exposure to chemicals (EDs) – 2-50%
  - Estimated share of phthalates contribution from all ED contribution (reduced by the share of DINP)
  - Estimated share of articles contribution

Assessment Results

- Cost-effectiveness
  - €130 per tonne of the four phthalates replaced or nearly 20 times more cost-effective than the restriction on toys & childcare articles adopted earlier

- Affordability
  - Market trends
  - Increase in price per tonne of imported articles in scope by about 2%

Assessment Results

- Break-even: fertility
  - Result: 3 655 cases or 0.1% of the average annual male births projected in the EU28
  - Social cost per case: €4 630
    - Direct and indirect cost of illness
    - Willingness to pay to avoid infertility (60% of social cost)
- Supplementary information

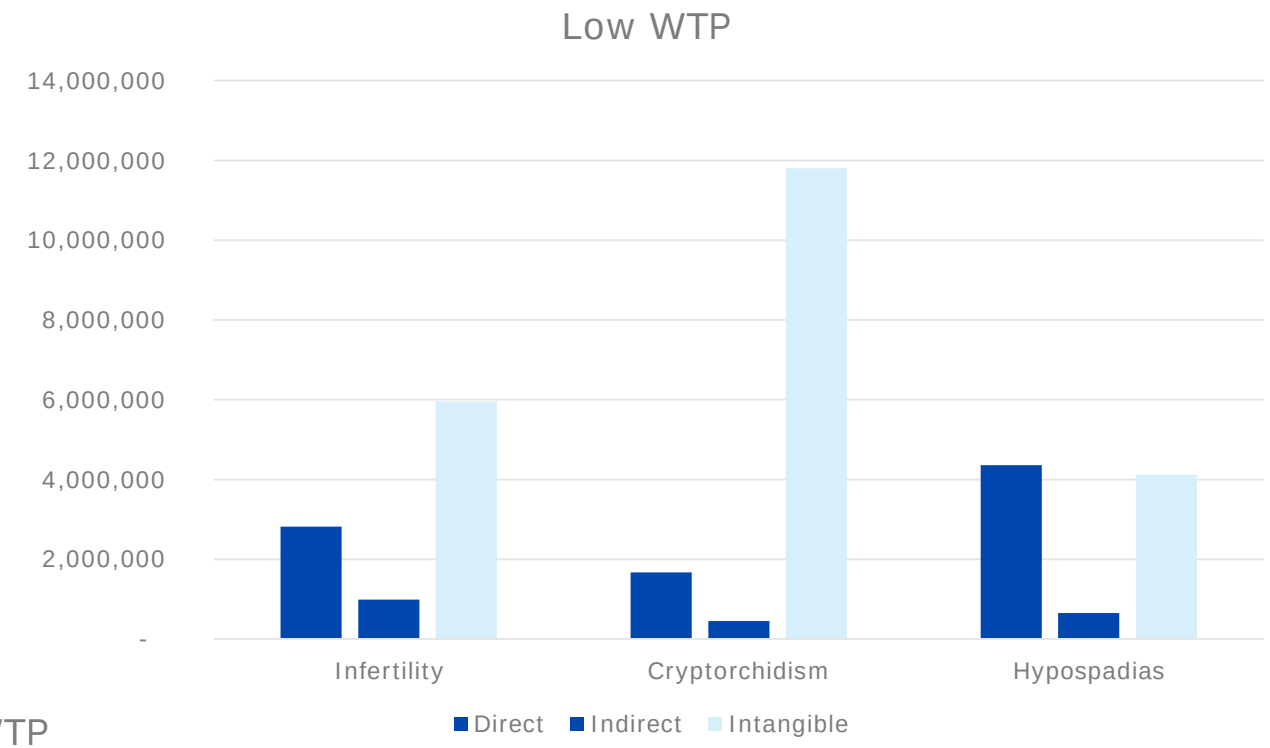
Health outcome	Cases	Social cost per case
Cryptorchidism	480	€29 000
Hypospadias	540	€17 100

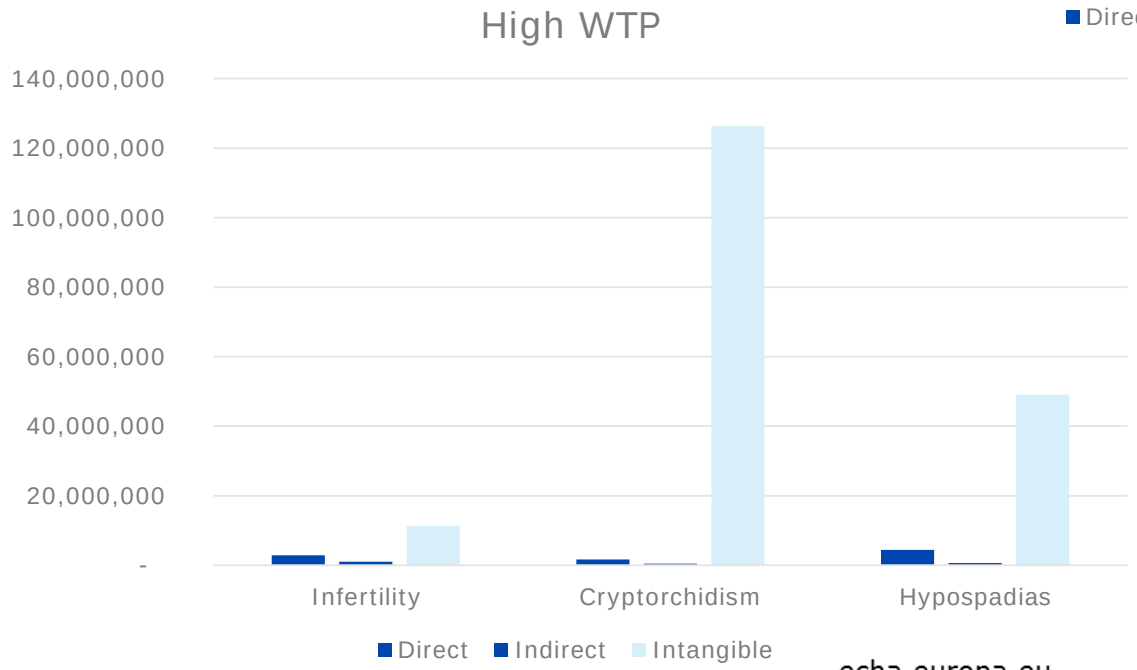
Challenges

- Aetiological fraction approach:
  - Advantages: easy to communicate, used in previous opinions, recent studies
  - Disadvantage: subjective
- Causality
  - Lack of strong epidemiological evidence
  - Issue with “jurisdiction”
- Latency

Opinion development

- Recalculation with 2% discount rate
  - Benefits: from €32 mill to €45.5 mill annually
  - Costs: from €17 mill to €19 mill annually
  - Discussion on declining discount rate
- Recalculation with higher WTP value
  - From €32 mill to €200 mill annually
- Immunological effects:
  - social costs of asthma added: €45 million/yr


Low WTP
14,000,000
12,000,000
10,000,000
8,000,000
6,000,000
4,000,000
2,000,000
-
Infertility
Cryptorchidism
Hypospadias
Direct
Indirect
Intangible


High WTP
140,000,000
120,000,000
100,000,000
80,000,000
60,000,000
40,000,000
20,000,000
-
Infertility
Cryptorchidism
Hypospadias
Direct
Indirect
Intangible

Proportionality: final opinion

- Cost-effectiveness
- Affordability
- Break-even: fertility

Restrictions in the pipeline

- Under development:
  - DE/SE: C9-C14 PFAS substances
  - NL: PAHs in plastic & rubber granulates for synthetic turf pitches
  - IT: DMF
  - ECHA
    - Substances in Tattoo inks
    - D4/D5 in leave on personal care & other consumer/professional products
    - 5 soluble cobalt salts for industrial and professional use
- For future consideration
  - Formaldehyde and formaldehyde releasers
  - Lead shot in non-wetlands/fishing weights
  - Cd in recycled plastics
  - BPS in thermal paper
  - Restriction review obligations: PAH (#50), lead in jewellery (#63)
  - Calcium cyanamide (fertilisers)

Thank you!

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Valuation of phthalate impacts

Mike Holland
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OECD SACAME Workshop,
Ottawa, August 2017

EMRC

Key questions

- What effects have been linked with phthalates?
  - Quantified?
  - Monetised?
- Differences in approach
- Robustness of analysis
- Potential for improving SEA work

Phthalates

- Large number of esters of phthalic acid
- Varying properties
  - Durable, heat and cold resistant, high electrical resistivity, colourless…
- Range of applications
  - Plasticisers, solvents, adhesives, cosmetics, medical equipment, erasers…
  - Use declining given health and environmental concerns and availability of alternatives
- Linked to a range of health and environmental impacts affecting the endocrine (hormone) system

Source: IHS Chemical

Impacts of endocrine disrupting chemicals (EDCs)

- Endocrine (hormone) system interference
  - Low semen quality
  - Genital malformation
  - Premature birth, low birth weight
  - Neurobehavioural disorders
  - Endocrine related cancers
    - Breast, ovarian, endometrial, prostate, testicular, thyroid
  - Earlier puberty
  - Obesity
  - Type 2 diabetes

Difficulties in predictive impact assessment

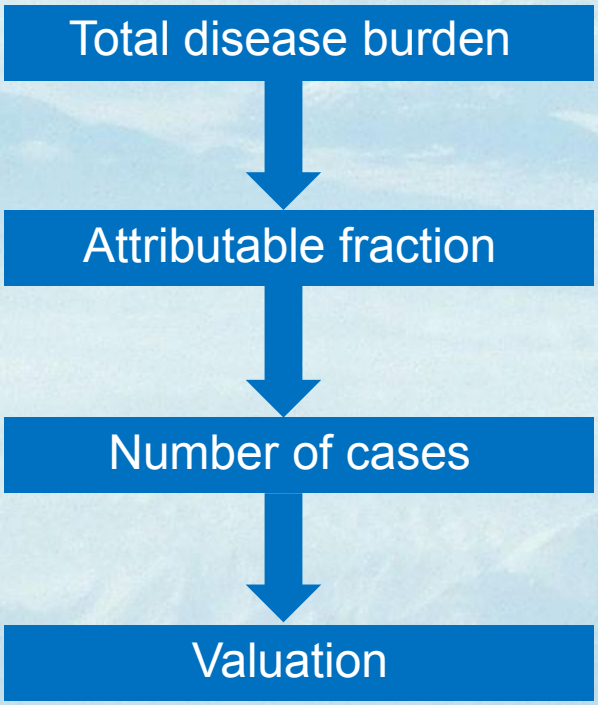
- Wide range of substances in common use identified as EDCs
- Exposure to phthalates is universal
- Presence of other relevant risk factors
  - Diet, obesity, smoking, alcohol…
- Need for extrapolation from animal studies
- Bias in research to certain substances
- Delay between relevant exposure and some important impacts

Main studies reviewed

- Trasande (2014): BPA, USA
- HEAL (2014): EDCs, EU
- Olsson et al (2014): EDCs, Nordic + EU
- Trasande et al (2015, 2016): EDCs, EU
  - Legler et al, Bellanger et al, Hauser et al, Hunt et al
- Attina et al (2016): EDCs, USA
  - comparison with Trasande et al (2016) for EU
- ECHA (2016, 17): 4 phthalates (DEHP, BBP, DBP, DIBP) in articles, EU, future policy
- AMEC (2017), EU, past policy

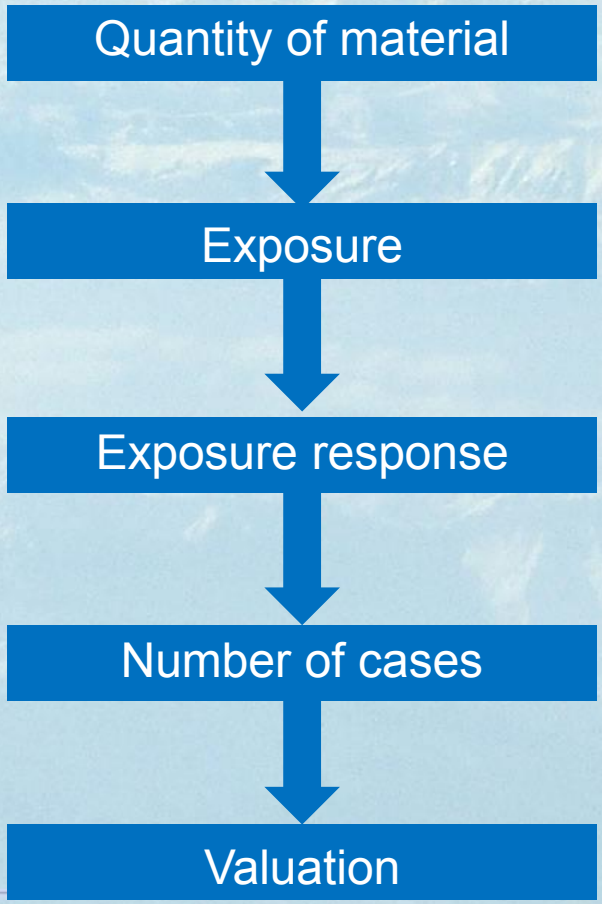
Approaches

Top down



Bottom up

(impact pathway approach)



Preferred approach

- Impact pathway approach
  - Clearer causal linkage
  - But more data demanding
- Top down approach can provide useful insight where there is a lack of data for scoping
  - What effects may be most important
  - Where research should be targeted

Implementation of the IPA for phthalate assessment (EU and USA)

- Release data
  - Good information on production and use
- Impact identification
  - Large number of effects linked to EDCs
  - Quality of association with specific phthalates is variable
  - Links to environmental impacts noted but insufficient data for quantification
- Impact assessment
  - Good information on population at risk, incidence of disease
  - Quantification of attributable fraction questionable
    - Extrapolation across species, concentration ranges…
  - Tendency to focus on effects for which best data are available
    - Are these economically important or just easy to measure?
    - Inference from ECHA (2017) is that important effects could be omitted

Omission of potentially important impacts

▪ Table 16. Summary of unit values used in the studies reviewed above. For key, see foot of table. All figures in EUR, price years in second row of table.

	Trasande 2014	HEAL 2014	Olsson 2014	Trasande 2015-2016	Attina 2016	ECHA 2017
Price year	2008	2010	2013	2010	2010	2010/12/14
Obesity, diabetes						
Childhood obesity	1,650				54,000	
Overweight children					26,000	
Adult obesity	39,000			290,000	215,000	[290,000]
Diabetes		unspecified		28,000	54,000	[29,600]
Neurodevelopment						
Autism		12,445		630,000	981,000	[630,000]
ADHD		10,650		77,000	119,000	[90,000]
IQ point loss				9,600	14,500	
Intellectual disability				360,000	1.0 mn	
Reproductive system						
Female infertility						[29,700]
Preterm birth with VLBW infant						[126,000]
Fibroids				2,900	5,200	[3,000]
Endometriosis				8,600	415,000	[8,620]
Male infertility			3,480	7,600	7,800--11,000	18,980
Cryptorchidism		5,715--8,415	34,674	28,000	6,291	28,000
Hypospadias		unspecified	39,617			16,900
Human fertility		4,500-51,822				

Thresholds

- How good is evidence of thresholds to individual substances?
- How useful is this when assessing impacts of exposure to multiple substances which may have similar modes of action?

Implementation of the IPA for phthalate assessment (EU and USA)

- Valuation of impacts
  - Direct costs (medical costs): good
  - Productivity losses: good
  - Loss of utility: limited, often reliant on QALY/DALY valuation
- Benefits transfer
  - Done well
  - Discounting reasonably consistent at 3% or 4%
- Uncertainty assessment
  - Several studies provide ranges for effects and values
  - Meaning and validity of these ranges unclear
  - ECHA (2017) provides a good example of uncertainty assessment in the context of BCA

Inclusion of loss of utility is important

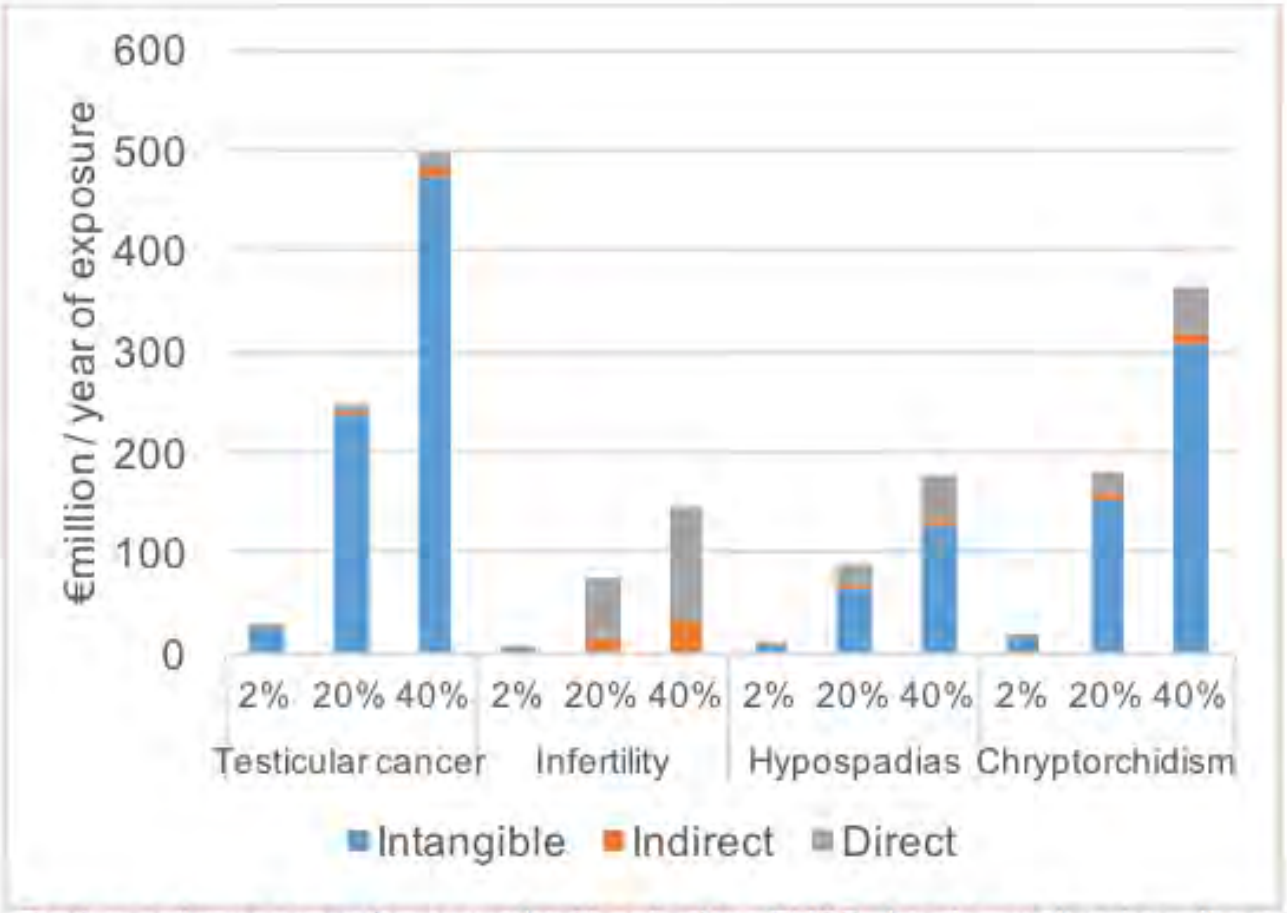


Figure 4. Costs on human male reproduction in the EU28 due to endocrine disruption for four effects with varying assumptions on attributable fraction. "Intangible" costs were not quantified for infertility. Source: Olsson et al.,2014.

Use of QALY, DALY valuations for lost utility

- Not clear how these valuations (in region of $50,000 per DALY) were derived
- Reason for derivation is efficient allocation of public resources for healthcare
- Different context to valuation of preferences
  - Are the two linked?

- Use of the word ‘intangible’

Agreement in unit valuations

- Many effects considered for EDCs
- Some agreement (some use of the same sources)
- Some disagreement
  - Different shares of healthcare costs, productivity losses, utility losses
  - Different time bases, annual vs lifetime
  - Account of co-morbidities
  - Or just different values

Relative values for different phthalates

- Important issue – where are the priorities?
- Consider both tox and epi data
- Substantial costs identified for DEHP
  - Adult obesity, diabetes
  - More harmful than other phthalates?
  - Or just more data?
- ECHA approach via oral DNELs for differentiation
  - How robust?

Key areas for improvement

- Response functions
  - Differentiation between substances
  - Identification of most economically important effects as well as those we can measure most easily
- Utility losses
  - Inclusion
  - Valuation
- Presentation of uncertainty
  - Context specific – different for BCA work compared to burden assessment

Comments on the Phthalates Piece by Mike Holland

By Anna Alberini

AREC, University of Maryland

Phtalates

- Used to impart flexibility to PVC and other materials, and improve texture of certain toiletry products
- Very widespread
- Endocrine disruptors
  - Reproductive system effects, esp. on males
  - Some are irreversible, others can be surgically fixed
  - ADHD, neurodevelopmental effects
  - Premature mortality due to disrupted testosterone
  - Cancer

What are the Benefits of Regulating Phtalates?

- Must quantify the share of all cases that is correctly attributable to phthalate exposure
- …and the change in that share if regulations are implemented
- Attach to each case a $ value

Approach

- Use a handful of studies that computed the cost of illness of certain phthalate outcomes (or similar outcomes caused by other substances)
- Too few studies to trust similarities or differences in $ figures
- Studies generally used Cost of illness (or human capital) approach and omitted value of disutility

Approach to attaching a $ value

- What is the value of avoiding illness?
  - WTP should be comprised of…
    - Work income lost to illness
    - Medical expenses
    - Averting costs
    - Value of the discomfort/disutility of the illness

Cost of Illness

- Must be modified when human capital accumulation is affected by the exposure
- Note that the COI approach does not capture the disutility of the illness

What is the WTP to avoid illness?

$$WTP = \left[w\frac{dW}{dD} + p_M \frac{dM}{dD} + p_A \frac{dA^*}{dD} - \frac{U_D}{\lambda} \right]$$

Work income or productivity lost to illness

Averting expenditures

Value of the disutility and discomfort of illness

Cost of illness

WTP to pay to avoid illness

When exposure affects human capital accumulation…

- Look at lifetime costs
- Link with school attendance, educational attainment, performance on labor markets and earnings (e.g., Landrigan et al., 2002; Grosse et al. 2002; Drake, 2016; Trasande, 2016)
- Value of suffering of affected individuals and their parents usually not available

When exposure affects reproductive system…

- Cost of fertilization treatments
- Value of statistical pregnancy, statistical baby
- Value of a healthy baby

Scasny and Zverinova (2014)

How can we improve this kind of analyses without requiring extensive and expensive original studies every time?

- Total WTP= $\alpha \cdot$COI, $\alpha>1$
- What is the value of α?
- Only two studies:
  - Rowe and Chestnut (1985)
  - Alberini and Krupnick (2000)
- α = 2 to 4

Mortality

- Agree that
  - the appropriate metric is the Value per Statistical Life (VSL)
  - Value of a Statistical Life Year (VOLY) not appropriate
    - Not truly compatible with theoretical models
    - Estimates of the VOLY usually derived from VSL
- QALY consistent with economic theory only if extremely restrictive assumptions are made

What is the Value per Statistical Life?

- WTP for a small reduction in the mortality risk
- Scaled up until we get “one statistical person saved”
- E.g., \$200 for $\Delta M=0.0001$, so VSL=\$200*10,000=\$2 million

Cancer

- VSL used in environmental policy analyses usually come from labor market studies (US) or from the transportation accident context (UK)
- But environmental exposures are very different
- Should the cancer VSL be different?

Mystery Numbers…

- What is the “value of cancer morbidity” on page 38 and why is it attributed to Alberini and Scasny?
- Alberini and Scasny conducted an original stated preference study to elicit the cancer VSC and the VSCC
  - Commissioned by ECHA
  - Done in four countries in 2014
- The study did not produce a “value of cancer morbidity” and it couldn’t have because
  - It only got people to value cancer, and not other illnesses
  - WTP, VSL and VSCC were <u>not</u> affected by quality of life with cancer and pain

Journal of Health Economics

Available online 19 August 2017

In Press, Accepted Manuscript

The Benefits of Avoiding Cancer (or Dying from Cancer): Evidence from a Four-country Study

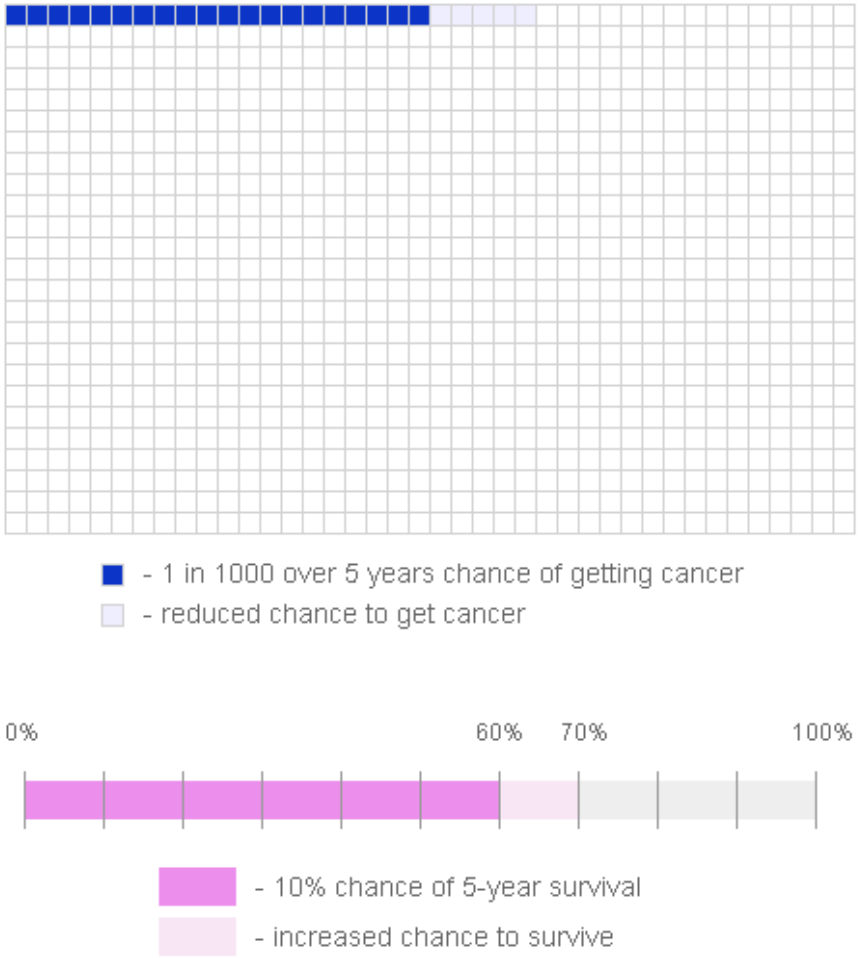
Anna Alberini [a] ✉, Milan Ščasný [b] ✉

Show more

https://doi.org/10.1016/j.jhealeco.2017.08.004

Example Choice Card

	The current situation	Option A (reduced risks)
Chance of getting cancer over 5 years	25 in 1 000	20 in 1 000
Chance of 5-year survival (if you get cancer)	60 %	70 %
Effects on everyday activities (if you get cancer)	Unable to work	Unable to work
Pain (if you get cancer)	Mild pain	Mild pain
Annual cost for each of the next 5 years (total in parentheses)	£ 0 (in total £ 0)	£ 210 (in total £ 1050)
Which would you choose?	The current situation	Option A (reduced risks)



Design

- 32 blocks where the risk-reducing alternative is selected at random from the full factorial design
- QOL and pain always the same for alternative and status quo, but change over the choice cards
- structure of the blocks:

	Blocks 1-16	**Blocks 17-32**
First 3 choice cards	$\Delta S=0$, only $\Delta R\neq 0$	$\Delta R=0$, only $\Delta S\neq 0$
Choice cards 4-7	ΔS and ΔR are both varied	ΔS and ΔR are both varied

The Model: Expected Utility Framework

utility is thus

(1) $$EU = (1-r)U(w) + r(1-p)(1-h)U(w),$$

where U( ) is utility in the healthy state, and h ($0 \leq h \leq 1$) represents the diminished utility of income when one is still alive but has had or has cancer (see Rheinberger et al., 2016).

Value per Statistical Case of Cancer

- Def.: WTP for a small decrease in the risk of getting cancer

$$VSCC = \frac{\partial w}{\partial r} = \frac{[p + h \cdot (1 - p)]U(w)}{[1 - m - h \cdot (m - r)]U'(w)}$$

- $m = p \cdot r$ is the unconditional risk of dying from cancer
- VSCC depends on p and h, unless $p = 1$

Cancer VSL

- Def.: WTP for a small change in *m*

$$VSL = \frac{\partial w}{\partial m} = \frac{p + h \cdot (1 - p)}{p} \cdot \frac{U(w)}{[1 - m - h \cdot (m - r)]U'(w)}$$

  - Likewise depends on *p* and *h*, unless *p*=1
  - VSL = VSCC/*p* (for any *h*)
  - VSL → VSCC as p → 1

In sum…

- The only way we can try to estimate a "morbidity value of cancer" is if VSL (and hence VSCC) are observed to change with h
- …but in our survey VSL and VSCC were insensitive to quality of life and pain (our way of measuring *h*)
- Figure used in Holland's piece is based on an outside report, unintelligible calculations, and we do not subscribe to them

Lessons learned

- VSCC 578,000 euro
- VSL approx. 2 to 5 million euro
- The theoretical models are one thing, …
- …the empirical findings are another
- I have seen this quite a few times
  - Cancer premium, no premium, or even discount
  - Ambiguity and its effect on WTP
  - Severity and its effect (or lack thereof) on VSCC, VSL

Thank you!

Comments and questions to
aalberin@umd.edu

What's *h*?

- h can be backed out if separate VSCCs (VLSs) are estimated for different levels of illness severity
- Divide h by the marginal utility of income and interpret that as the value of (morbidity) disutility of cancer?
- Rheinberger et al. (2015) refer to "value of palliative care"
- But in the Alberini and Scasny study VSCC and VSL were insensitive to severity

HASSENFELD
CHILDREN'S
HOSPITAL
OF NEW YORK
AT NYU LANGONE

Comments re: Holland phthalate report to OECD SACAME meeting

Leonardo Trasande, MD, MPP
Associate Professor of Pediatrics, Environmental Medicine, and Population Health

General Comments

- Thoughtful overview
- As primary/senior author on multiple manuscripts reviewed in report, helpful to see findings reconfirmed and refined (e.g., unit cost assumptions are being rechecked as a result of Holland comments)
- Overview focuses chiefly on modeling and economics
- My comments focus on:
    - ECHA phthalate analysis
    - AMEC report
    - ”[R]isk that conclusions reached from the analysis become accepted without full debate”

ECHA phthalate analysis

Models infertility in subsequent generation of in utero exposed population.

Holland report conclusion: ECHA benefits grossly underestimated

- Missing: obesity, autism, low testosterone
- Bias to underestimation in infertility rate
- Missing: direct, indirect intangible costs of IVF

ECHA phthalate analysis (issues in need of addition)

- Odd and incorrect choice given that infertility studies in humans are of contemporaneous exposure (effects are in current generation)
- Modeling impacts in subsequent generation discounts future costs of phthalate exposures by more than half
- Focus on effects of proportion attributable to indoor environment, food, and articles misleading in that phthalates do not have a natural source (underestimation)
- Focus on abnormal semen parameters (excludes effects on female found in epidemiology studies, and in subclinical range in men)

Conclusion (same): ECHA benefits grossly underestimated

AMEC report

Note: chiefly derived from Trasande and other reports

Biomarker models used based on very small sample sizes of population (overestimate likely)

Does not account for probability of causation (overestimates benefits)

Comment of concern in Holland report

“It is noted that a large number of the studies considered here were carried out by the same group of people. Given the multidisciplinary nature of the work there is some risk that the conclusions reached from the analysis become accepted without full debate, as few will feel comfortable commenting on the overall analysis given that their expertise lies in specific elements of the approach rather than the whole.”

Related footnote: “A counterpoint to this lies in problems of publishing multi-disciplinary work, where it is considered to stray outside the scope of specific journals, or where the expertise of reviewers does not cover the breadth of analysis.”

“Full debate”

Meaning here unclear

- Peer review (Attina paper vetted with five anonymous reviewers) of all seven manuscripts with a minimum of three anonymous reviewers
- External publication with opportunities for letters to editor (e.g., Middlebeek and Veuger re Bellanger et al in JCEM; Swaen and Otter re Hunt et al in JCEM; Jaacks and Prasad re Attina et al in Lancet Diab Endo)
- Scientific norms carefully followed here. If this method of open debate is questioned then entire scientific enterprise should be reconsidered.

“Full debate”

In addition, efforts to rebut related work have been made by Bond (a consultant to American Chemistry Council) and Dietrich (a toxicologist who has been described as having “ties to industry” in http://www.environmentalhealthnews.org/ehs/news/2013/eu-conflict) in Nature, J Epi Comm Health and Archives of Toxicology.

- They focus in particular on costs of organophosphate pesticide and flame retardant effects on the developing brain.
- They argue that systematic reviews were not used in evaluating evidence for causation.
- They cite systematic reviews to suggest lack of evidence for causation.

“Full debate” re flame retardants

Both reviews regarding flame retardants actually support the strength of evidence selected by the expert panel!

Roth and Wilks: All studies “reported significant or highly significant inverse associations between prenatal and/or postnatal exposure to individual PBDEs congeners or their sum (mainly PBDE-47, -99, -100, -153, -154, -209) and the various test cognitive scales (i.e. Bayley, Wechsler, McCarthy).”(Roth and Wilks Toxicol Lett, 2014) All three birth cohort studies were rated as high quality by Roth and Wilks.

Kim et al suggest some inconsistency in the effects of PBDE on IQ by including a study of adults,(Kim et al. Chemosphere, 2014), yet adulthood represents an altogether different phase of life in which effects of thyroid hormone are unlikely to impair IQ that has already crystallized.

Most recently, Lam et al published a systematic review and meta-analysis that used superior methods to evaluate study quality for flame retardants and cognitive function, including the Risk of Bias tool. This systematic review identified “sufficient evidence supporting an association between developmental PBDE exposure and reduced IQ.”(Lam et al. EHP, 2017)

“Full debate” re organophosphates

Bond and Dietrich cite a review article that examines pesticide exposure generically, also lumping populations without regard to windows of susceptibility.(Ntzani et al., 2017)

Another review they cite (Burns et al., 2013) fails to accurately represent the findings of a birth cohort study at Columbia University which occurred contemporaneously with a ban of chlorpyrifos and diazinon in households to control pests.

- Before the ban, they found decreases in birth weight and length in relationship to levels of chlorpyrifos in newborn cord blood. After the ban, as levels substantially decreased, associations with these strong predictors of adult neurocognitive and cardiovascular outcomes disappeared (Whyatt et al., 2004).

Burns et al also misinterpret findings from two other cohorts, suggesting that divergent findings of maternal and urinary biomarkers in the CHAMACOS cohort (Eskenazi et al., 2010) together with different findings by race/ethnicity in another New York City-based cohort (Engel et al., 2011) clouds the etiologic role of OPs.

A pooled analysis of four birth cohorts provides the most thoughtful interpretation of this issue thus far. The more appropriate interpretation is stated thusly: “Subgroups with unique exposure profiles or susceptibilities may be at higher risk for adverse neurodevelopment following prenatal exposure.” (Engel et al., 2016)
Burns et al also neglect studies of later neurocognitive outcomes that confirm adverse effects.(Bouchard et al., 2011b)

“Full debate” re organophosphates

In selecting these suboptimally conducted reviews, Bond and Dietrich also neglect another review that identified all but one of 27 studies evaluated with “some negative effects of pesticides on neurobehavioral development.” (Munoz-Quezada et al., 2013)

They also neglect to mention neuroimaging studies that document frontal and parietal cortical thinning consistent with the neurobehavioral deficits identified in psychological testing (Rauh et al., 2012).

- This last consideration is crucial in its independent replicability, a major component of responsible science. (Munafò et al., 2017) Using the Bradford Hill criteria,(Hill, 1965) these findings speak to consistency and coherence, adding to strength of causal inference.

“Full debate” re organophosphates

Bond and Dietrich use a US EPA Science Advisory Panel report to suggest that IQ impairment due to OPs is not supported by the weight of the evidence.

- The rationale underlying the statement, which Bond and Dietrich directly quote, that “impaired working memory and lower IQ measures observed are caused primarily by a single insecticide (chlorpyrifos) and predicted by the blood levels at time of delivery is not supported by the scientific weight of evidence.” (US EPA, 2017) merits further discussion.
- While one study leveraged cord blood chlorpyrifos measurements in association with adverse neurocognitive outcomes, the other studies examined prenatal measurements of multiple organophosphate pesticides known to disrupt thyroid hormone in urine.(Bouchard et al., 2011a; Engel et al., 2011)
- This distinction is crucial because the expert panel identified very high probability of causation for organophosphates, not for chlorpyrifos alone. At best, the use of the EPA Science Advisory Panel report by Bond and Dietrich is a sleight-of-hand or misrepresentation.

Summary

Estimates of EDCs in the peer-reviewed literature have received a thorough, full and public vetting, and have withstood concerns chiefly voiced by industry affiliates.

In addition, readers should consider three crucial points when reading a critical review of another paper:

- Do the authors have conflicts of interest and do they acknowledge them?
- Do they have the scientific expertise and credibility in the field being reviewed?
- Did the journal editors and reviewers assure that the critical review is focused on the science and scientifically defensible data and is devoid of biased statements?

Dietrich and Bond's critique fails on all three points, including failing to state funding sources for their work, and does a disservice to the scientific community.

German Environment Agency

Umwelt Bundesamt

OECD Workshop: *Best Practices in Assessing the Social Costs of Selected Chemicals*, Ottawa, Canada, 30-31 August

Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

Experience in preparing a restriction proposal under REACH

Karen Thiele
International Chemicals Management (Section IV 1.1)

Outline

- Background: Per- and polyfluoroalky substances (PFASs)
- Substances targeted in the restriction
  - concerns
  - uses
  - alternatives
  - emissions
- Socio-economic analysis (SEA)
  - challenges
  - approach
  - evaluation of impacts
- Conclusions

Per- and polyfluoroalky substances (PFASs)

- up to 3,000 substances
- concerns about persistency and mobility in the environment
- monitoring data show occurrence in humans and the environment
- attention by general public
  - → related to textiles, fire-fighting foams
  - → contamination of drinking water
- Other (regulatory) activities on risk management such as
  - → US EPA PFOA stewardship program
  - → OECD/UNEP Global PFASs Group
  - → Perfluorooctane sulfonicacid (PFOS) POP in Stockholm Convention
  - → Several long-chain PFASs listed as PBT or vPvB under REACH, incl. PFOA
  - → PFOA and long-chain PFCAs prohibited in Canada
  - → POP proposal on PFOA, its salts and PFOA-related substances
  - → …

Substances targeted in the restriction

PFOA

PFOA-salts

listed as **PBT** and reprotoxic (1B) under REACH

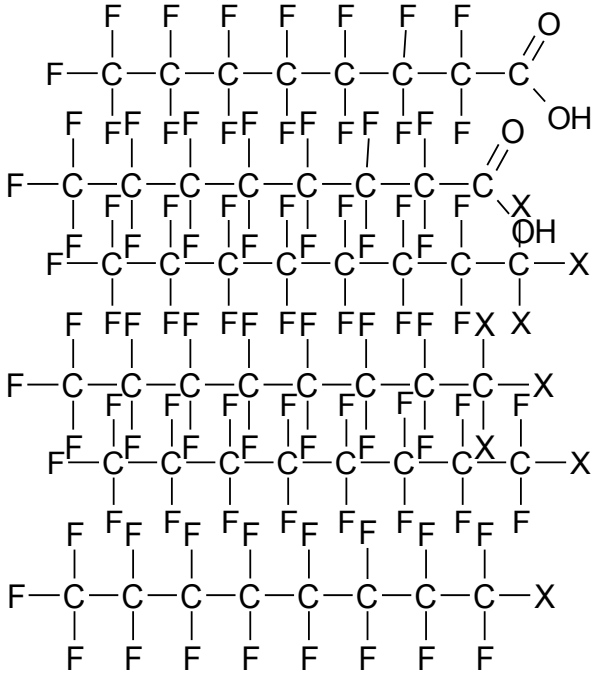
in addition classified Carc. 2 and STOT RE 1 (liver)

PFOA-related substances

(degrade to) same perfluorinated chain as PFOA

→ degrade to PFOA

→ also have to be considered **PBT**-substances



→ **Goal: Minimise emissions of PFOA, its salts and PFOA-related substances**

Uses of PFOA and PFOA-related substances

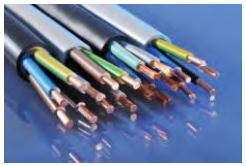
PFOA (+ salts)

use as an emulsyfying agent

fluoropolymer manufacture

Tobilander/Fotolia.com

Stillfx/Fotolia.com



demarco/Fotolia.com

< 20 t/a
imported in mixtures and articles

PFOA-related substances

use in polymers and surfactants to achieve chemical stability as well as water and oil/dirt repellency

textile treatment

Jürgen Fälchle/Fotolia.com

Luisa Leal/Fotolia.com

fire-fighting agents

Kzenon/Fotolia.com

paper treatment

PhotoSG/Fotolia.com

paints and inks

industrieblick/Fotolia.com

100 – 1,000 t/a
produced in the EU

100 – 1,000 t/a
imported as substance

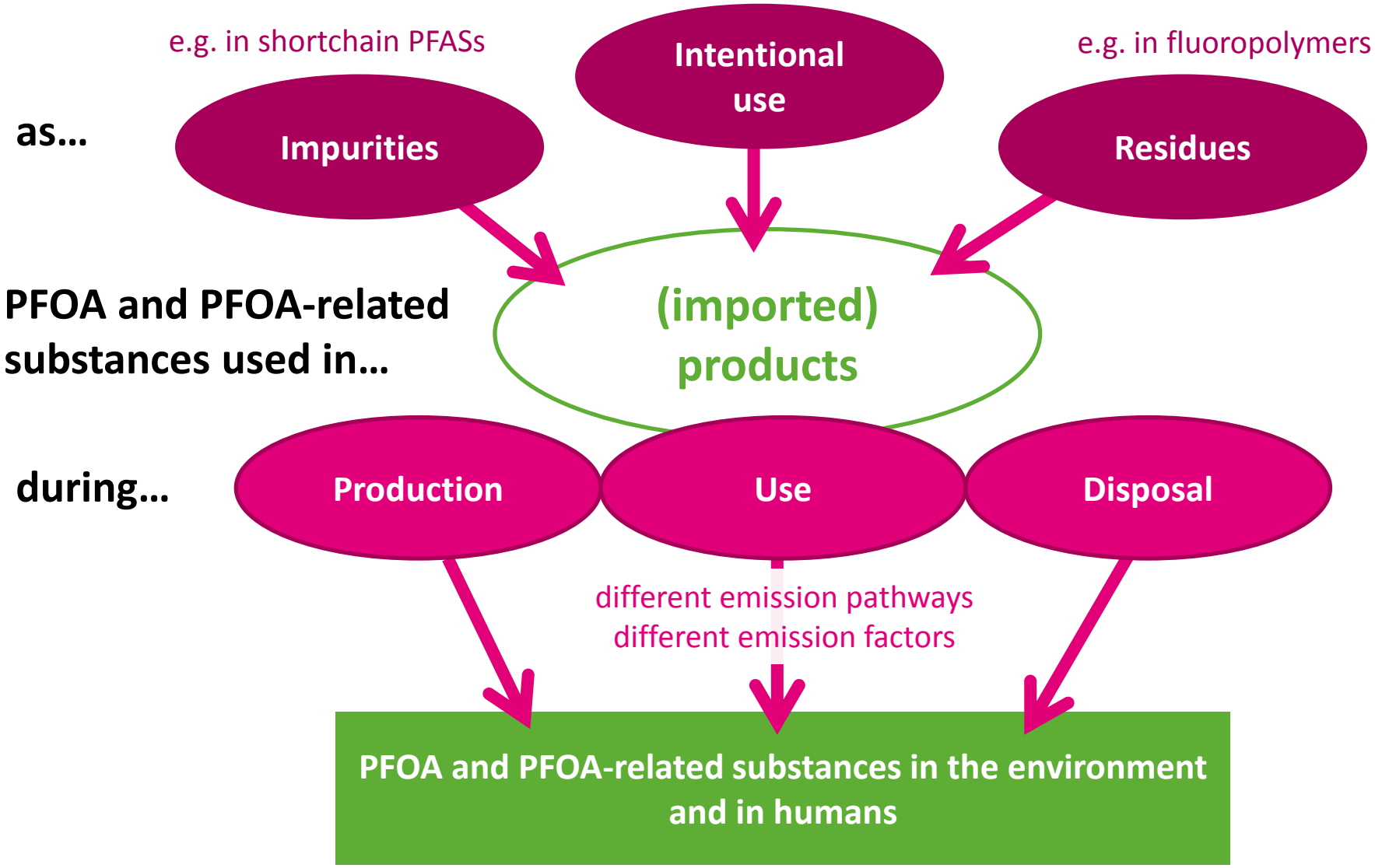
1,000 – 10,000 t/a
imported in articles

etc.

Alternatives

- fluorinated and non-fluorinated substances available for most uses
- most likely to be used: short-chain PFASs
  - → very persistent as well
  - → mobile in the environment (soil and water)
  - → may contain PFOA and PFOA-related substances as impurities
  - → lower potential for bioaccumulation expected compared to PFOA
- Overall, in terms of their PBT properties alternatives likely to be less hazardous than PFOA

Emissions


e.g. in shortchain PFASs
Intentional use
e.g. in fluoropolymers
as…
Impurities
Residues
PFOA and PFOA-related substances used in…
(imported) products
during…
Production
Use
Disposal
different emission pathways
different emission factors
PFOA and PFOA-related substances in the environment and in humans

Effective regulation of PFOA…

- has to cover all substances that can degrade to PFOA
  - → PFOA-related substances are an important stock of PFOA in the environment
- has to include all emission sources
  - → also unintentional use of PFOA and PFOA-related substances (as impurities/residues) contribute significantly to emissions
  - → emissions occur during every life-cycle step of related products

(close to a)

total phase out of PFOA and PFOA-related substances = effective risk reduction

Socio-economic Analysis (SEA): Challenges

- restriction proposal primarily based on **PBT** concern of PFOA
  - → not possible to quantify the impacts on the environment and human health based on standard methodologies and data
- broad scope of the proposed restriction
  - → multitude of substances and uses
  - → large data gaps, even with extensive efforts to improve evidence base (through research, literature review and consultation with industry)
- a lot of assumptions and generalisations needed, e.g. in the assessment of
  - → uses and corresponding volumes
  - → emissions
  - → costs

SEA: Approach

- not possible to carry out a cost-benefit analysis
  - → not possible (or adequate) to quantify and monetise environmental and human health impacts
  - → not possible to conclude on proportionality of the restriction based on quantitative comparison of different impacts
- Instead: cost-effectiveness analysis of emissions reduced + qualitative information on impacts
  - → using all relevant information
  - → taking into account the uncertainties involved

Baseline Scenario

- volumes and emissions estimated for a representative year post 2015 without the restriction
- reflects activities to manage the risks of PFOA
  - → assumption: 70 % reduction of volumes used due to voluntary industry agreement (US EPA Stewardship Program)
- takes into account available information on market trends
- use of ranges to reflect uncertainties in volumes

Economic impacts: Costs

- estimation of substitution costs of PFOA and PFOA-related substances based on
  - → **volumes** of PFOA and PFOA-related substances used ‘post-2015’
  - → **higher loading** of short-chain PFASs to be used in the specific application to achieve similar performance (0 – 40 %)
  - → **price increase** of short-chain PFASs compared to PFOA and PFOA-related substances or fluoropolymers (PTFE) when manufactured without PFOA (0 – 20 %)
- investment costs or other economic impacts not quantified
  - → major investment by industry already took place, unclear what further investment would be triggered by the restriction proposal

Costs: Overview

Use/Source	volume used/imported (t/a)	substitution costs million €
Import of PFOA	0	0
in articles	3	?
Fluoropolymers		
import and use of PTFE mixtures	15	0 – 37.34 (9.3)
Textiles		
Use in EU	300	0.6 – 10.6 (4)
Import in articles	300 - 3,000 (1,500)	0.6 – 106 (19.9)
Fire-fighting foams	15 – 30 (23)	0.06 – 1.6 (0.5)
Paper	45 – 60 (53)	0.1 – 2.1 (0.7)
Paints and inks	15 – 30 (23)	0.03 – 1 (0.3)
Photographic applications	0.001/0.1	?
Semiconductors	0/0.02	?

Environmental & human health impacts: Benefits

- benefits assessment was based on
  - → estimates of the **emissions** to be reduced as a proxy of the benefits of the proposed restriction
  - → the **specific characteristics of PFOA** in the environment and in the population exposed that contribute to its overall 'damage potential' (compared to a substance that would just fulfil the P, B and T criteria)
  - → a **qualitative discussion of the human health impacts** of PFOA.
  - → information on **remediation costs incurred** for PFASs contaminations including PFOA and PFOA-related substances.
  - → information on society's **willingness-to-pay for precautionary control of PBT substances**

Benefits: Emissions reduced

PFOA and PFOA-related substances in...	volume used/imported t/a	emission factor %	emission estimate t/a
Total **PFOA / PFOA-related substances**	**18/** **675 – 3,420** **(1,900)**	**> 38/** **1.7 -2.8** **(1.9)**	**>5.7/** **18.8 – 55.2** **(35.2)**
(volume used outside EU)	**(9 - 280)**	**(80)**	**(7.2 - 224)**

→ only emissions occurring within the EU considered

→ emissions outside the EU during the manufacture of products imported into the EU expected to be significant

Benefits: Qualitative information

- specific characteristics of PFOA
  - → one of the most persistent substance known
  - → ubiquitously present in the environment and humans
  - → mobile in the environment, including water bodies
  - → long-range transport and findings in remote areas
  - → human health effects: reprotox, hypercholesterolemia, developmental toxicity and cancer
- PFASs contamination of (drinking) water and soil caused high costs for remediation
- general willingness-to-pay for precautionary control of PBT substances

Rudolf Lettner/Fotolia.com

Zauberhut/Fotolia.com

staphy/Fotolia.com

Tomasz Trojanowski/Fotolia.com

Cost-effectiveness analysis

	emission estimates t/a	costs million €/a	cost effectiveness €/kg
PFOA	>5.7	0 – 37.4 (9.4)	0 – 6,561 (<1,649)
PFOA-related substances	18.7 – 56.7 (36.4)	1.4 – 121 (26.7)	4 – 3,533 (734)

→ ranges reflect the high uncertainties involved

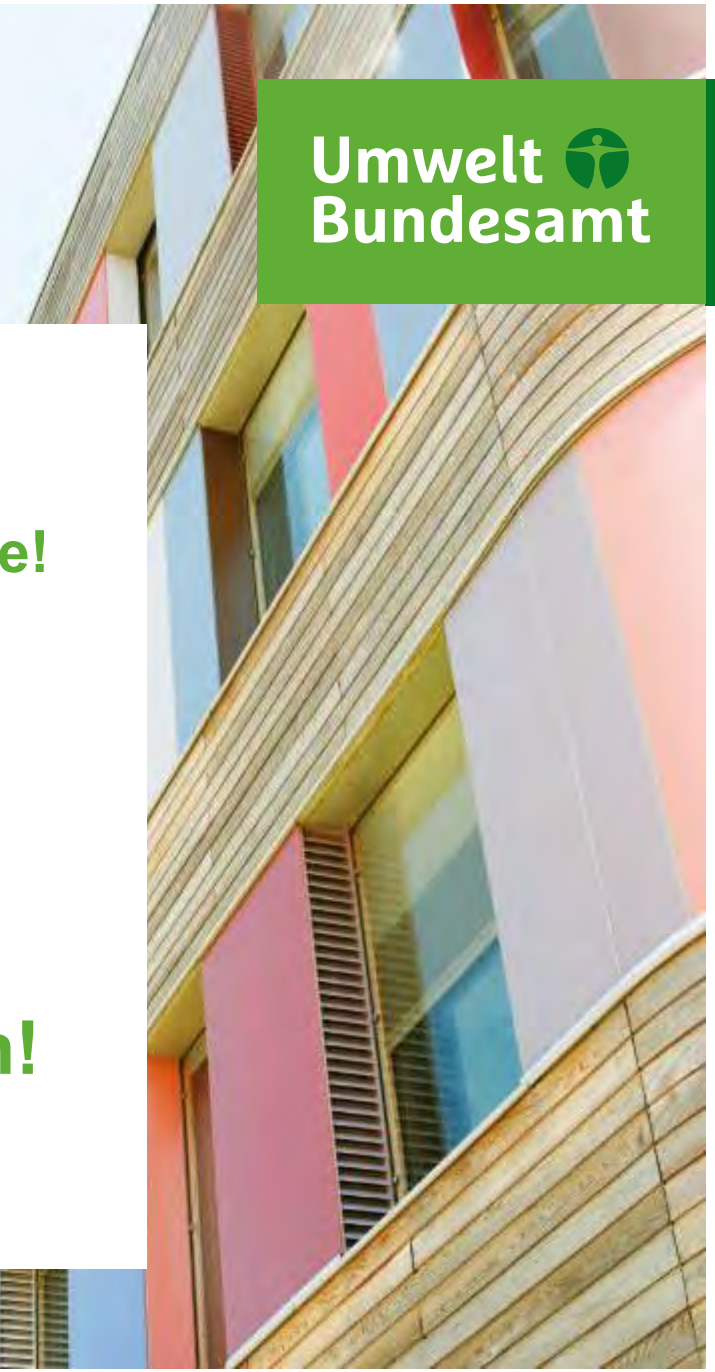
→ cost-effectiveness estimates in the same order in magnitude as for other restrictions on PBT(-like) substances under REACH

→ however: limited validity to conclude on proportionality based on a comparison of cost-effectiveness

→ **conclusion on proportionality was made in combination with available qualitative information**

Conclusions

- PFOA case illustrates the difficulties to assess the environmental and human health impacts of PBT substances from a socio-economic perspective
- multiple sources (PFOA-related substances) and emission pattern represented an additional challenge
  - → extensive efforts in data gathering did not result in a well-grounded evidence base
  - → a lot of assumptions and generalisation needed
- important to consider qualitative information for a balanced analysis/decision



Thank you to my colleagues

Annegret Biegel-Engler and Lena Vierke!

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Thank you to for your attention!

Economic assessment and valuation of environmental and health impacts caused by PFOA and its salts

Case study presented at the OECD SACAME workshop
"**Best Practices in Assessing the Social Costs of Selected Chemicals**",
30-31 August 2017, Ottawa, Canada

Silke Gabbert, Wageningen University, The Netherlands

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Overview

1. The concept of 'social costs' in chemicals risk management and regulation

2. Existing economic assessments related to PFOA and its salts: A systematic literature analysis

3. Results of and conclusions from the literature analysis

4. Opportunities and requirements for improving valuations of PFOA and its salts from a social cost perspective

1. The concept of 'social costs' in chemicals risk management and regulation

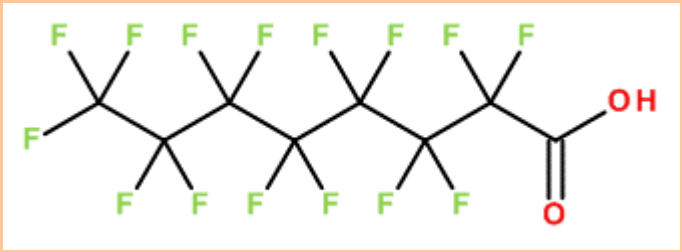
General definition:
Social costs = Private costs + external costs

	Private costs	External costs
Use scenario	Market-based costs related to the production, retail, research and development of a substance	Non-market costs of chemicals use, e.g. environmental damage costs, health damage costs
Non-use scenario	Market based costs related to the emission reduction/abatement of a substance	In case of reduced emissions: Non-market costs of a reduced use; In case of ban/substitution: Long-term non-market costs; non-market costs of substitutes

Gabbert (2017), PFOA case study presented at OECD SACAME workshop, 30-31 August, Ottawa, Canada

2. Existing economic assessments for PFOA and its salts

Perfluorooctanoic acid (PFOA)



Source: http://nipsect.dk/wp-content/uploads/2016/12/PFOA.bmp

and its salts, e.g. Ammonium perfluorooctanoate (APFO)

- In use since the 1950s (i.e. long emission history)
- Wide variety of applications and uses:
  - Polymerization aid in fluoropolymer manufacturing (main global use)
  - Surface tension and electrostatic charge control in manufacturing of silver halide photographic film
  - Component in photoresists, anti-reflective coatings, and etching solutions for photolithography in semiconductor industry

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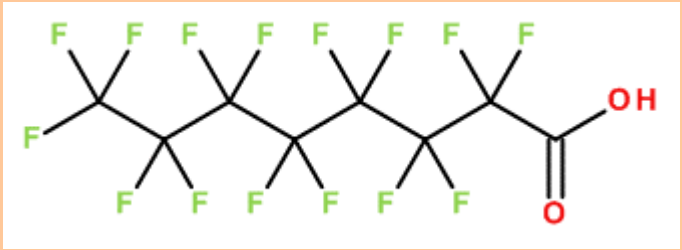
2. Existing economic assessments for PFOA and its salts

Perfluorooctanoic acid (PFOA)



Source: http://nipsect.dk/wp-content/uploads/2016/12/PFOA.bmp

and its salts, e.g. Ammonium perfluorooctanoate (APFO)

- Under REACH: Substance of Very High Concern (SVHC)
  - Meets criteria for being classified as PBT
    - Not degradable in water, soil and sediment (ECHA 2014)
    - Degradation half-life in air: 130d (ECHA 2013)
  - CMR properties (in particular toxic for reproduction)

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2. Existing economic assessments for PFOA and its salts

- Literature analysis: Considered sources
  - Information and economic assessments submitted to the Stockholm Convention;
  - REACH Annex XV restriction proposal on PFOA, its alts and PFOA-related substances (ECHA 2014), including opinion documents provided by ECHA-RAC and ECHA-SEAC;
  - Economic assessments provided the Canadian Environment Agency to support the prohibition of PFOA and its salts, including an analysis for PFOS;
  - Scientific literature using a keyword-based search in Scopus and Google Scholar.

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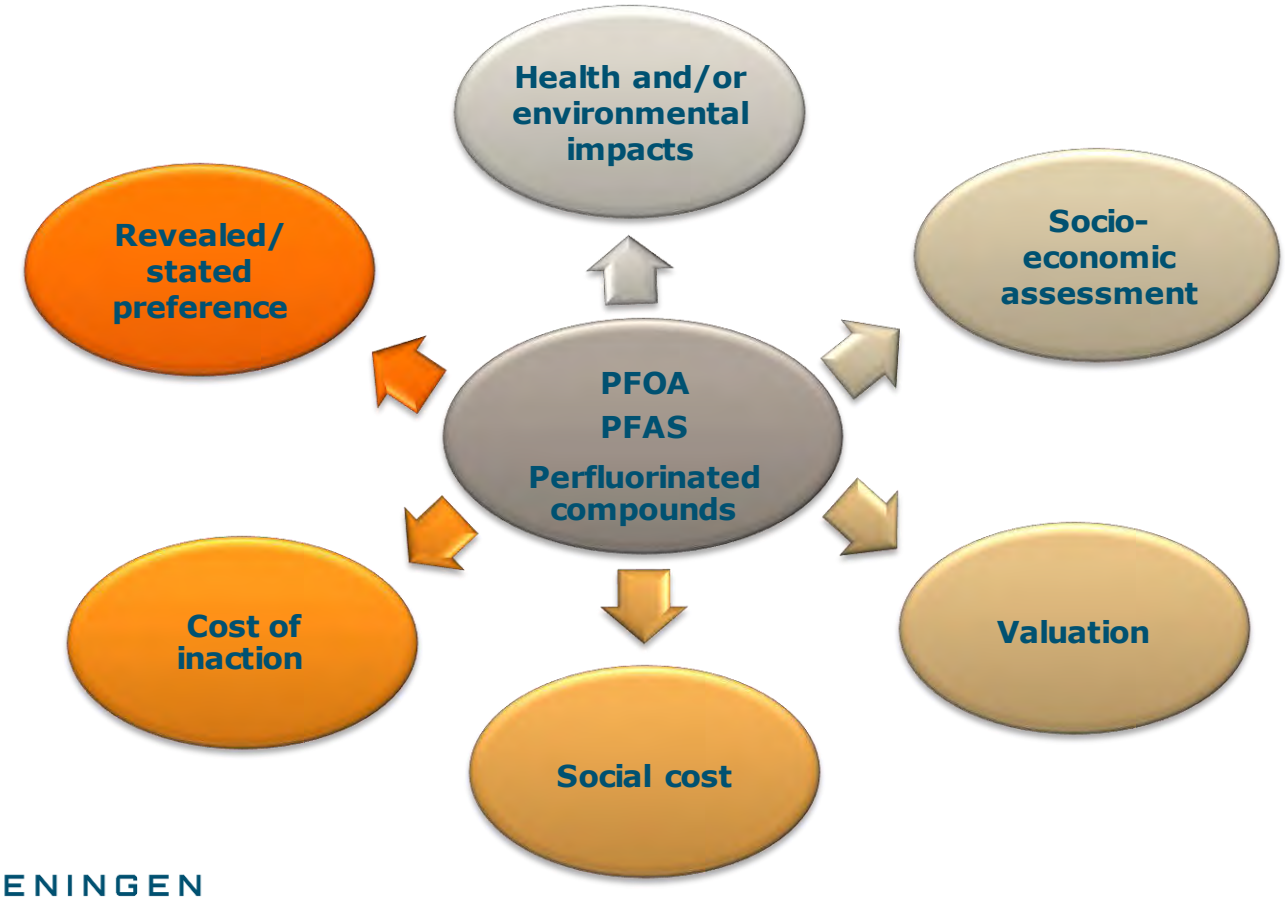
2. Existing economic assessments for PFOA and its salts

- Literature analysis: Search terms



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2. Existing economic assessments for PFOA and its salts

- Literature analysis: Evaluation criteria

Criteria
• Risk management context
• Methodological approach
• Quantitative SEA included?
• Assumptions of the assessment
• Time horizon of the assessment
• Effects/endpoints/impacts considered
• Valuation method
• Aggregation mechanism of impacts
• Data sources
• Documentation of data or knowledge gaps
• Treatment of uncertainties

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3. Results from the literature analysis

- Overall: 80 documents included in analysis
  - 72 documents submitted to Stockholm Convention
  - 5 documents from literature search
  - REACH Annex XV restriction proposal
  - 2 documents from Environment Canada (PFOA, PFOS)

- Only 11 documents included quantitative estimates on costs related to an emission reduction or a phasing out of PFOA and its salts.

3. Results from literature analysis

- Focus of current economic assessments PFOA and its salts:

	Private costs	External costs
Use scenario	Market-based costs related to the production, retail, research and development of a substance	Non-market costs of chemicals use, e.g. environmental damage costs, health damage costs
Non-use scenario	Market based costs related to the emission reduction/abatement of a substance	In case of reduced emissions: Non-market costs of a reduced use; In case of ban/substitution: Long-term non-market costs; non-market costs of substitutes

Gabbert (2017), PFOA case study presented at OECD SACAME workshop, 30-31 August, Ottawa, Canada

3. Results from literature analysis

- Focus of current economic assessments PFOA and its salts:

	Private costs
Use scenario	Market-based costs related to the production, retail, research and development of a substance
Non-use scenario	Market based costs related to the emission reduction/abatement of a substance

- Industry costs emission reduction

  -Overall EU
  → 0-6561 €/kg emission reduction

  -Capital and operating costs for implementing leachate technologies
  → 0.59-7.09 USD per m^3 processed

Gabbert (2017), PFOA case study presented at OECD SACAME workshop, 30-31 August, Ottawa, Canada

3. Results from literature analysis

- Focus of current economic assessments PFOA and its salts:

	Private costs
Use scenario	Market-based costs related to the production, retail, research and development of a substance
Non-use scenario	Market based costs related to the emission reduction/abatement of a substance

- Governmental costs (Canada) in case of prohibition of PFOA and its salts:
  -Administrative activities
  -Industry compliance with other regulatory requirements
  -Enforcement
  -Promotion activities
  → PV 2.4 Mio CAD
- Industry costs for substitution:
  -PFOA substitution EU
  → 0-2493 €/kg PFOA substituted
  -R&D expenditures
  → 500 Mio USD
  -Transition and qualification costs of downstream users
  → 1 Mio USD per use and company
- Industry costs emission reduction
  -Capital and operating costs for implementing leachate technologies
  → 0.59-7.09 USD per m^3 processed

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Gabbert (2017), PFOA case study presented at OECD SACAME workshop, 30-31 August, Ottawa, Canada

3. Results from literature analysis

- Focus of current economic assessments for PFOS regulation (emission reduction and substitution) in Canada :

	Private costs	External costs
Use scenario	Market-based costs related to the production, retail, research and development of a substance	Non-market costs of chemicals use, e.g. environmental damage costs, health damage costs
Non-use scenario	Market based costs related to the emission reduction/abatement of a substance	In case of reduced emissions: Non-market costs of a reduced use; In case of ban/substitution: Long-term non-market costs; non-market costs of substitutes

- Industry costs (improved emission controls, disposal and replacement)
  → PV costs: 5.97 Mio CAD (25 year period, discount rate 5.5%)

- Consumer benefits (avoided costs alternate water supply)
  → PV benefits: 6.35 Mio CAD (25 year period, discount rate 5.5%)

3. Results from literature analysis

- Endpoints and concerns addressed in the studies (though not included in economic assessments):
  - Persistence
  - Bioaccumulation in biota and humans
  - Acute toxic effects (carcinogenicity, mutagenicity, hepatotoxicity, developmental toxicity, reproductive toxicity)
  - Endocrine disrupting effects
  - Long-range transport potential
  - Long-term health and environmental effects in general (e.g. biodiversity loss, intergenerational toxicity, stress and anxiety in affected populations)

3. Results from literature analysis

- Conclusions:
  - Only few quantitative cost assessments for use and non-use scenarios of PFOA and its salts available
  - Existing monetary cost estimates cannot be compared due to different assessment perspectives, time periods, and monetised components
  - External costs and benefits are usually ignored, and if included they are expressed in non-monetary terms
  - Based on existing knowledge conclusions about the social costs of reducing/substituting PFOA and its salts are not possible.

4. Opportunities for improving valuations

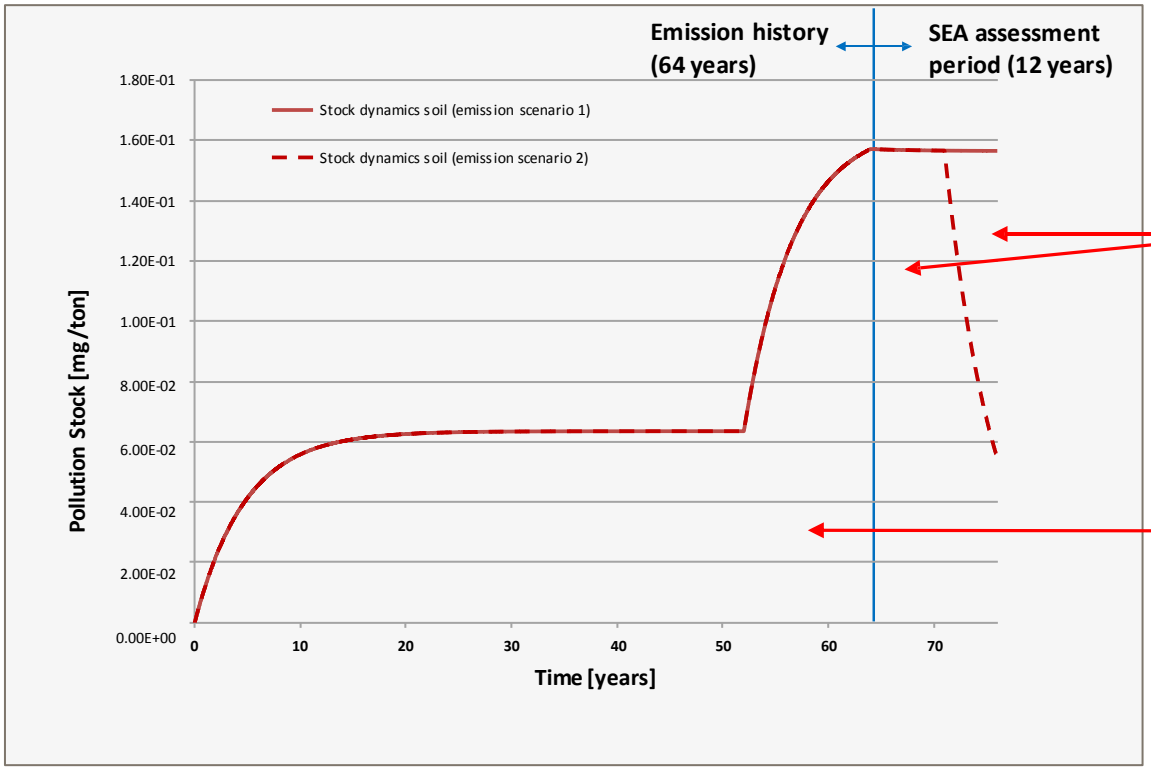
1. Set an appropriate conceptual frame

- Assessing external costs from PFOA use and/or non-use is mandatory for drawing conclusions on social costs
  - ➢ Valued environmental impacts
  - ➢ Valued health impacts (via the environment)
  - → Depends on (change of) exposure concentrations

- Focus on a concern-driven impact assessment/valuation
  - ➢ Due to PBT properties PFOA is a stock pollutant, i.e. on-going and constant emissions environmental cause exposure concentrations to increase over time
  - ➢ Impacts arise from the stock, not from the flow
  - ➢ Emission reduction measures affect the stock indirectly via reducing the flow
  - → Assessing stock pollution effects (i.e. the time path of pollution) must be the starting point of any impact assessment!

4. Opportunities for improving valuations

1. Set an appropriate conceptual frame



Source: Gabbert (2017), own calculations.

4. Opportunities for improving valuations

2. Define the scope for impact assessment and valuation

Complete lack of evidence on long-term impacts

Full evidence on long term impacts

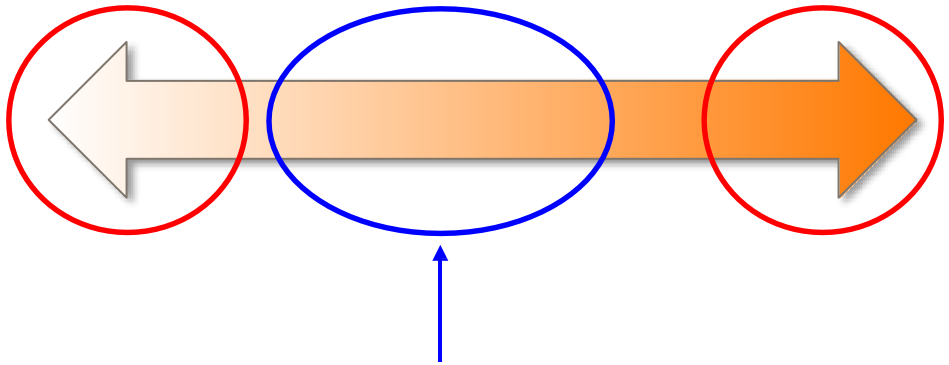
With full or deep uncertainty about a substance's properties, environmental behaviour, emissions etc. an SEA is not possible.

- Consider alternative decision rules, e.g. minimax regret approaches

With full knowledge a quantitative assessment of (long-term) social costs is straightforward

4. Opportunities for improving valuations

2. Define the scope for impact assessment and valuation

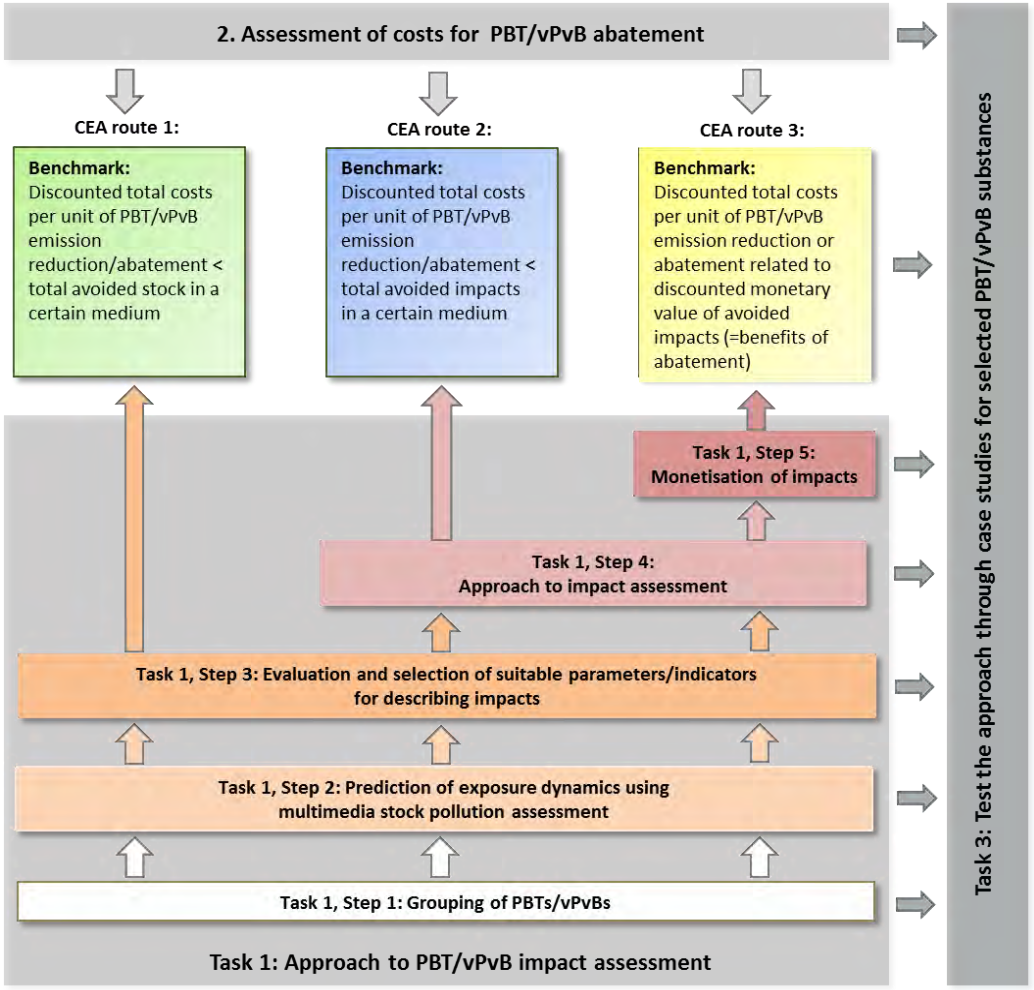


PFOA and its salts:

- Global emission data for different uses (starting 1951)
- Data on physico-chemical properties
- Uncertainty regarding data about degradation half-lives
- Toxicity data about aquatic toxicity, human toxicity, secondary poisoning
- Scattered information on health impacts

Gabbert (2017), PFOA case study presented at OECD SACAME workshop, 30-31 August, Ottawa, Canada

4. Opportunities for improving valuations



Approach to PBT evaluation for socio-economic assessment for REACH authorisation and restriction procedures.

Source: Gabbert et al. (2017).

3. Impact assessment and valuation of PBT substances requires a 'paradigm-shift' towards an integrated modelling approach!

- Combine tox- and ecotox data and assessment approaches with economic methods
- Trans-disciplinary collaboration
- Investment into capacity building

Thank you for your attention!

Gabbert S., Hilber I. (2016): Time matters: A stock pollution approach to authorisation decision-making of PBT/vPvB chemicals under REACH. Journal of Environmental Management 183(1), 236-244

Gabbert et al. (2017): A benchmark level approach for evaluating PBT and vPvB chemicals in REACH authorisation and restriction procedures. Poster presented at the 27th Annual Meeting of the Society for Environmental Toxicology and Chemistry (SETAC), 7-11 May 2017, Brussels, Belgium

OECD Workshop: Best Practices in Assessing the Social Costs of Selected Chemicals

Prepared observations in relation to

PFOA and Salts Case Study

Anthony Footitt -RPA

Thursday 31 August 2017 (AM)

Ottawa

RPA
Risk & Policy Analysts

Anthony Footitt

Principal consultant - Policy and regulatory appraisal

- Chemicals work began with EU Risk Reduction Strategies and impact assessments under the then ESR (including NPEs, Zinc, DecaBDE, PFOS).

- Since the EC White Paper on chemicals in 2001 work on chemicals mainly CBA and IA of future and current regulation for the European Commission (REACH, CLP amongst others).

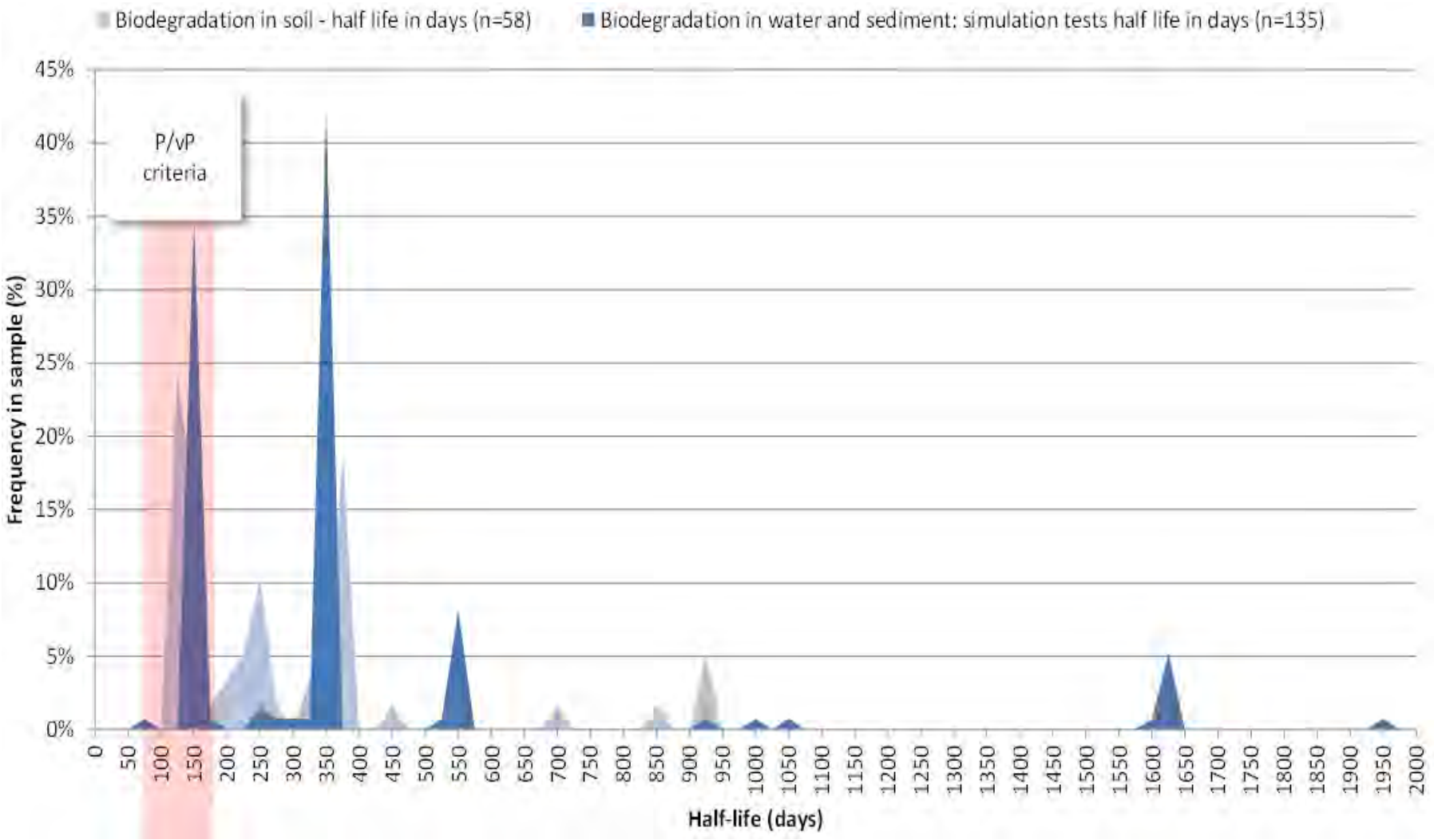
RPA
Risk & Policy Analysts

Very brief comments

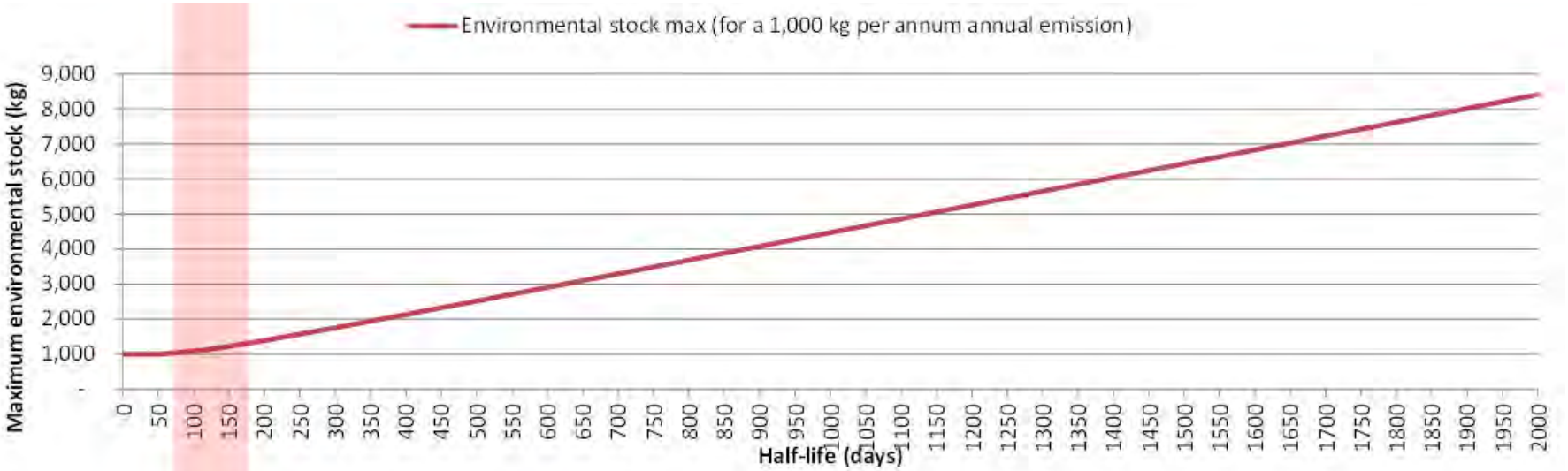
- As the paper has also found, PBTs present a tricky problem for which no satisfactory solution has yet been generally applied.
- during my own work (e.g. on benefits of identifying PBTs via REACH) I also concluded that attributes such as the time-path/stock pollution of PBTs need to be captured.
- PBTs are unlikely to be equally ‘bad’ – some are likely to be a lot ‘worse’ than others.

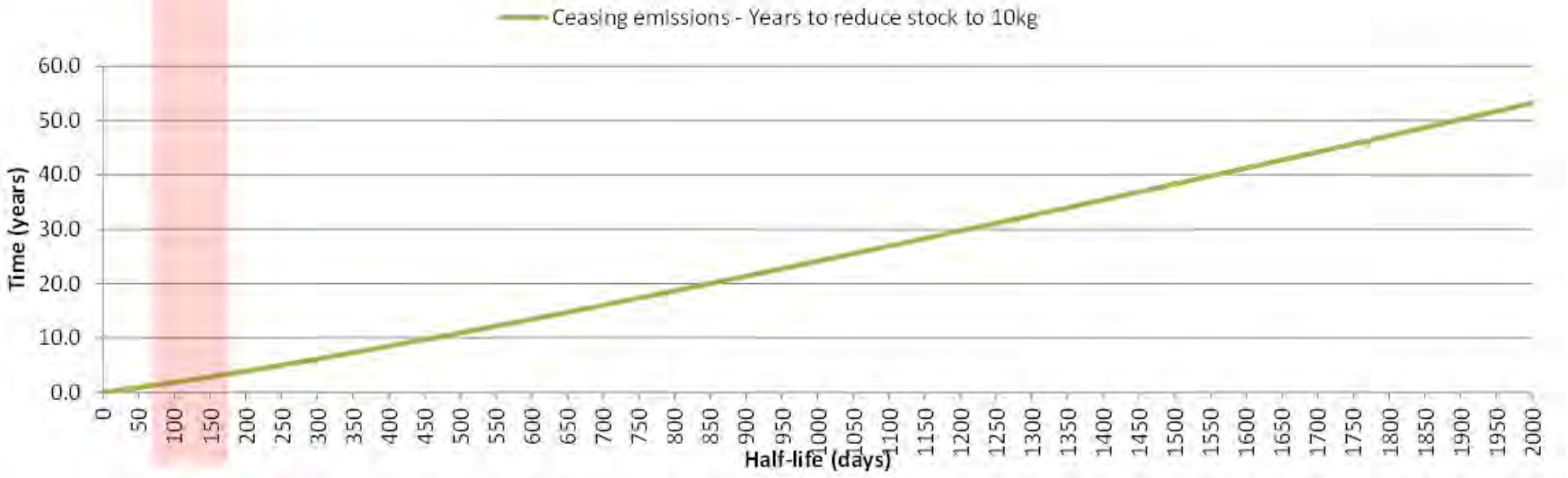
RPA
Risk & Policy Analysts

P data from eChemportal (not all PBT/vPvBs)

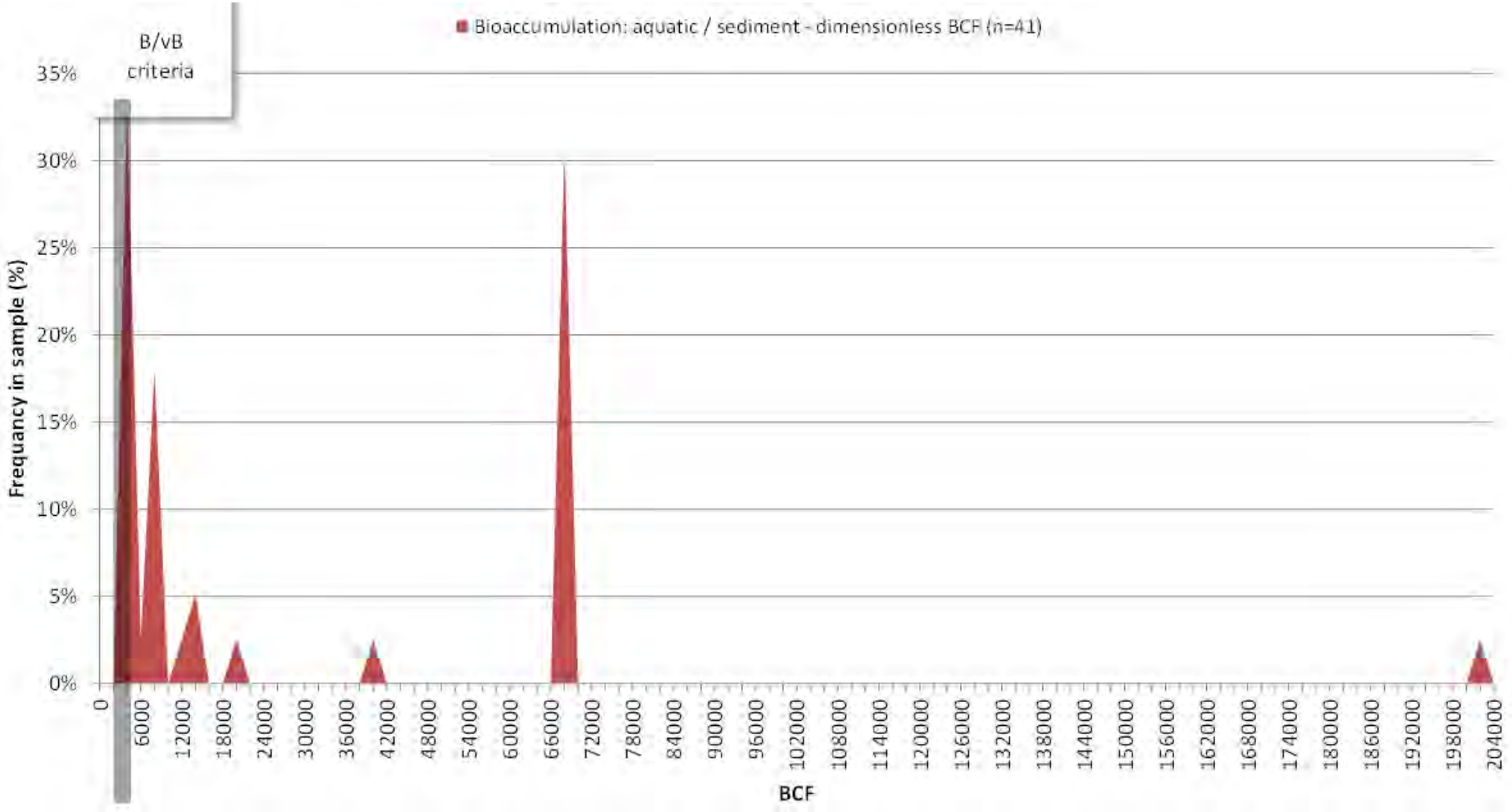


Stock levels accruing from 1,000kg/year emission





BCF data from eChemportal (not all PBT/vPvBs)



Very brief comments

- These variations should be reflected in economic analysis for PBTs (and vPvBs).

- Accounting for variations in time-paths/stocks would provide a means to achieve this (even with data availability issues).

- Furthermore, employing stock dynamics may help decision making especially when an immediate cessation of all uses may be problematic.

RPA
Risk & Policy Analysts

Switching the reference point/objective

From: low/zero emissions

To: low/near zero environmental stock

Would allow regulators to:

- plot time-pathways to the defined objective such as a low/near zero environmental stock
- predict/assess the impact of different control options on pathways (e.g. the delay in achieving the objective)
- In the light of the above –consider the relative cost-effectiveness and proportionality of the control options

RPA
Risk & Policy Analysts

Thank you

anthony.footitt@rpaltd.co.uk

Linkedin

RPA
Risk & Policy Analysts

Prepared Comments to the Background Paper and General Discussion

Kai-Volker Schubert

OECD SACAME Workshop
"Best Practices in Assessing the Social Costs of Selected Chemicals"
August 30-31, 2017
Ottawa, Canada

FluoroCouncil
Global Industry Council for FluoroTechnology

All FluoroCouncil members are signatories of the US EPA PFOA Stewardship Program and virtually eliminated PFOA, its precursors, and higher homologs globally from facility emissions and product content. FluoroCouncil is advocating and working to turn this voluntary program into responsible global regulation.

Discussion of the Background Paper and General Discussion

Objective:

- **Observations and Additions on the Paper**
- **Reflections on key gaps and opportunities for improving valuations in a regulatory context**

Discussion of the Background Paper and General Discussion

Key Finding:

- Of the socio-economic assessments (SEA) evaluated, “only few quantitative assessments of impacts and costs exist.”
- Approaches to SEA are not harmonized – often comparison of findings is not possible
- Social Costs evaluations focus on economic costs, i.e., direct costs for manufacturers or governments resulting from emission reduction efforts and switch to alternatives (“Private Costs”)
- External Costs - “non-market costs” – are not quantified but relevant endpoints are qualitatively addressed

Discussion of the Background Paper and General Discussion

Suggestions to consider when conducting future SEA:
Collect comprehensive quantitative data along the entire value chain, incl.:

1. Impact on Substance Manufacturers
2. Impact on Value Chain (incl. non-EU origin imports)
3. Impact on Consumers
4. Effectiveness of Regulatory Measure
5. Modelling Stock Pollution Effects (i.e., the time path of pollution)

to allow for quantitative Private Costs + External Costs calculation to more precisely determine the Social Costs

Opportunity:
Framework for a quantitative assessment, incl.

1. Impact on Substance Manufacturers

- Employment and Cost Aspects:
  - Detailed timeline*, resource needs*, other costs (e.g. engineering*, **) to bring alternatives to market**
  - Cost to “others” to enable salability: For example,
    - Testing to meet regulatory criteria* (animal welfare aspect)
    - Regulatory dossier preparation and review by respective competent authorities*

* One-time Cost
** Operating Cost

Opportunity:
Framework for a quantitative assessment, incl.

2. Impact on Value Chain:

- Employment and Cost Aspects:
  - Implementation of substitute in customer's process*,** and ongoing operating costs**
  - Compliance* with market specifications
    - For example, Medical Applications, Safety Applications, etc.
  - Effect of substitution on local and global competitiveness
  - Impact of "continued use" to produce imported material

* One-time Cost
** Operating Cost

Opportunity:
Framework for a quantitative assessment, incl.

3. Impact on Consumer:

- Article/product performance and durability
- Effects on pricing

4. Effectiveness of Regulatory Measure

- Ability for enforcement
  - Development, costs and implementation of sound analytical methods
  - Cost of compliance to entire value chain, incl. the enforcement agency
  - Impact of non-compliance
- Substitutes: effects on human health and the environment

Opportunity:
Framework for a quantitative assessment, incl.

5. Modelling Stock Pollution Effects

- Consider including impact of imports from non-EU REACH economies
- Consideration of long-range transport properties post “coming into force” – the “late impacts”
- Time path assessment of environmental distribution patterns
- Model “optimal period use*” – resulting in general decision rules

* See, e.g., S. Gabbert et al., J. Environ. Management 183 (2016) 236 - 244

Discussion of the Background Paper and General Discussion

Suggestions to consider when conducting future SEA:
Collect comprehensive quantitative data along the entire value chain, incl.:

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Contact

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National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Introduction into the case study of NMP

REACH restriction proposal of the Netherlands

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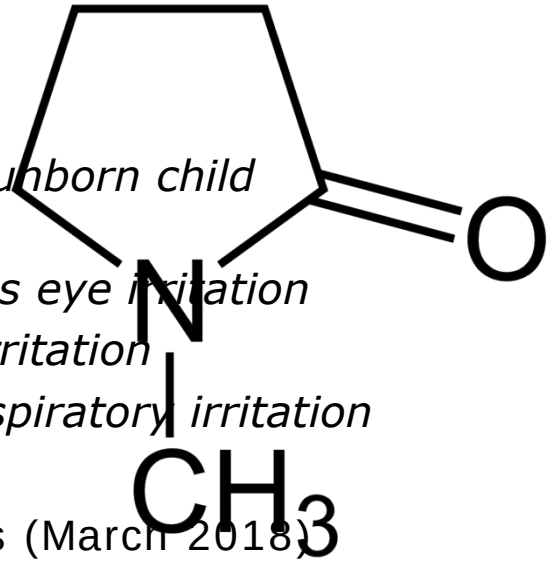
National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Contents

1. Brief introduction into N-Methylpyrrolinone (NMP)

<u>The substance</u>

- Aprotic and highly polar organic solvent
- Correct properties for cleaning or coating applications where there is a need for dissolving 'polymers' in combination of water in a wide temperature range



<u>Current classification</u>

Reprotoxic cat. 1B	*May damage unborn child*
Eye irritation cat. 2	*Causes serious eye irritation*
Skin irritation cat. 2	*Causes skin irritation*
STOT single exp. cat. 3	*May cause respiratory irritation*

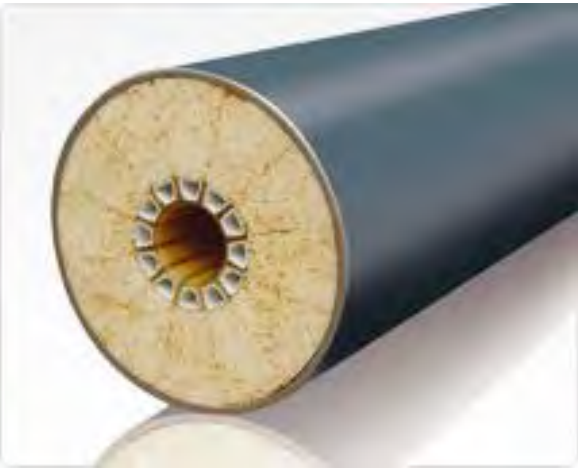
Concentration limit of 0.3% in consumer products (March 2018)

Uses of NMP

- Consumer applications phased out in Europe due to Classification
- Concerns exist for the use by workers (professional and industrial)
- Risks for all workers in general and for pregnant workers specifically
- High tonnage substance: 40,000-60,000 tons per year in Europe
- Uses are diverse, some examples

Wire-coating industry

Semiconductor industry



Membrane industry

Alternatives

- Alternatives are (technically) available for several uses for which less specific solvents are required (replacement ongoing)
  - Acetone, MEK, ethyl lactate and *DMSO* => less toxic, however, no technical alternative for all uses

- For uses where technical functionality is crucial, alternatives appear not to be available or have comparable hazard characteristics
  - NEP, DMF, DMAC, DCM and HMPA => similar functionality and toxicity

2. Regulatory measure

- REACH restriction proposal for the EU
- Restriction proposal targeted to industrial and professional use
- Various risk management options (RMOs) considered:
  - RMO1: restriction; total ban
  - RMO2: restriction; targeted ban with exemptions
  - **RMO3: restriction; mandatory exposure limit**
  - RMO4: authorisation

3. The socio-economic analysis

- Questions to be answered:
  - What impacts are expected from the various proposed regulatory measures?
  - Can the relevant impacts be quantified?
  - Can the relevant impacts be monetized?

Aim: comparison of costs and benefits of various proposed regulatory measures compared to the business as usual situation

SEA approach for the NMP restriction proposal

- Market analysis
  - Consultation of industry actors and literature/internet research
  - To get an impression of the NMP market and industry responses to the proposed measures

- Cost analysis
  - Consultation of industry actors and literature/internet research
  - To get an idea of the expected costs (compliance costs, relocation costs, losses in revenue)

- Benefit analysis
  - Risk assessment as the starting point
  - No quantitative estimate of avoided health effects possible due to limitations in data (no dose-response)
  - Qualitative description of health effect and semi-quantitative indicators

Expected impacts

- 1. **Total ban:** Uses for which alternatives are available will shift. Others will go out of business or move outside Europe
- 2. **Partial ban:** Uses for which alternatives are available will shift. Others are exempted from ban (risks remain)
- 3. **Mandatory limit value:** ...ely depends on the level at which the DNEL is set.
  - currently the advice in ... (iOEL)
  - practice varies over count... mg/m³
  - **/m³**, 20 mg/m³
  - ...n handle 10-20 ... actors for which
- 4. ...rable to manda... lar... en for both com...

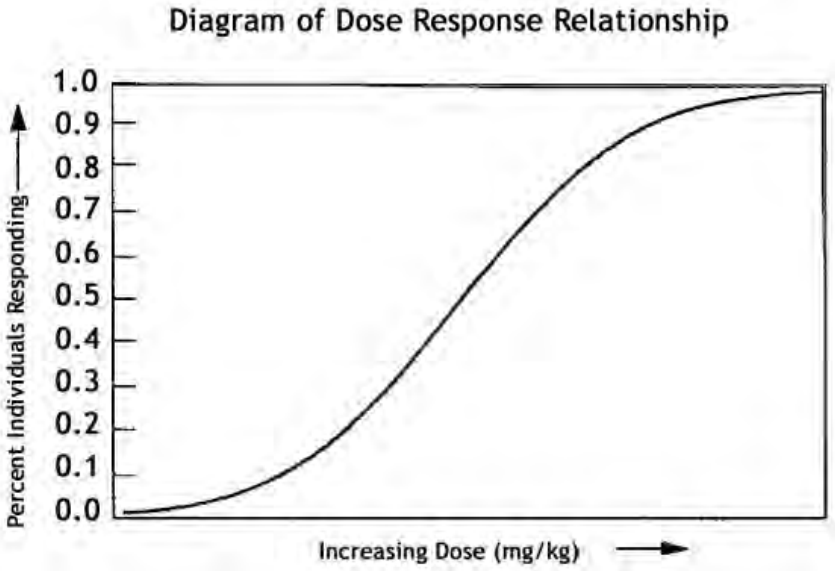
Costs and wider socio-economic effects

Industry response	Costs	Wider socio-economic effects
Substitution	- **Compliance costs** - Administrative costs	- Possible impact on production quality - Employment impact
Exposure reduction	• **Compliance costs** • Administrative costs	• Change in labor conditions
Relocation	- **Relocation costs** - Possible capital destruction	- **Change in employment** - **Transfer of value added** - Indirect impact trough economic linkage
Termination	• Possible capital destruction	• Change in employment • Transfer of value added • Indirect impact trough economic linkage

What costs and wider socio-economic effects were quantified varies per RMO (industry response) and per industrial sector

Benefits: avoided effects on human health

- Not enough information available to quantify or monetize health effects



- What has than been done?
  - Qualitative description of potential health effects
  - Indication of the expected risk reduction (changes in RCRs)
  - Quantification of the population at risk per industry sector, per type of worker (general and pregnant worker)

Benefits: avoided effects on human health

Animal effects

- Lowered maternal bodyweight
- Reduced food consumption
- Reduced fetal bodyweight
- Skeletal variations / malformations
- Increased fetal resorption

- Reduced body weight (gain)
- Reduced food consumption
- Testicular atrophy
- Thymic atrophy
- Swelling / distal kidney tubuli
- Local respiratory tract irritation

Human health effects

- IUGR
- Stillbirth

- Reduced body weight (gain)
- Reduced food consumption
- General loss of well-being
- Potential effects in organs
- Respiratory tract irritation

Example from the wire-coating industry

- This sector in particular says to have problems complying with limit values below 20 mg/m^3
  - 10-20 wire-coating SMEs in EU that each have around 100s production lines of 150,000-250,000€ each with a life time of 20-30 years
  - 50% already complies with the limit value of 10 mg/m^3 in continuous operation
  - For the other 50% of the older machines, exposure is higher
- Measure would require early replacement of machines
- Small margins and low capacity to bear further cost increase
- Number of workers in this sector: confidential business information
- What did we do? Further elaboration on the effect of an extended implementation period for this sector on the compliance costs to find acceptable timing for the sector

How to conclude?

- Quantitative comparison of costs and benefits not possible for this case
- Answer to the question whether the proposed measure is better for society as a whole not possible based on the available information
- However, what could be done:
  - Comparison of expected costs and wider socio-economic effects of the various RMO's
  - Comparison of expected risk reduction of the various RMO's
  - Discussion of the economic feasibility of the costs for various industry sectors
  - Indication of the compliance costs as part of the total production value per industry sector
  - Estimation of the cost-effectiveness (€/worker) per industry sector

4. Challenges

- Various challenges along the road
  - Number of RMO's and industry sectors result in large amount of data that needs to be processed in a logic storyline
  - Various uncertainties that could often not be quantified
  - Difficult to get grip on what will actually happen in case of proposed measures (impacts)
  - Difficult to validate received cost data
  - What to do in case of partial cost and benefit estimates?
  - How to conclude whether or not society is better of with the proposed measure?

Take home messages

- Important to get feeling with industry sector(s) in which the substance of concern is used
- Full quantification and monetization of impacts often wished for but not often received for several reasons
  - Lack in data
  - Lack in available resources and time
- Especially on the human health side, improved information availability is not to be expected
- Think about improvements of SEA, not only looking at quantification and monetization
- Broader SEA information could be relevant as well
- Key question: What information do regulators require as basis for their decision making?

Questions? Comments? Thank you for your attention!

U.S. Experience with Socio-Economic Analysis: Proposed TSCA Section 6(a) Rule

N-Methylpyrrolidone (NMP) in Paint and Coating Removal

OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management

August 31, 2017

U.S. Environmental Protection Agency

Outline

- Background on paint removers and affected industries, users
- Proposed rule options
- Contribution of economic analysis to policy formulation
  - Cost estimates
  - Unable to quantify or monetize benefits
  - Breakeven analysis based on cost of illness

Background: Paint Removers

- "Paint removers" refers to chemical methods of removing coatings (paint, varnish, lacquer) from a variety of substrates (wood, metal, masonry)
  - Does not include products designed to remove adhesives
- Chemicals typically used in formulated paint removers include: methylene chloride, NMP, benzyl alcohol, ATM, dibasic esters, and some caustic chemicals

Background: Paint Removers

User Sector	NMP Firms	NMP Direct Users
Aircraft	Found not to use NMP	n/a
Art Restoration & Conservation	40	125
Automotive	40	40
Marine craft	Found not to use NMP	n/a
Furniture Refinishing	220	660
Graffiti Removal	2,700	11,500
Professional Contractors	1,280	6,470
Bathtub Refinishing	Found not to use NMP	n/a
Consumer Users	n/a	732,000

Background: Paint Removers

- Margin of Exposure Approach
  - For non-cancer endpoints, a margin of exposure (MOE) method was used to assess risk for acute and chronic exposure scenarios.
  - The benchmark MOE used for the NMP risk assessment is 30 (based on 3x residual uncertainty in extrapolating from animals and 10x for variability in humans.)
  - EPA identified risks of concern when MOEs were below the benchmark MOE of 30.

Background: Paint Removers

- Risks to both workers and consumers from NMP
  - For pregnant workers, developmental toxicity concern based on chronic and acute exposure scenarios
  - For pregnant consumers, developmental toxicity concern based on acute exposure scenarios
- To reduce exposure below the benchmark MOE of 30, users must wear appropriate gloves and a respirator APF 10 (midpoint exposure range)
  - Scenarios at the high end of the exposure range, an MOE below 30 was not achievable in all cases

NMP Risk Estimates

Scenario (covers several industries and consumer use, assumes no gloves used)	Benchmark MOE (acute & chronic exposure)	MOE acute exposure		MOE chronic exposure, non-cancer effects	
		High End Estimate	Central Tendency	High End Estimate	Central Tendency
Miscellaneous stripping Non-consumer uses, assumed mostly indoor	30	**0.7** [a]	**12.7** [b]	**0.1** [a]	**5.4** [b]
Graffiti removal Assumed mostly outdoor but may include semi-confined spaces	30	**0.7** [a]	**14.1** [b]	**0.1** [a]	**6.1** [b]
Consumer use - Brush application	30	**15** [c]	108 [d]	**n/a**	**n/a**

Notes:

[a] High end non-consumer estimate used 1.0 weight fraction, 890 cm^2 skin surface area, 8 hours

[b] Central tendency non-consumer estimate used 0.625 weight fraction, 668 cm^2 skin surface area, 4 hours

[C] Scenario representing high end consumer exposure was brush application in a workshop with closed windows to a large table and 8 chairs, 0.5 weight fraction, 490 cm^2 skin surface area, 7 hours

[d] Scenario representing central tendency consumer exposure was brush application in a workshop with open windows to a coffee table, 0.25 Weight fraction, 490 cm^2 skin surface area, 30 minutes

Key Proposed Rule Provisions: NMP in Paint and Coating Removal (Option 1)

- Prohibit the manufacturing, processing, and distribution of NMP for paint and coating removal for consumer uses and for all commercial uses except for uses proposed to be critical for national security.
- Prohibit commercial use of NMP for paint and coating removal except for uses proposed to be critical for national security.
- Require any paint and coating removal products containing NMP for uses proposed to be critical to national security be distributed in containers with volumes no less than 5 gallons.
- Require downstream notification when distributing NMP for other uses. This could be in the form of a Safety Data Sheet.
- Require recordkeeping relevant to these prohibitions.

Key Proposed Rule Provisions: NMP in Paint and Coating Removal (Option 2)

- Require that paint and coating removal products contain no more than 35% NMP by weight in product formulations
- Require that formulators of any paint and coating removal products containing NMP test gloves for the product formulations being processed and distributed in commerce identify specialized gloves that provide protection for users and keep records relevant to these tests.
- Require that formulators of any paint and coating removal products containing NMP label products with information for consumers about the risks presented by products that contain NMP, including identifying which specialized gloves provide protection against the specific formulation
- Require that commercial users establish a worker protection program for dermal and respiratory protection, including hazard communication
- Require downstream notification when distributing NMP for other uses.
- Require recordkeeping relevant to these prohibitions.

Economic Analysis

- Identified health endpoints for NMP
  - Acute effects: fetal death
  - Chronic effects
    - Low birth weight
    - Delayed ossification
    - Growth retardation
- Unable to quantify or monetize any of the identified health endpoints
  - NMP rule has monetized cost estimates, but no monetized benefits

Economic Analysis

Regulatory Option	Discount Rate	Costs		Benefits[1]		Net Benefits	
		Scenario 1	Scenario 2	Scenario 1	Scenario 2	Scenario 1	Scenario 2
NMP Proposed Option 1: Ban of NMP	3%	$27,624,000	-$1,484,000	n/a	n/a	-$27,624,000	$1,484,000
	7%	$27,668,000	-$1,251,000	n/a	n/a	-$27,668,000	$1,251,000
NMP Proposed Option 2: PPE required	3%	$56,146,000	$47,098,000	n/a	n/a	-$56,146,000	-$47,098,000
	7%	$56,404,000	$47,274,000	n/a	n/a	-$56,404,000	-$47,274,000

[1] Due to the inability to quantify or monetize the prevention of adverse developmental impacts of NMP exposure, there are no monetized benefit estimates for NMP.

Economic Analysis

- Issue: help decision makers evaluate potential magnitude of benefits against cost estimates
- Endpoints:
  - Low birth weight
  - Fetal death
- Approach: Breakeven analysis - a type of threshold analysis that addresses how high benefits would have to be to exceed costs

Economic Analysis

- Low Birth Weight (chronic, workers only)
  - Cost of Illness
    - Based on perinatal hospitalization (maternal & infant)
    - Did not include lifetime costs of LBW (still under development)
    - Did not include WTP to reduce risk of LBW
  - Population potentially experiencing reduced risk
    - Estimate of pregnant workers (552 pregnancies)
      - Estimated number of female workers of child bearing age, CDC pregnancy rate
    - Estimate of LBW pregnancies (44 cases)
      - Percent of live births expected to be LBW
      - Unable to narrow estimate beyond “all-cause” due to the varying factors influencing the birth weight

Economic Analysis: LBW Calculations

Category	Value	Applied to	Result
Female workers	46.45%	18,957 workers	8,805
Pregnant workers	2.91%	18,957 workers	552
Live births LBW	8.02%	552 pregnancies	44
All cause low $	$14,723	44 cases	$647,812
All cause high $	$53,866	44 cases	$2,370,104

Economic Analysis

- Fetal Death (acute, workers & consumers)
  - Cost of Illness
    - Based on medical treatment costs (ranging from outpatient to inpatient treatment)
    - Did not include WTP to reduce risk of spontaneous abortions or stillbirth
  - Population potentially experiencing reduced risk
    - Estimated number of pregnant users
      - Estimated number of female users of child bearing age, CDC pregnancy rate
    - Number of these potential pregnancies which may experience fetal death
      - Percent pregnancies for both spontaneous abortions and still birth (CDC rates)
      - Narrowed estimate to “unknown” causes (removed % for genetic issues, infections, and trauma)

Economic Analysis: Fetal Death Calculations

Category	Value	Applied to	Result
Female workers	46.45%	18,957 workers	8,805
Female workers below MOE 30	30%	8,805 female workers	2,642
Spontaneous abortions - workers	11.8/1,000	2,642 female acutely exposed	31
Stillbirths - workers	6.1/1,000	2,642 female acutely exposed	16
Female consumers	20.2%	732,189 consumer users	147,922
Female consumers below MOE 30	30%	147,922 female consumers	44,377
Spontaneous abortions-consumers	11.8/1,000	44,377 female acutely exposed	524
Stillbirths - consumers	6.1/1,000	44,377 female acutely exposed	271
$ Spontaneous abort. Low	$379	555 spontaneous abortions	$210,345
$ Spontaneous abort. High	$1,373	555 spontaneous abortions	$762,015
$ Stillbirth – total	$8,399	287 stillbirths	$2,410,513

Economic Analysis

- Breakeven analysis summary
  - Only able to develop cost of illness (COI) estimates for the endpoints
  - Full benefit of WTP for risk reduction not captured by COI. No WTP studies were found for either endpoint.
  - Breakeven estimates as calculated do not exceed high-end costs for any of the options
  - Difficulty communicating results given the limitations of approach

- Thank you!
- Acknowledging Judith Brown, economist responsible for economic support for this rulemaking

- Link to docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0001
- Link to Economic Analysis: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0270

UNIVERSITY OF BATH

Economic Valuation in 1-Methyl-2-Pyrrolidone (NMP) Regulation

Alistair Hunt & Nick Dale
Ottawa, 31 August, 2017

OECD Workshop on Best Practices in Assessing the Social Costs of Selected Chemicals

Outline of Talk - NMP

- Summary of uses targeted by risk management activity
- Summary of the main endpoints of concern
- Use of assessments in informing regulatory decision-making?

- Valuation of endpoints of concern in economic assessments to date
- Data & methodological gaps in assessments;
- Key differences in endpoints & valuation methods between studies
- Scope for improving economic valuation

Summary of uses targeted by risk management activity

- N-Methyl-2-pyrrolidone (NMP) - organic solvent, colourless liquid

- Used in industrial & consumer product sectors:
  - Petrochemicals, plastics, microelectronics fabrications
  - Manufacture of compounds: pigments, cosmetics, drugs, insecticides, herbicides and fungicides.

- Used as substitute for chlorinated hydro-carbons as solvent

NMP Market Size

- Global NMP market value - > $1 billion (2015)
- Global production - > 150,000 tonnes (2014)

Geographical region	Number of production sites	Capacity (t/a) [year] (2007)
Europe	3	30.000 – 50.000
USA	3	60,000 - 80,000
Asia	4	10,000 - 20,000
Global	10	100,000 - 150,000

- Continued expected growth, from demand in Petro-chemicals, Pharmaceuticals, Electronics

NMP: Summary of the main endpoints of concern Human Health (Occupational)

Type of health effect	Potential endpoints or specific conditions
Developmental effects	Intra Uterine Growth Retardation Stillbirth Decrease in foetal body weight gain Lack of appetite
Chronic and acute health effects	General loss of well-being Potential effects on organs Respiratory tract irritation Skin & eye irritation

ECHA priorities: General worker population – repeated dose toxicity
Pregnant workers – developmental toxicity

US EPA priorities: Pregnant workers – developmental toxicity

NMP: Summary of the main endpoints of concern Environment

- US EPA: Low bio-accumulation potential & low persistence

- Environment Canada: “low risk of harm to organisms and the broader integrity of the environment…not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity…”

State of NMP Risk Management

- EU REACH:
  - Current CLP restriction – included in list of hazardous substances
  - Proposed restriction on manufacture & use – normal: <5mg/m3; peak: <10mg/m3
- US EPA: National & State level regulation
  - Proposed action to prohibit NMP in paint & coating removal manufacture, processing and distribution
- Australia: labelling requirements, and risk management assessment of exposure for workers & public (domestic products)
- Canada: concentration limits in pharmaceutical products
- Asia-Pacific: No NMP regulatory actions to date found in research.

Use of assessments in informing regulatory decision-making?

- US - direct link between findings of regulatory assessment contained in US EPA (2010) and (2017) and proposed rule:

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under Toxic Substances Control Act, Section 6(a) (US EPA, 2017).

- Given attention now given to economic assessment in REACH and monetary valuation of potential health impacts (ECHA, 2016)

→ likely that European regulations will be similarly evaluated.

Costs in NMP economic assessments to date

- EU: 2 core studies – by consultancy AMEC (2013a & 2013b) for 3 Risk Management Options: compliance cost & market assessment
  - Data limitations impact on robustness of results
    - Partial coverage of industries affected
    - Cost estimates supplied by industry difficult to corroborate
    - Reports heavily caveated as a result

- USA: 2 studies – US EPA (2017a & 2017b) for 3 RMOs: compliance cost analysis
    - Compiled by EPA, independent of industry
    - Bottom up, using average sectoral wage rates, market price data, etc.

Valuation of endpoints of concern in economic assessments to date

- Quantification limited by lack of established dose-response relationships linking NMP exposure to health end-points
- Suspected links:

Type of health effect	Potential endpoints or specific conditions
Developmental effects	Intra Uterine Growth Retardation (IUGR) Stillbirth Decrease in body weight
Chronic and acute health effects:	Decrease in body weight gain Lack of appetite General loss of well-being Potential effects on organs Respiratory tract irritation

Valuation of endpoints of concern

- US EPA
  - Break-even analysis – how many avoided cases of health impacts necessary to result in net benefit? Are these numbers plausible?
  - Health impacts considered: low birth weight; pregnancy loss
  - Cost side also includes cancer risks possible where regulation leads to substitution of NMP for Methylene Chloride in paint remover products
  - Other health impacts from Methylene Chloride excluded: hepatic effects; neurological impairment, immune effects; kidney effects, and; gastrointestinal irritation
  - <u>Conclusions from US EPA studies</u>:
    - Net benefits unlikely under realistic scenarios for the two health impacts
    - Limited health impact coverage suggests under-estimation of true benefits

Valuation of endpoints of concern: Low Birth Weight & Pregnancy loss

Health end-point	Valuation per case (2014)	Derivation
Low birth weight risk	USD 55,000	Schmitt et al. (2006): Hospital treatment costs (Infant & Mother) for infants born < 2,500g
Pregnancy loss	Spontaneous abortion USD 379 - 1,373	Rausch et al (2012); Gold et al. (2013) Surgical and medical treatment costs
	Stillbirth USD 8,399	

Notes:

1. LBW costs exclude possible lifetime costs, including special education, lost parent productivity, lost earnings

2. LBW & pregnancy loss costs exclude disutility costs

3. Alternative measures for pregnancy loss: COI - fertility treatment costs (USD 4,124 - 38,015 (Katz et al. 2011))
   VSL
   Cost/QALY → Cost-effectiveness analysis

Valuation of endpoints of concern

- Cancer unit valuation (for Methylene Chloride)

Health end-point	Valuation per case	Derivation
Liver/Lung cancer - fatal	US$ 9.77 million	WTP derived from Weibull-mean of sample of VSL estimates from wage-risk and contingent valuation studies made in 1974-1991, in US EPA (2010)
Liver/Lung cancer – non-fatal	US$ 830,000 US$ 5.8 million	WTP derived from Viscusi et al. (1991) – to avoid chronic bronchitis (median value used) WTP derived from Magat et al. (1996) – to avoid non-fatal lymphoma
Benign Mammary gland tumors	US$ 2,200	COI derived from estimates of a) treatment costs for alternative tumor scenarios, and; b) opportunity costs, weighted for different activities (work & non-work)

- Unit valuation derived by weighting incidence of fatal & non-fatal cancers, and discounting over 15 years

NMP: Data & methodological gaps in assessments

US experience

- Limited treatment of uncertainties
  - Transfers of unit values from:
    - One health end-point to another
    - One study context to another
    - One time period to another
- Incomplete coverage of treatment and opportunity costs & disutility value components
- Reliance on older studies - methodologically dated?

Scope for improving economic valuation I

- Low birth weight
  - Transfer existing data: Ščasný and Zvěřinová (2014) → ECHA (2016) Eur 126,100

- Stillbirth
  - Transfer evidence of parents' valuation of their children's lives (see e.g. OECD, 2010)

Scope for improving economic valuation II

- Cancer (fatal)
  - Up-date VSL meta-analyses for:

a) more recent VSL studies (and re-weight towards those with sound methodologies?)

b) Recognition of cancer premia (if exist for specific context/type of cancer)

Note: recent EPA guidance recognises these limitations

  - Undertake primary valuation work on specific types of cancer – liver & lung

Scope for improving economic valuation III

- Cancer (non-fatal)
  - Undertake up-date of Magat et. al. lymphoma study – ensure COI components fully incorporated in survey design
  - Value specific cancer types using a value of a statistical case (VSCC) metric (see e.g. Adamowicz, 2011; Alberini & Scasny, 2014)

Conclusions/discussion points

- Need for investment in epidemiological studies
- Break-even analysis approach useful in absence of established epidemiological evidence; needs to be extended to all relevant end-points
- Given the potential importance of fertility/developmental impacts of NMP, primary valuation studies required – particularly in N. America & Asia, reflecting production locations

Environment Center
Charles University
in Prague

Economic Valuation in 1-Methyl-2-pyrrolidone (NMP) Regulation: Comments

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SECAME Workshop, Ottawa, Canada, 30-31 August 2017

A summary

Health risks

- skin, eye, and possibly respiratory irritation
- repro-toxic category 1B> reduced foetal body weight, foetal resorption
- But „…**no** quantitative relationship [ERFs] could be derived b/w human health impacts effects and exposure“. (ECHA 2014, cited in Para 18)

Environmental effects

- Risks are **low**, to have **low** bioaccumulation potential, **low** persistence → **low** acute and chronic toxicity to aquatic organisms and birds

Subject to regulation

- in the EU, USA, CAN, AUT, but <u>not</u> in Asian Pacific, esp. in China

Review

- Costs: two studies – the assessment of **REACH** (ECHA 2014; AMEC 2013) and **US's TSCA S6** (USEPA 2017a; 2017b; 2017c)
- Benefits: **no** study, but US EPA (2017) – with absence of DRFs – covers valuation of **LBW** and **pregnancy loss**

EU's REACH vs. US' **TSCA**

Assessment (AMEC 2013): termination of operations, employee exposure, relocation & transfer of VA from EU, losses of jobs

Quantification (AMEC 2013): 15-year PV for compliance costs + losses in turnover

- €24-38 **bln** (RMO1 all uses) vs. €23-58 **mil** (RMO2 prof uses);
- €24-37 **bln** (RMO3 10 mg) vs. €96-180 **mil** (RMO3 20 mg)
- total ban >€25-50 mil, RMO3b (DNEL 20 mg) €0-150 mil (ECHA 2014)

No benefits due to insufficient data.

Assessment by USEPA (2017) covers i) costs of product reformulation, and ii) cost of users for switching to alternatives, both as incremental over 20 years

- Annualised costs m$2.8-51 at **3%** and m$51.1- at **7%** for the first option *(firms?)* and m$114.2-124.8 at **3%** and 114.7-125.4 at **7%** *(users?)*

Benefits not available due to no DRFs, but benefits due to avoided cases of **LBW** and **pregnancy loss** quantified based on **COI** (<$2 mil), with **disutility (WTP)** neglected.

However, **increased cancer risks** due to risky substitutes used of $0.01 up to $0.112 mil

Uncertainty> **non-fatal liver and lung cancers** based on WTP of avoiding CB

EU's REACH vs. US' **TSCA**

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Why the compliance costs (by AMES 2013) are smaller for lower concentrations (see RMO3 with 10 mg vs. 20 mg per m3, also at page 14)? Are some costs really in billions and other in millions?

No benefits due to insufficient data.

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Why the costs are **higher** for **larger discounts** (compare

Benefits not available due to no DRFs, but benefits due to avoided cases of **LBW** and **pregnancy loss** quantified based on **COI** (<$2 mil), with **disutility (WTP)** neglected.

However, **increased cancer risks** due to risky substitutes used of $0.01 up to $0.112 mil

Uncertainty> **non-fatal liver and lung cancers** based on WTP of avoiding CB

Benefit estimation: Low Birth Weight

- Nastis and Crocker (2007): 6:1 ration derived from a production function
- Ščasný and Zvěřinová (2014): value of a statistical case of VLBW for the EU of €126,200 *(a study commissioned for ECHA)*

Very Low and Low Birth Weight

Very low birth weight (ECHA 2014, HCAN 2016)

- lower prevalence (**1.5%** children born)
- **better evidence** about health and developmental difficulties

Low birth weight (HCAN 2016)

- high prevalence (**one-in-fifteen** babies born)
- **smaller differences** between LBW and normal birth weight infants in terms of health and developmental difficulties

	Neurosensory problems	Behavioural and social competence problems	Intellectual and learning disabilities
Description	◦ Chronic disability that restrict children's daily life caused by: ◦ Cerebral palsy (motor conditions that cause physical disability) ◦ Hydrocephalus (fluid collecting in the brain), blindness or deafness, and epilepsy	◦ behavioural problems ◦ hyperactivity and attentional weaknesses ◦ disruptive behaviour ◦ impulsivity	◦ Subnormal intelligence (IQ less than 70) ◦ Poorer language abilities, memory, motor coordination ◦ Learning problems
Share of children that have these health problems	◦ 7 % for low birth weight ◦ Less than 1 % for normal birth weight	◦ 12 % for low birth weight ◦ 7 % for normal weight	Subnormal intelligence (IQ less than 70) ◦ 4% for low birth weight ◦ 2% for normal birth weight School problems ◦ 24% for low birth weight ◦ 14% for normal birth weight
Treatment	◦ is not curable - only improvement ◦ rehabilitation (physical therapy, remediation of impairments and disabilities, medicines, orthopedic surgery, pain management)	◦ is not curable - only improvement ◦ medication, diet, psychotherapy, education or training to reduce negative impacts on life	◦ special education assistance and help
Quality of life impact	◦ more impaired self-reported health and functional status ◦ usage of more medications, feeding tubes ◦ respiratory problems, disorder of movement and motor function ◦ need of assistance	◦ social problems, difficulty organizing tasks and activities ◦ special educational needs ◦ reduction to vocational achievement	◦ Impairments in life skills (communication, self-care, home living, social skills) ◦ school problems (grade repetition or placement in special education programs)

VLBW & LBW: The Good We Are Valuing

- we do not value specific problem (such as IQ), but VLBW (or LBW) as an **'umbrella' outcome** → W*TP for* ***reducing the probability of your child having a very low birth weight***

- problems related to VLBW **described in detail** (description, share of children, treatment, quality of life impact)
  - ➢ neurosensory problems
  - ➢ behavioral and social competence problems
  - ➢ intellectual and learning disabilities

  and are **ranked** wrt their severity as perceived by a respondent

- preferences elicited again for both **private good** and **public good**

Very low birth weight: Valuation scenario

- About **15 per 1000 children born** in Europe are born with a very low birth weight, meaning that a child weighs less than 1,500 grams at birth.
- Very low birth weight infants experience **many more health and developmental difficulties** than infants with normal birth weight.
- vitamins with the same basic characteristics as before, but they reduce the probability of very low birth weight **by 7 per 1,000 newborn children** and therefore they also lower the probabilities of above described adverse health effects
- are **taken during pregnancy** (for 8 months) once a week
- **will not affect working performance**, in the case that the pregnant woman has a job, and so it will not have any effect on her earnings.
- have an effect only during the period of usage but **no effect on future pregnancies**
- are **not available from the National Health Service** nor would be covered by any private health insurance,
- respond **on behalf of yourself and your partner**

Benefit estimation: Low Birth Weight

- Nastis and Crocker (2007): 6:1 ration derived from a production function
- Ščasný and Zvěřinová (2014): value of a statistical case of VLBW for the EU (CZ, IT,NL,UK)
  - VSC(VLBW) private context (novel vitamins): **€126,200** *(want a child)*
  - VSC(VLBW) public good (regulation of chemicals): **€548,000** *(genpop)* **to €405,000** *(want a child)*
  - both derived from WTP for reducing probability of **very low birth weight** in CZ, IT, NL, and UK, the EU average value based on simple benefit transfer (with e[y]=0.7)
- Ščasný and Zvěřinová (2016): value of a statistical case of **VLBW** and of **LBW** for

F

	WANT A CHILD				General population	
	VLBW vitamins	**VLBW** regulation	LOW-BW vitamins	LOW-BW regulation	**VLBW** regulation	LOW-BW regulation
HCAN: Central value estimate, no Zika-effect	€ 201 858	€ 875 380	€ 136 032	€ 702 401	€ 423 547	€ 220 834
HCAN: protesters excluded	€ 238 212	€ 881 130	€ 163 305	€ 848 258	€ 455 198	€ 230 724
EU-ECHA pooled data for the 4-countries	€ 134 206	€ 402 293	*NA*	*NA*	€ 477 838	*NA*

“Private Good“ vs. “Public Good“ Scenario

“Complex of vitamins and minerals”

- private good
- only people **who intend to have a baby**
- **a new and novel complex of vitamins and minerals** would be taken by you once a week for a year while trying to conceive
- **approved** and is just on the market
- has **no side (positive or negative) effects**
- not available from the **National Health Service** nor covered by any private health insurance
- will not affect your **working abilities** and thus will not have any effect on your earnings
- will reduce the amount of money you can spend on other things
- WTP per month **over one year** (Fert, BirthDEF), over **eight months** (VLBW), as **one-time payment** (IVF)

“Chemical-free products”

- public good
- **general public**
- studies have shown that people exposed to some chemicals have lower probability of conception. Various **products**, such as clothes, textile, furniture, and electronics contain such chemicals.
- **a new, stricter regulation** that will restrict problematic chemicals in products in the EU will be introduced in order to decrease concentration of such chemicals
- **certificated chemical-free products** at the EU
- cost for the regulatory service and additional costs of companies to make product chemicals-free will lead to **higher product prices** and will reduce your spending on other things
- WTP monthly **over 10 years**

transfer)

People who want a child – private good

Health outcome	Conservative values	Sensitivity analysis
Value of a statistical pregnancy	21,600	34,700
Value of a statistical infertility (in vitro fertilisation treatment)	29,400	
Value of a statistical case of Healthy Child:		
-- MINOR birth defects	4,300	12,000
-- defects on EXTERNAL body parts	26,000	108,000
-- defects in INTERNAL organs	128,000	178,000

General population – public good

Health outcome	Conservative values	Sensitivity anal
Value of a statistical pregnancy	12,500	38,000 41,000*
Value of a statistical case of Healthy Child		
-- MINOR birth defects	51,000	42,000*
-- defects on EXTERNAL body parts	454,000	330,000*
-- defects in INTERNAL organs	771,000	712,000*

*Note: **The conservative values** are based on WTP estimates after controlling **the effect of considering other co-benefits** while stating WTP for improving health risks. * Values estimated from preferences stated for the public good improvement by **people who want a child**.*

Benefit estimation:
Health outcomes with no monetary values

Stillbirth

- No valuation → **VSL for children**. Why? Stillbirth need not mean to die prematurely
- If VSL for children is defensible, **a child premium** may be **small and may vary across illnesses** (≈30-50% for road traffic and respiratory illness, but no for cancers, for Italy and Czech Republic, see Alberini and Scasny 2011)

Body weight, loss of appetite, well-being

- no valuation → SP study needed, the conditions are familiar

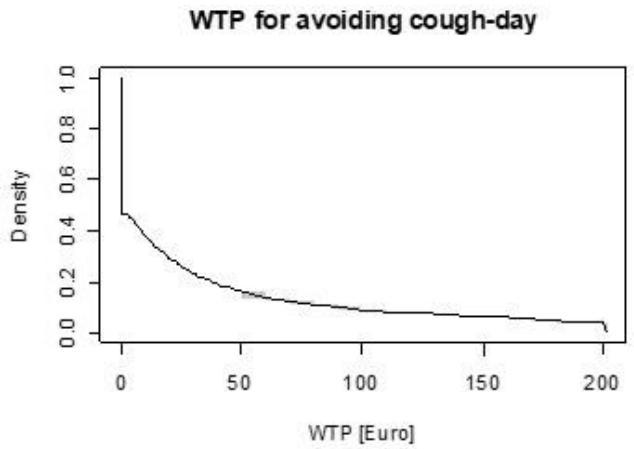
Respiratory irritation

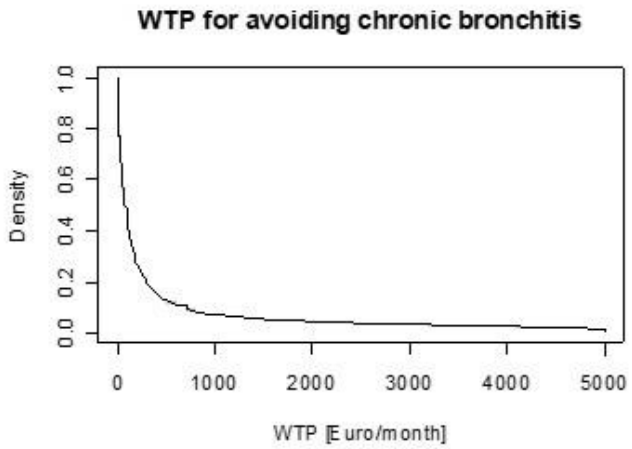
- The Report: A small body, quite outdated, studies on RAD or MRAD (Ready et al. 2004; Johnson et al. 2000; Berger et al. 1987)
- **HEIMTSA SP survey** in six European countries by Maca et al. (2010; 2012) elicited WTP for avoiding **a day with cough** (MRAD), **chronic bronchitis**, and mild and severe **chronic obstructive pulmonary disease** (COPD), and **asthma attack**
- Grey (not published) literature (for instance, WTP for **eye irritation**, **cough**, **HA**, staying at bed,.. – similar as in Ready et al. – for the Czech Republic)

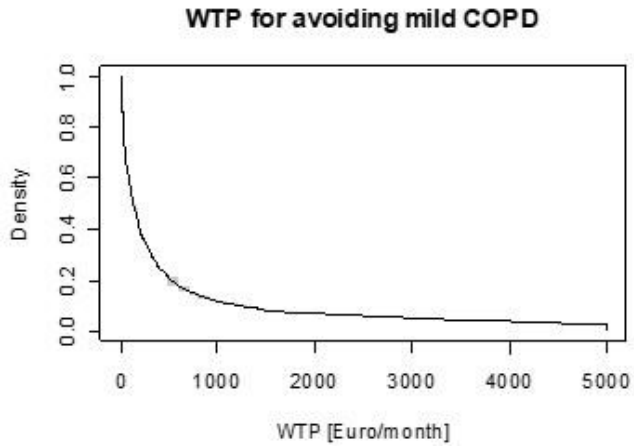
HEIMTSA valuation study on respiratory illness

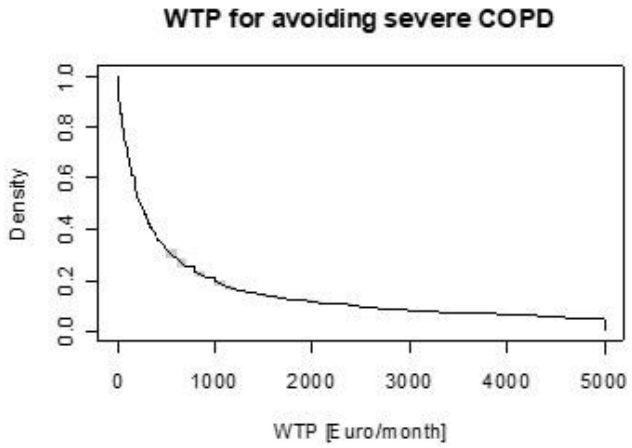
(Máca, Ščasný, Hunt, Navrud, Payre 2010)

Kaplan-Meier survivor functions for WTP to avoid individual endpoints









HEIMTSA valuation study (Maca et al. 2010)

Non-parametric estimates (Kaplan-Meier survivor functions for WTP)

			Czech	German	English	French	Greek	Norwegian
Cough day	*€ per case*	mean	15	30	12	35	39	28
		median	0	0	0	15	13	0
		99% C.I. (mean)	13; 16.75	25.73; 33.59	10.24; 14.55	31.64; 37.68	34.97; 43.11	25.08; 31.74
Chronic bronchitis	*€ per month*	mean	183	276	281	248	606	387
		median	50	60	49	70	150	120
		99% C.I. (mean)	162.1; 222.7	241.5; 323.5	236.5; 342.3	202.9; 283.9	526.3; 672.2	348.2; 453.7
Mild COPD	*€ per month*	mean	293	391	441	354	818	679
		median	90	110	70	120	250	270
		99% C.I. (mean)	253.4; 331.3	328.7; 443.9	359.4; 510.5	292.4; 396	742.3; 891.8	611.8; 742.1
Severe COPD	*€ per month*	mean	459	570	731	530	1312	959
		median	150	190	180	160	500	490
		99% C.I. (mean)	405.2; 511.9	502.9; 630.8	651; 793.1	456.1; 595.7	1195; 1373	855.4; 1067.8
Asthma medication discomfort	*€ per case*	mean	48.7	48.4	27.7	50.3	78.9	76.7
		median	21	15	0	29	60	40
		99% C.I. (mean)	37.46; 60.23	28.91; 66.46	20.5; 36.01	34.92; 65.15	61.34; 102.88	60.82; 90.3

HEIMTSA valuation study (Maca et al. 2010)

Non-parametric estimates (up) and parametric models (down), interval data

Endpoint		mean	99% C.I. (mean)	Median
Cough day	*€ per case*	25.6	23.8; 26.5	0
Chronic bronchitis	*€ per month*	318	304; 339	70
Mild COPD	*€ per month*	480	459; 505	140
Severe COPD	*€ per month*	734	698; 767	230
Asthma medication discomfort	*€ per case*	53.1	48.59; 59.34	19

Endpoint		Model 1				Model 2				Turnbull non-parametric
		full		simple		Full		simple		
		Mean	Std.Dev.	Mean	Std.Dev.	Mean	Std.Dev.	Mean	Std.Dev.	Mean
Cough day	€ per case	53	60	53	60	36	50	35	48	26
Chronic bronchitis	€ per month	322	839	334	867	305	742	312	754	318
Mild COPD	€ per month	481	1005	499	1041	464	919	476	938	480
Severe COPD	€ per month	553	875	552	883	544	838	537	833	734
Asthma discomfort	€ per case	97	87	92	81	66	57	61	52	53

HEIMTSA valuation study on respiratory illness

(Máca, Ščasný, Hunt, Navrud, Payre)

Kaplan-Meier survivor functions for WTP to avoid individual endpoints

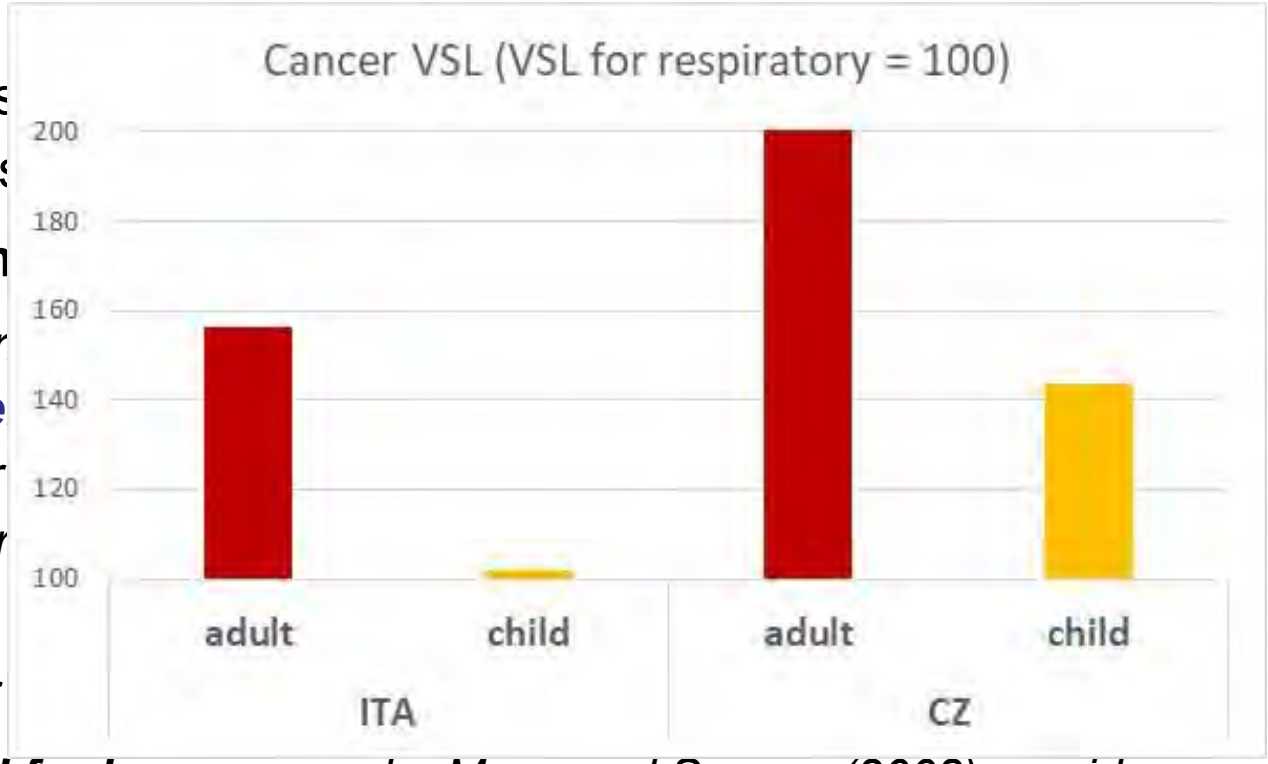
		Two-part model (interval data)	Non-parametric (interval data)	Two-part model (opened ended)
Cough day	€ per case	**36**	**26**	**30**
Chronic bronchitis	€ per month	**305**	**318**	**178**
Mild COPD	€ per month	**464**	**480**	**284**
Severe COPD	€ per month	**544**	**734**	**443**

Chained approach: CV → Standard Gamble *(interval data)*

- WTP(mild COPD) = **748 €** (conventional=CB)
- WTP(severe COPD) = **1,155 €** (conventional=mild COPD)
- WTP(severe COPD) = **1,800 €** (conv.1=CB, conv.2=mild COPD)

Dis-benefits (due to using substitutes) Fatal liver and lung cancer

- A small range of s
  and contexts, no s
- **Cancer premium**
  - *Cancer premiur*
    *vary **across be***
    vs. small-no for
    even after contr
    (AA+MS 2013)
- Similar with other
  - *a review of **COI for lung cancer** by Maca and Scasny (2008) provides a range between €5-7,000 (Abal Acra et al 2006 for ES; Maca & Scasny for CZ) and €22-28,000 (Dedes et al 2004 for CH; Vergnenegre et al 2004 for FR)*



Dis-benefits (due to using substitutes) Fatal liver and lung cancer

- A small range of studies to value lung cancer, using various methods and contexts, no study on liver
- **Cancer premium**: 50% (US EPA 2010) to 0% (OECD meta-review)
  - *Cancer premium wrt VSL for road accident or for respiratory illness may vary **across beneficiaries** **and across** **causes of death** (large for adults vs. small-no for children, see, AA+MS 2011); the premium may still exist even after controlling for **risk perception, personal exposure, or dread** (AA+MS 2013)*
- Similar with other background Papers → **adding COI** to **WTP**
  - *a review of **COI for lung cancer** by Maca and Scasny (2008) provides a range between €5-7,000 (Abal Acra et al 2006 for ES; Maca & Scasny for CZ) and €22-28,000 (Dedes et al 2004 for CH; Vergnenegre et al 2004 for FR)*

Review of COI studies on lung cancer: medical treatment costs

Author	country	approach	viewpoint	discounting	Medical treatment cosi in national currencies					€2005 in exchange rate	
					Currency	lung cancer	NSLC	SCLC	%NSCLC	lung cancer	NSLC/SCLC
Koopmanschap (1994)	Netherlands	incidence prevalence	not specified	no	NLG 1988	10,126			n.a.	6,846	
Evans et al. (1995)	Canada	incidence	GOV	no	CAD 1988	21,003	19,782	25,988	90%*	20,907	20,309
Berthelot et al. (2000)	Canada	incidence	GOV	no	CAD 1995		24,828	41,178	90%*		21,434
Wolstenholme Whynes (1999)	UK	incidence	Hospital	yes (6%)	GBP 1993		6,150	5,668	90%		12,179
Weissflog et al. (2001)	Germany	prevalence	Sickness fund	no	DM 1996	32,415			n.a.	18,703	
Serup-Hansen et al. (2003)	Denmark	incidence	?	yes (3%)	DKK 2002	143 685			n.a.	20,173	
Braud et al. (2003)	France	incidence	Hospital	no	Euro 2001	12,518	13,969	7,369	90%*	13,637	14,499
Chouaid et al. (2004)	France	incidence	Healthcare payment	no	USD 1999		24,242	26,009	79%		23,189
Vergnenegre et al. (2004)	France	incidence	Healthcare payment	no	Euro 1999		24,984	24,759	90%*		28,431
Dedes et al. (2004)	Switzerland		Health service expenses	?	Euro 1999		19,212	20,992	89%		22,105
Abal Arca et al. (2006)	Spain	incidence	?	?	Euro 2003	4,643	5,070	3,692	74%	4,835	4,906
our study (2008)	Czech Republic	incidence	GOV	yes (1%)	CZK 2007	176,600			n.a.	6,221	

Source: Ščasný, Máca, Melichar, 2008 (EU funded DROPS project)

Review of COI studies on lung cancer: medical costs plus loss of productivity

Author	country	approach	discounting	€2005 by exchange rate		
				medical treatment	loss of productivity	total
Weissflog et al. (2001)	Germany	prevalence	no	18,703	151,327	170,031
Serup-Hansen et al. (2003)	Denmark	incidence	yes (3%)	20,173	35,608	55,781
our study (2008)	Czech R	incidence	yes (3%)	6,221	33,746	39,967
our study (2008)	Czech R	incidence	yes (1%)	6,221	38,043	44,264
our study (2008)	Czech R	incidence	no	6,221	40,580	46,800

Source: Ščasný, Máca, Melichar, 2008 (EU funded DROPS project)

Economic Valuation of 1-Methyl-2-pyrrolidone (NMP) Regulation

Roy Brouwer

Department of Economics, University of Waterloo

General comments

- Cost assessment because lack of human health dose-response relationships
- Low environmental hazard profile in OECD's Screening Information Datase (SIDS) Initial Assessment Profile
- No benefits assessment although US EPA uses cancer unit values for avoided damage costs of substitutes
- No economic valuation studies related to NMP (Sørensen et al. 2016)
- US EPA study furthermore focuses on production and use in paint and coating removal while list of industrial and consumer uses and applications is much wider (completeness/representativeness?)

Appeal

- Identification of ***Risk Management Options***

(sensitivity analysis, addressing the uncertainties involved)

Remarkable

- Disagreement about threshold values? UK limits 2x lower than ECHA restriction (5-10 mg/m^3 during normal operating conditions and 10-20 mg/m^3 during peak exposure)
- Enormous range of cost estimates (23 Million – 38 Billion euros)
- Higher end costs don't make sense (even if PV over 15 years): global NMP market value (2015) was U$ 1.07 billion
- Part of the large costs is found in relocation and termination "threat" from industry (cost estimates in AMEC (2013) study largely based on interviews)
- Loss of jobs described only qualitatively

Database cost indicators

- **<u>Structured Excel data base</u>**:
  - Bibliographic study details
  - Country and study year
  - D4/D5, dBDE, HBCDD, HCB/HCH, PCB, PFOA,PFOS
  - Application substance
  - Measure (substitution, emission control, remediation)
  - Costs (PPP adjusted 2014 €)
  - Emission reduction (tons)
  - ***Cost-effectiveness indicator***

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Environmental Policy & Regulation

Towards a Proportionality Assessment of Risk Reduction Measures Aimed at Restricting the Use of Persistent and Bioaccumulative Substances

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ABSTRACT

International chemicals legislation aims at adequately controlling persistent organic pollutants (POPs) and substances of very high concern (SVHCs), such as persistent, bioaccumulative, and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, with a view to progressively substitute these substances with suitable less-hazardous alternatives. Using cost-effectiveness analysis (CEA) to assess the (dis)proportionality of measures to control such substances (collectively called "PBT" in the present paper) requires benchmarks. The present paper provides building blocks for possible benchmarks by looking at the cost-effectiveness estimates for regulatory measures that have been applied or considered for various PBT substances. These cost-effectiveness estimates vary widely, and the main factors possibly explaining this variation are discussed. The available cost estimates currently do not allow deriving a value for society's willingness to pay to reduce PBT presence, use, and emissions because decisions referring explicitly to these estimates are scarce. Roughly speaking, the available evidence suggests that measures costing less than €1000 per kilogram PBT use or emission reduction will usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely. More research is needed to strengthen the evidence base and further elaborate a systematic approach toward proportionality benchmarking. *Integr Environ Assess Manag* 2017;00:000–000. © 2017 The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals, Inc. on behalf of Society of Environmental Toxicology & Chemistry (SETAC)

Keywords: PBT and vPvB substances POPs REACH Proportionality assessment

INTRODUCTION

International chemicals legislation aims at adequately controlling persistent organic pollutants (POPs) under the Stockholm Convention (2001) and substances of very high concern (SVHCs), such as persistent, bioaccumulative, and toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances, under the European Union's Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH; EU 2006). Substances are designated as PBT when they meet the criteria for persistence, bioaccumulation, and toxicity as laid down in the REACH regulation (Annex XIII). One of the persistence criteria is evidence that the half-life of the substance in freshwater is greater than 40 d. An overview of the criteria in the REACH regulation and the Stockholm Convention is provided in Rorije et al. (2011). Persistence and bioaccumulation are not inherent properties of a substance and may vary considerably. Both characteristics are more extensively discussed in Boethling et al. (2009) and Arnot and Gobas (2006). When a substance meets the criteria, this may lead to the substance being put on the list of PBTs, and protective measures have to be taken independently of its specific persistence and bioaccumulation characteristics (see, for instance, article 3 of the Stockholm Convention, 2001).

As with other SVHCs, restriction proposals and authorization applications for PBT and vPvB substances ("PBTs" hereafter) and proposals to phase out POPs have to be assessed in terms of their proportionality, that is, how the proposed measures compare to the expected environmental and human health risks and reductions thereof (see REACH regulation (EU 2006), articles 60(4) and 69(6b) and Annex XVI; Stockholm Convention (2001) Annex F). There is no clear-cut

This article includes online-only Supplemental Data.

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Screenshot database

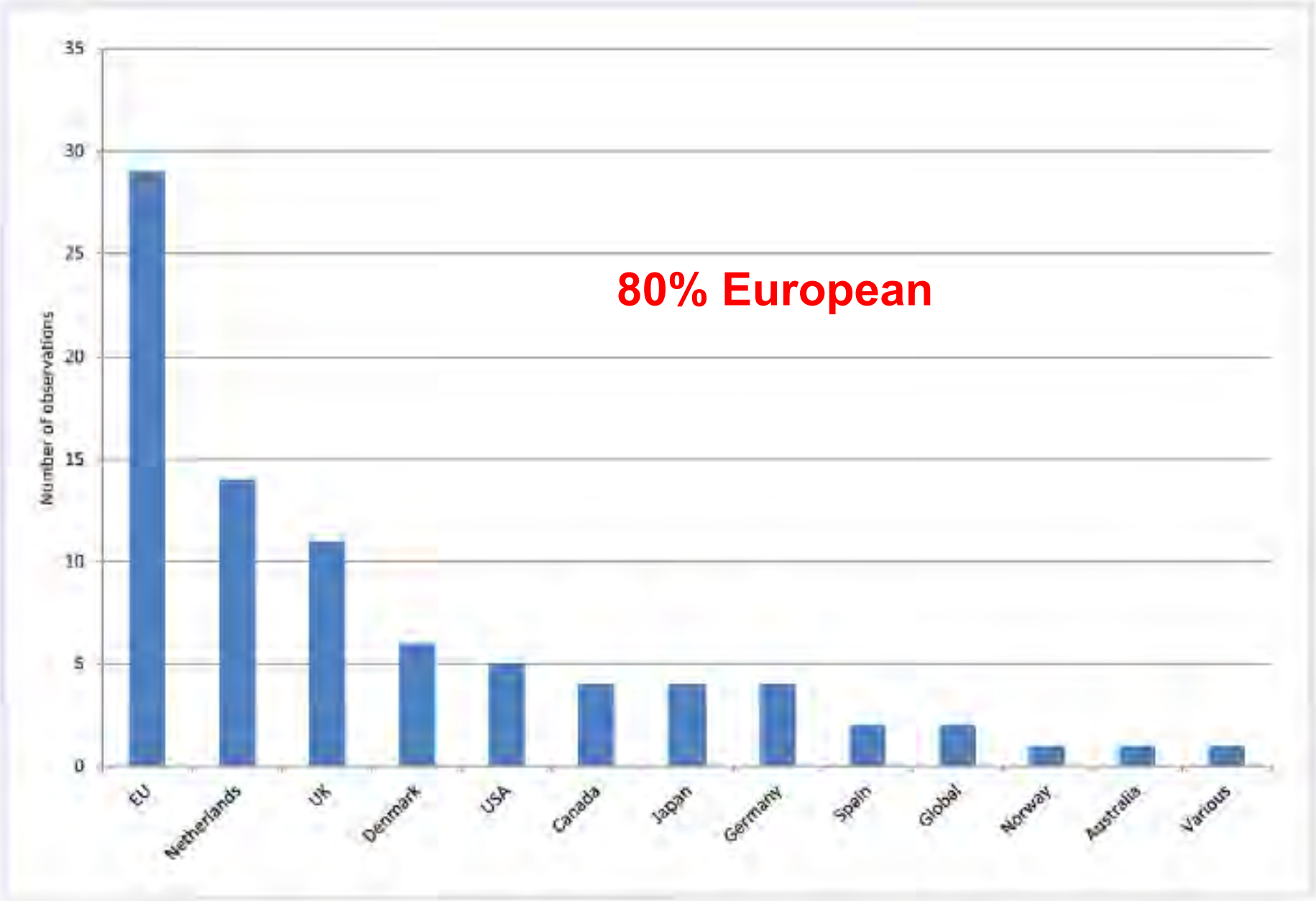
Study number	Obs. number	Bibliographic details	Substance	Application	Measure	Study country	Study year	Total annual costs	Currency	Cost type	Tons of substance substituted /prevented /avoided /removed	Cost-effectiveness indicator (cost/kg)	Price level 2014 (own currency)	Euros 2014	PPP adjusted 2014 Euros
dBDE-1	1	ECHA (2014)	deca-BDE	textiles and plastics	substitution by EBP	EU	2014	2,200,000	EUR	cost of substitution (price difference)		EUR 0.50 per kg deca-BDE	0.5	0.5	0.4
dBDE-1	2	ECHA (2014)	deca-BDE	textiles indoor	substitution by EBP	EU	2014	1,086,800	EUR	cost of avoided emission	1.44	EUR 756 per kg deca-BDE	754.7	754.7	535.8
dBDE-1	3	ECHA (2014)	deca-BDE	textiles outdoor	substitution by EBP	EU	2014	57,200	EUR	cost of avoided emission	1.9	EUR 30 per kg deca-BDE	30.1	30.1	21.4
dBDE-1	4	ECHA (2014)	deca-BDE	plastics indoor	substitution by EBP	EU	2014	1,054,944	EUR	cost of avoided emission	1.37	EUR 773 per kg deca-BDE	770.0	770.0	546.7
dBDE-1	5	ECHA (2014)	deca-BDE	plastics outdoor	substitution by EBP	EU	2014	1,056	EUR	cost of avoided emission	0.04	EUR 30 per kg deca-BDE	26.4	26.4	18.7
dBDE-1	6	ECHA (2014)	deca-BDE	textiles and plastics	substitution by EBP	EU	2014	2,200,000	EUR	cost of avoided emission	4.74	EUR 464 per kg deca-BDE (range: EUR 125 to EUR 4000 per kg)	464.1	464.1	329.5
dBDE-2	1	Environment Agency (2011)	deca-BDE	textiles	substitution by phosphorus fire retardant	UK (analysis applies to EU)	2011	7,248,000	GBP	cost of avoided emission	50.2	GBP 144 per kg deca-BDE	152.9	189.6	132.7
dBDE-2	2	Environment Agency (2011)	deca-BDE	plastics	thermal oxidation of emissions to air	UK (analysis applies to EU)	2011	1,817,000	GBP	cost of avoided emission	0.08	GBP 22,659 per kg deca-BDE	24052.5	29830.0	20881.0
dBDE-2	3	Environment Agency (2011)	deca-BDE	plastics (HIPS)	replacement with other BFRs to fire safety standard UK 94 V-1	UK (analysis applies to EU)	2011	2,417,000	GBP	cost of avoided emission	0.08	GBP 30,887 per kg deca-BDE	31995.0	39680.2	27776.2
dBDE-2	4	Environment Agency (2011)	deca-BDE	plastics (HIPS)	replacement with other BFRs to fire safety standard UK 94 V-0	UK (analysis applies to EU)	2011	5,639,000	GBP	cost of avoided emission	0.08	GBP 72,071 per kg deca-BDE	74646.3	92576.3	64803.4
dBDE-2	5	Environment Agency (2011)	deca-BDE	plastics (HIPS)	replacement with halogen-free flame retardant	UK (analysis applies to EU)	2011	15,306,000	GBP	cost of avoided emission	0.08	GBP 195,620 per kg deca-BDE	202613.2	251280.9	175896.6

Observations per substance

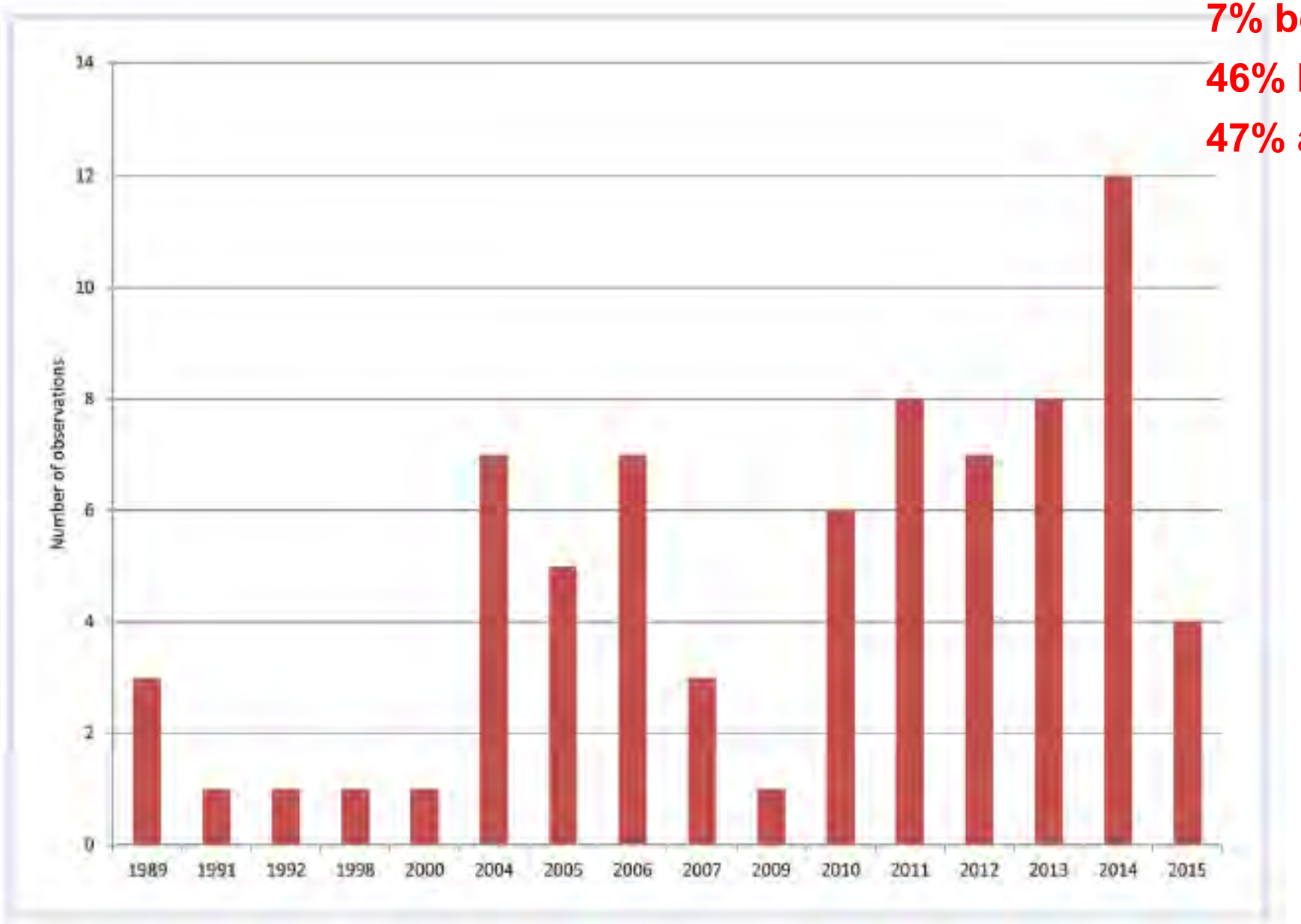
- D4/D5 3 studies, 9 observations
- HCB/HCB 4 studies, 10 observations
- PFOA 3 studies, 4 observations
- dBDE 5 studies, 14 observations
- HBCDD 6 studies, 14 observations
- PCBs 7 studies, 10 observations
- PFOS 8 studies, 23 observations

>> 36 studies, 84 observations

Origin and timing of studies



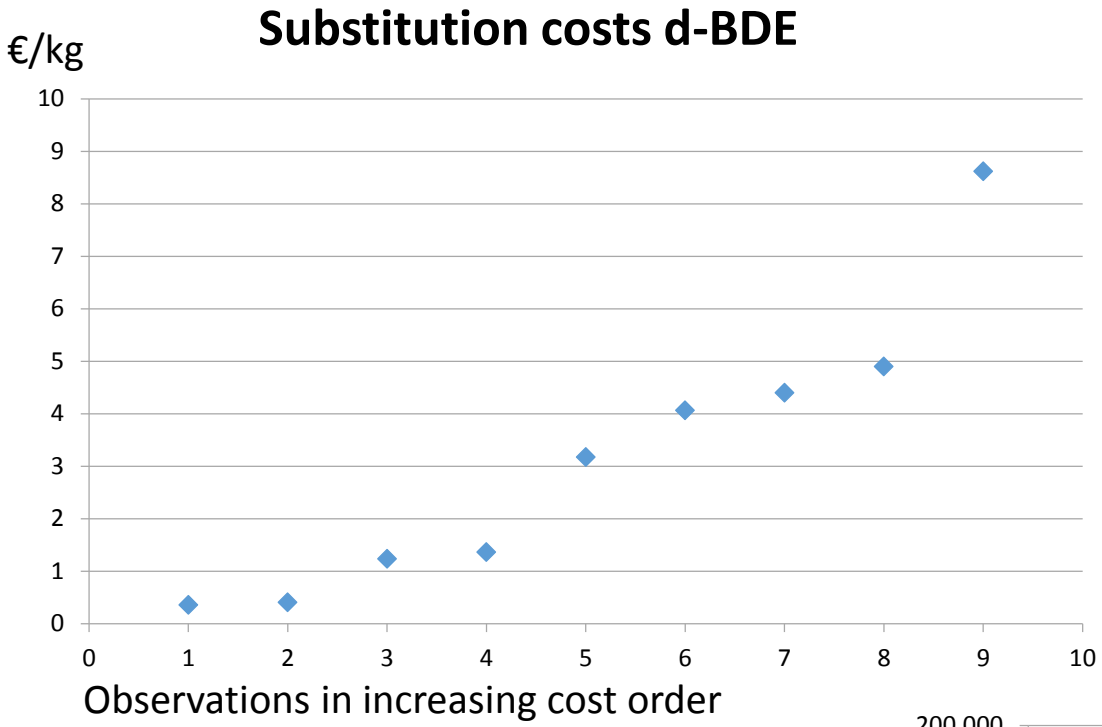
Origin and timing of studies



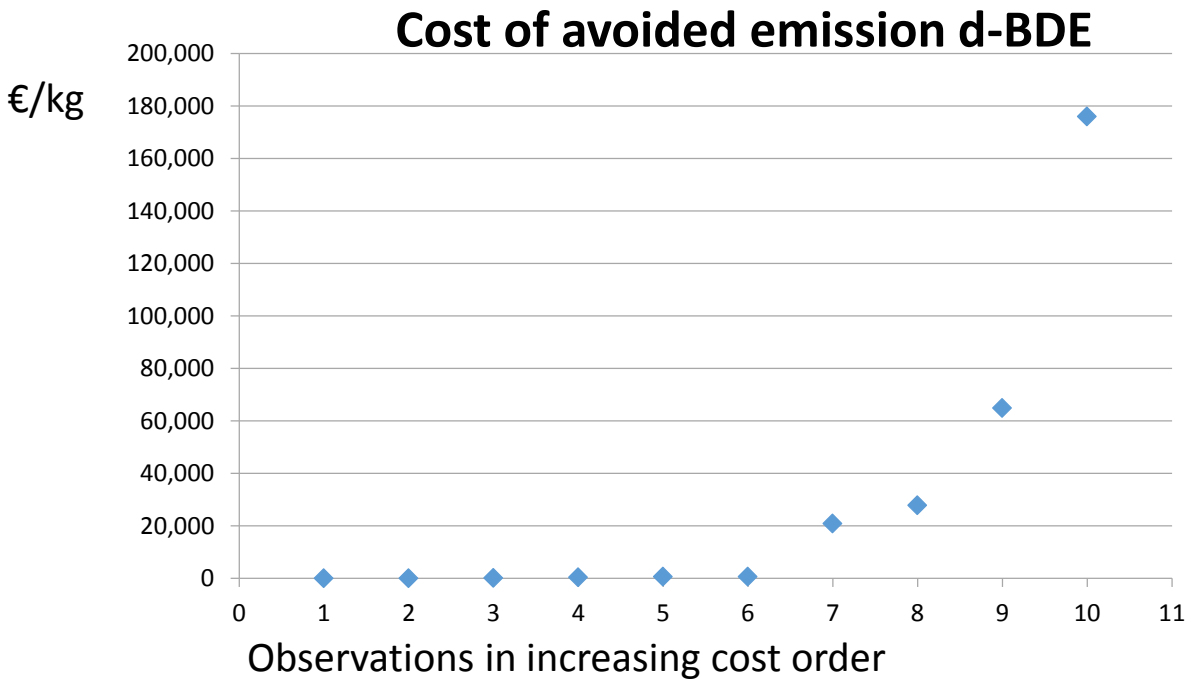
7% before 2000

46% between 2001 and 2010

47% after 2010



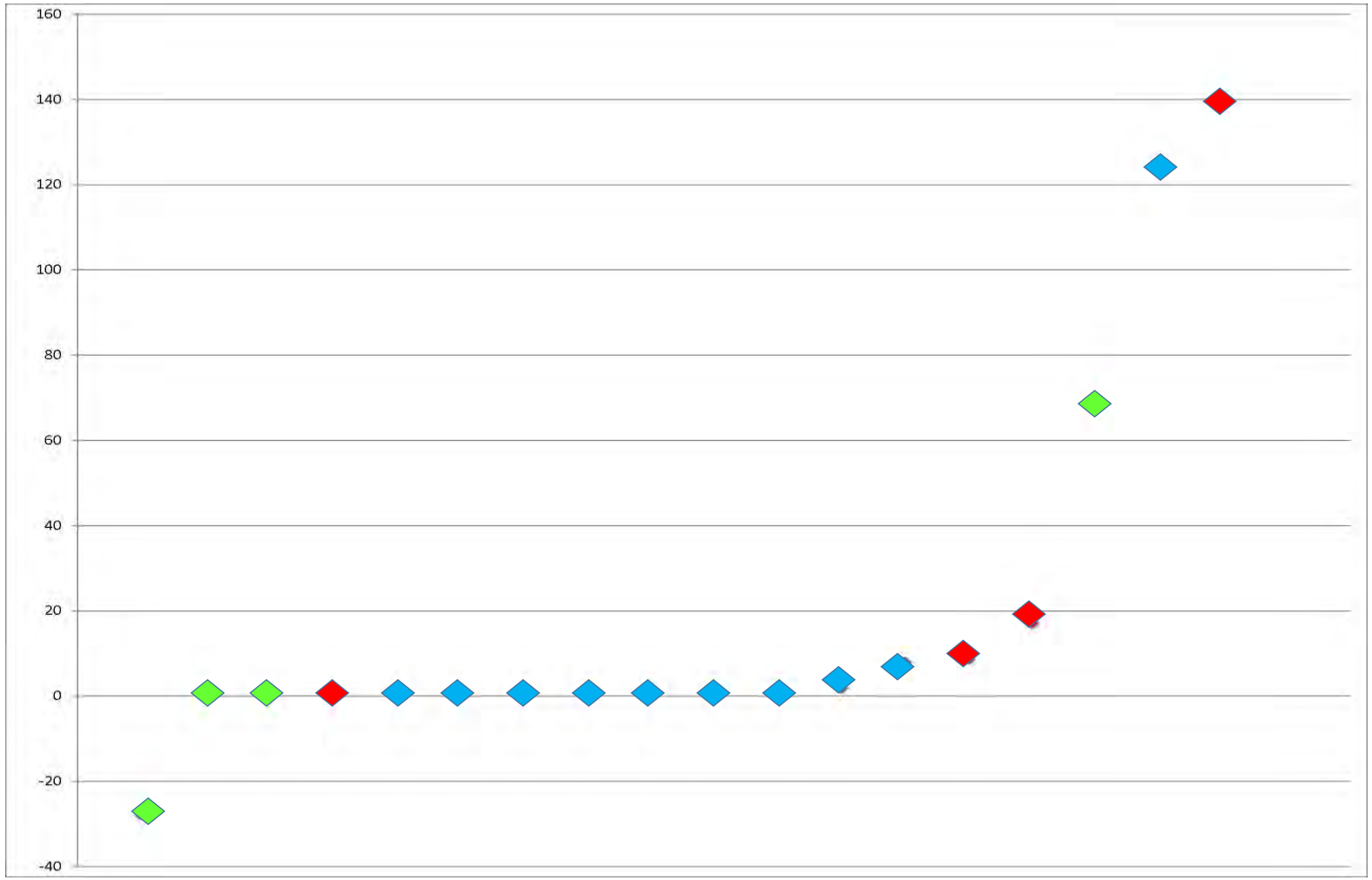
Conclusion: control costs many orders of magnitude higher than substitution costs



D4/D5 substitution costs
PCB disposal costs
HCB/HCH remediation costs

Conclusion: hard to conclude that the costs of substitution < disposal < remediation

€/kg



D4/D5	-27.9
D4/D5	0.0
D5	0.0
HCH	0.5
PCBs	1.0
PCBs	1.0
PCBs	1.1
PCBs	1.1
PCBs	1.3
PCBs	1.5
PCBs	1.6
PCBs	1.8
PCBs	7.9
HCB	8.6
HCH	17.0
D4/D5	68.1
PCBs	125
HCH	141

Observations in increasing cost order

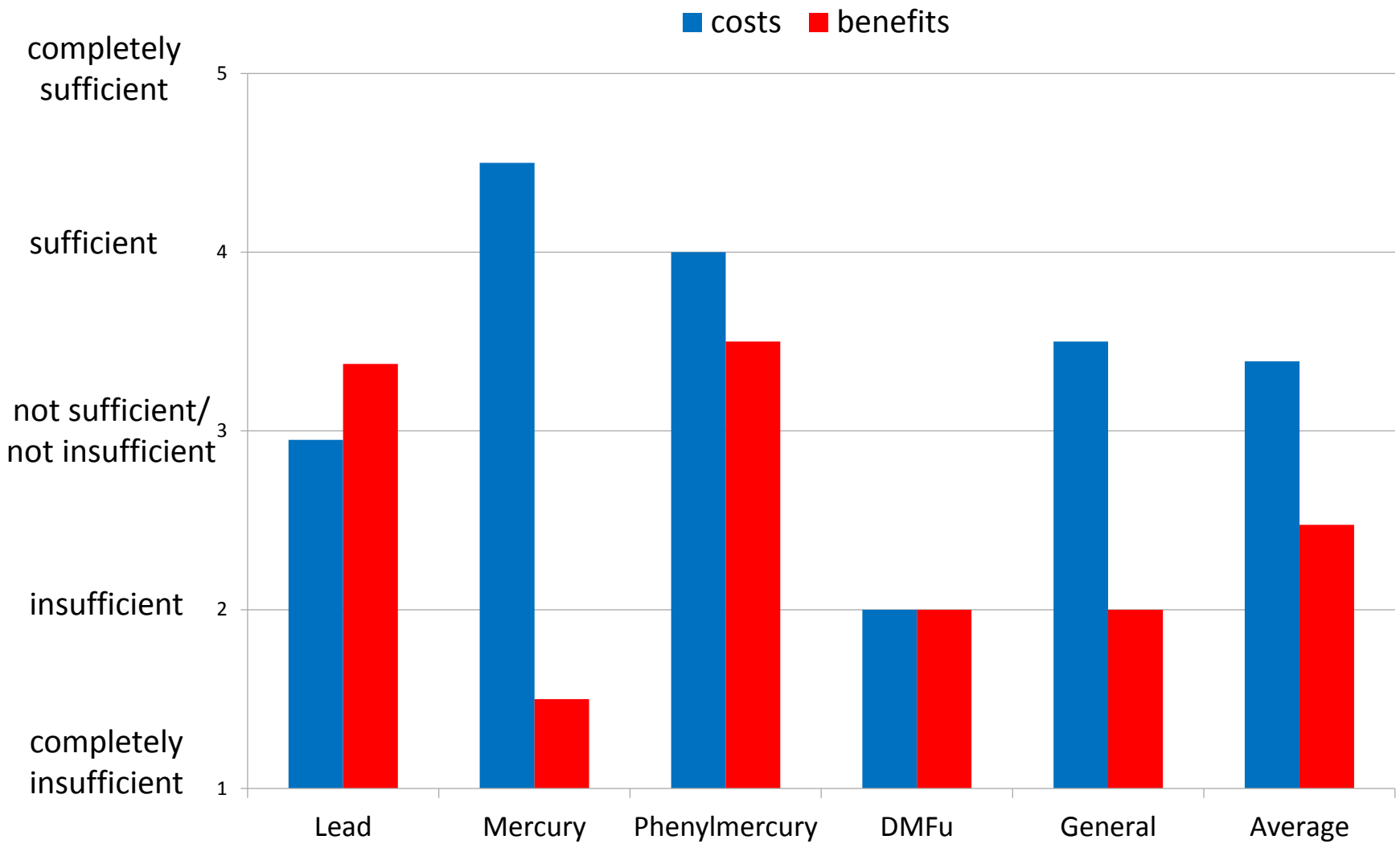
Table 3. Results of the linear regression analysis[a]

Explanatory factor	Coefficient estimate	Standard error
Constant	12.950***	2.289
Amount of substance (ln(kg))	−0.976***	0.252
Substance (baseline is PFOS and PFOA)		
D4 and D5 (dummy)	−1.676	2.732
HCH and HCB (dummy)	−1.080	2.448
HBCDD (dummy)	1.797	2.211
deca-BDE (dummy)	−0.410	1.813
PCB (dummy)	−0.794	2.325
Cost type (baseline is remediation)		
Substitution (dummy)	−3.262**	1.503
Emission control (dummy)	−1.851	2.859
European study (dummy)	−0.686	1.686
Study year (0–26)	−0.100	0.143
Model summary statistics		
F statistic	5.537***	
Adjusted *R*-square	0.519	
N	42	

Some preliminary results:

- Once control is included for the amount of substance and type of measure, no significant differences can be found between:
  - Substances
  - Countries
- Economies of scale: 1% increase of removed substance reduces unit cost proportionally by almost 1%
- Substitution significantly lower unit cost than control/remediation

Expert assessment reliability available information



across REACH restriction dossiers

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Regulatory decision-making under uncertainty: Are costs proportionate to benefits when restricting dangerous chemicals on European markets?

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ABSTRACT

Since 2007 regulation 1907/2006/EC concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is in force in Europe to reduce the adverse effects of hazardous chemical substances on human health and the environment. Implementation of the regulation by the European Chemicals Agency (ECHA) is supported by a Socio-Economic Analysis (SEA) Committee, consisting of European experts who help prepare ECHA's opinion on proposals for either restricting or authorizing dangerous substances. This paper presents the outcomes of the SEA underlying the first restriction proposals. Member states proposing a restriction have to show that it will reduce the risks to an acceptable level at a cost which is proportionate to the avoided risk. What is considered proportionate is not clearly defined in REACH. The opinion making process is characterized by many uncertainties: the expert group had no previous experiences to fall back on and limited information about the expected costs and benefits of the proposed restrictions. The study provides insight into expert opinions on environmental and health risks under uncertainty in the specific context of REACH. Particular attention is paid to the confidence experts place on the estimated socio-economic benefits of the avoided risks compared to the estimated compliance costs.

1. Introduction

Environmental regulatory decision-making in the European Union (EU) has led to the existence of a wide variety of directives and regulations. In conjunction with many of these European directives and regulations, a number of European committees and working groups have been formed, usually consisting of representatives from national regulatory authorities, experts and stakeholder groups in individual member states, to discuss, advise on, and take decisions regarding joint implementation of these directives and regulations in the member states. Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is an example of such European legislation. REACH aims to reduce the hazards and likely harm inflicted on human health and the environment of chemical substances manufactured, placed on the market and used, on their own or in articles. Implementation of REACH is managed by the European Chemicals Agency (ECHA) in Helsinki. Since its establishment in 2007, ECHA supervises the various REACH processes, ensuring consistency at EU level, and providing individual member states with expert advice on chemicals which fall under REACH.

Within ECHA, a Socio-Economic Analysis Committee (SEAC) exists, in which experts nominated by individual member states, are responsible for preparing the opinion of the Agency on applications for authorization to use certain substances of very high concern, or proposals from individual member states for restricting certain dangerous substances. Socio-economic analysis (SEA) forms an important part of these regulatory processes, and aims to provide support to decision-making as to whether it is a good idea for society as a whole to either impose a restriction (compared to continued use or using other risk management options) or grant an authorization (compared to refusing the authorization) for a hazardous substance. Authorization will only be granted if the applicant can prove 'adequate control' of the substance, or if it can show that the socio-economic benefits outweigh the associated risks to human health or the environment and if there are no suitable alternative substances or technologies. In the case of a restriction, the costs of complying with the restriction, including any shift to alternatives, are compared to the benefits from the reduced level

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0273-2300/

ure proportionality assessments

Thermometers >200°

19200

X 12

X 10

X 40

4100 mercury

1300

677

enylmercury

OECD SACAME Workshop: Best Practices in Assessing the Social Costs of Selected Chemicals
Ottawa 30-31 August 2017

Assessing Economic Valuation of the Benefits of Regulating Chemicals: Lessons Learned from Five Case Studies

Ståle Navrud

School of Economics and Business

Norwegian University of Life Sciences

Content

- Aim
- Similarities and differences across the five case studies
- Lessons learned
- Conclusion and way forward

Aim

Look across the five case studies:

- Mercury
- Formaldehyde
- Phthalates
- PFOA and its salts
- NMP

Discuss **similarities and differences across the five case studies**, and assess whether **similar endpoints** have been **valued in similar ways** in similar regulated uses, to identify opportunities for harmonization of approaches

Similarities and differences across the five case studies analysed looking at: (Table 1)

i) **whether used economic benefit estimates** of regulating the substance in question for health and environmental impacts

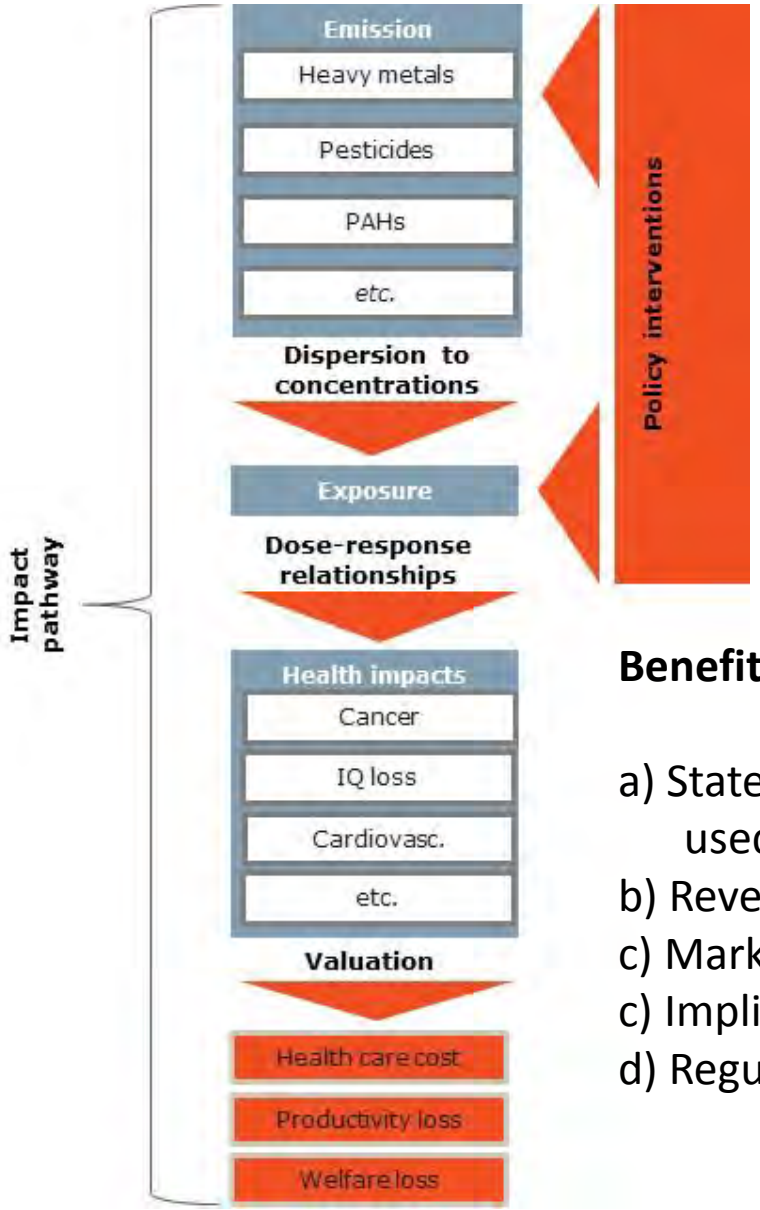
ii) the **number of such studies**;

iii) the **general valuation approach** (in terms of an impact-pathway approach (IPA) and/or expert assessments) and **the benefit valuation methods used**;

iv) whether **non-monetary assessment of impacts** was performed for impacts that were not valued (qualitative, quantitative or none);

v) whether **dose-response (environment) / exposure-response (health)** functions are available for the impacts

vi) whether the **costs of regulation** were considered.



Impact Pathway Approach (IPA) / Damage Function Approach

- Substances and exposure routes covered
- Avertive and adaptive behavior
- Health and environmental (ecosystem services) impacts
- Degree of complexity and uncertainty
- Scientific evidence – D-R/E-R vs. Expert Assessments
- Transfer of information across space and time
- Aggregation of uncertainty over all steps of IPA

Benefit Valuation methods:

a) Stated preference approaches (i.e. contingent valuation/ discrete choice analysis) used to elicit willingness-to-pay (WTP),
b) Revealed preference (hedonic wage analysis, avertive costs, travel cost/recreation)
c) Market prices (loss of earnings, Cost-of-illness, replacement costs))
c) Implicit valuation (based on pervious regulatory decisions)
d) Regulatory costs / break-even analysis

Source: *Sørensen, Carlsson Feng, von Bahr, Marcelia Sletten, Kiiski & Krarup (2017)* Valuation Literature on Chemicals: A Description of an Inventory of Valuation Literature on Chemicals

Case study substance	Economic benefit estimate (Y/N)	No. of studies considering benefits	Valuation approach (Benefit valuation approach)	Non-monetary assessment of impacts (quantitative, qualitative, none)	Dose-response functions (Y/N)	Costs of regulation estimate (Y/N)
Phthalates -Health -Environment	 Y N	6	Impact Pathway Approach (IPA) / Damage Function Approach (DFA) (Cost-of-illness (COI) and loss earnings for morbidity impacts, some studies use human capital method for mortality impacts; expert assessments to determine impacts and attributable fractions	 Quantitative	 N (relies on Attributable Fractions (AF) from expert assessments N	N
Mercury -Health -Environment	 Y Y	13	IPA/DFA (COI, Loss of earnings, expert assessment (disability weights). Stated Preference studies of selected endpoints, as well as impacts on recreational and commercial fishing)	 Quantitative	 Y (for IQ points lost; uncertain for cardiovascular effects) Y (for impacts on fish)	Y (both on changes in producer and consumer surplus)
PFOA and its salts -Health -Environment	 N N	0 No benefit estimates (due to lack of quantified impacts), but 2 out of 10 studies on costs of regulation assume abatement costs to be a proxy for social benefits	Integrated Multimedia Stock Pollution Model (Similar to IPA/DFA) (Implicit valuation, i.e. assuming that abatement costs reflects policymakers - and thus people´s - willingness-to-pay (WTP) to avoid environmental and health impacts.	 None None	 N N	Y (direct costs to industry and government; one study on wider economic impacts like employment)
NMP -Health -Environment	 Y N	1	DFA, but Break Even Analysis (BEA) for reductions of number of low birth weight and pregnancy loss due to lack of dose.-response functions (but with unit value estimates from ECHA (2014a)	 None None	 N N	Y
Formaldehyde -Health -Environment	 Y N	2	Cost-of-illness (COI) and Disutility for nasopharyngeal cancer and eye irritation	 DALY None	 Y (for nasopharyngeal cancer and eye irritation); but not for nose/mouth/throat irritation, risks to female fertility, bronchitis, pulmonary function, skin allergies and asthma attacks N	Y (costs for producers; not consumers)

Lessons learned

- **Geographical borders of the analysis**

Most often a country or region (EU), but trans-border life cycle effects

- **Ecosystem lags**

Persistence, bioaccumulative and toxic (PBT) properties, scientific evidence, exposure, stock pollutant approach in PFOA case study, choice of discount rate – constant or dimininshing over time)

- **Environmental impacts and endpoints**

Not quantified nor valued; lack D-R funtions to calculate impacts of regulation; have economic values for some environmental goods but need to be «translated» to ecososystem services (ES) and be based on best practise benefit transfer guidance)

Lessons learned (cont.)

- **Health impacts and endpoints**

- Morbidity, variety of morbidity endpoints; valued in terms of lost earnings and public expenditure (but not private); pain and suffering (disutility) costs not included –> likely underestimates

- **Mortality;** different approaches used;
- i) mortality risk reductions multiplied by VSL (often not based on most recent VSL literature),
- ii) life years gained multiplied by Value of a Life Year (VOLY), which varies across case studies (mainly due to different methodology)
- iii) QALYs (and DALYs) multiplied by VOLY

Lessons learned (cont.)

- **Impact Pathway Approach (IPA) / Damage Function Approach**

Used in most case studies, but often in a simplified form with the use of expert assessments and break-ecven analysis

- **Transferability /Benefit transfer**

Economic unit values (often in terms of economic value of certain health impacts per kg of chemical) from an existing study conducted years ago, and in a different geographical area and (regulating) context used unadjusted (or if adjusted; not adjusted according to current guidelines for benefit transfer or value transfer)

Since the transferred value is not the value per health endpoint, but rather a unit value per kg of emission, information from all steps of the IPA is transferred. This procedure is based on the strict assumption of similar relationships at all steps of the DFA

Conclusions

- **Lack quantified health and environmental impacts of regulation**

Within the IP approach, the major uncertainty is often the lack of exposure data and behavioural adaptation as well as DR /ER functions rather than monetary estimates of impacts. Use expert assessments when lack DR/ER functions.

- **Lack complete valuation of health endpoints, especially disutility costs of morbidity (pain and suffering, but also anexiety)**
- **Lack valuation of environmental impacts; focus should be on Ecosystem Services rather than environmental goods**
- **Treatment and communication of uncertainties**

How to best present the non-quantified and/or non-monetised impacts, and the uncertainty in all steps of the IP approach to allow for regulatory management decisions under incomplete information and high uncertainty.

Way forward

- **Identification of the potentially most important health and environmental impacts** in term of aggregate economic benefits (which is determined by the size of the exposed or affected population through different media (air, water, soil), the number of cases (from expert assessment or dose-response functions) and the potential economic value of each of the health and environmental impacts and endpoints.
- **Quantification of the impacts** of these potentially most important impacts (through expert assessments or Delphi methods; and development of DR/ER functions
- **New economic valuation studies (across different countries in order to improve transfer);** based on the recent guidance for Stated Preference studies (Johnston et al., 2017) of the quantified impacts. **Health endpoints:** Focus on Stated Preference studies of disutility from quantified acute and chronic morbidity impacts; including disutility of not-fatal cancer types and their treatments), but also health endpoints not quantified due to no or highly uncertain ER functions but that could be potentially large (and especially morbidity endpoints which are common for many substances. Updated VSL values in all countries. **Environmental endpoints:** Focus on effects on **Ecosystem Services(ES**); non-use (passive use) values could be potentially large (due to large population affected).
- **Updated and improved guidance for benefit transfer with better communication of uncertainty (forthcoming general guidance, but practical guidance for chemicals regulation);** not only for IP approaches in CBAs, but also for break-even analysis in CBAs/CEAs

Comments on Navrud Paper

OECD SACAME Workshop

Ottawa, Canada

August 30-31, 2017

RESOURCES FOR THE FUTURE

Motivation

- The point of this paper is to take a global look across all the literature review papers in this symposium and see what conclusions or generalizations can be reached
- Important as a guide to prioritizing future research
- And important to highlight issues in CBA's for toxics that need answers and harmonization across OECD countries ➔ Do we want harmonization? How far? How to get it?

RFF

Navrud points and comments

- Mostly descriptive, so not much to critique.
- Table helpful
- I like categorizing abatement cost and breakeven analysis under implicit valuation, although BE can do other things (implicit impact quantification). Maybe can also put replacement cost there
- There could have been some additional categories examined, e.g., whether substitute chemical risks were addressed; how uncertainties/missing data were addressed
- Validates our emphasis on health, because so little is known about ecosystem impacts. Validates our concern about lack of disutility valuation for morbidity.
- Notes that best valuation practices not always followed
- Issues with $/kg chemical emissions reduced. Practical idea to present ranges
- Idea to develop BT guidance for transfers from the group of chemicals to individual chemicals

RFF

A Suggested List of Issues

1. How to treat uncertainties/missing information in:
   - Standards of evidence?
   - Expressing uncertainty in causality
   - DR (breakeven analysis)
   - Valuation (breakeven analysis)
   - DR and Valuation (hopeless case; qualitative, CEA)
   - Going further up the damage function chain for cost-effectiveness analysis; are we comfortable with DALYs as an effectiveness measure?
   - Or just using costs (knee of the curve) But costs with risk tradeoffs gets back to valuation
   - Discounting (range)
   - Expressing statistical and model uncertainties quantitatively
   - Expressing uncertainties via an appendix
   - Addressing uncertainties through changing the rule

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More

2. Global versus domestic benefits
3. Within Valuation
    a. Is extrapolating from COI to WTP (disutility) acceptable?
    b. Parents valuations for themselves vs. children
    c. Different valuations by HH member
    d. When, if ever, to use VOLY?
    e. Treatment of labeling, notification, chain-of-custody, recordkeeping, and other administrative requirements. Cost is pretty easy, but getting the effect on compliance is hard.
    f. Use of outdated studies: Are valuation databases adequate?

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Research Needs

- Prospective studies: Valuation study across multiple countries. Asia
- Retrospective studies: What and how to build into regulation reporting requirements
- BCA for eliminating regulations

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From Holland

Table 4.1. Comments on the strength of assessment at different stages of the impact pathway.

Stage of assessment	Comments
Release of phthalates	Good information on phthalate production and use is available.
Exposure assessment	Data on exposure to phthalates is available from biomonitoring studies including the COPHES / DEMOCOPHES project in Europe (Schindler et al., 2014[58]) and NHANES in the USA. The extent to which this provides information on a range of different phthalates, rather than a limited number considered as key indicators, is questionable.
Impact identification	A large number of health impacts have been identified as linked to exposure to phthalates. These affect the reproductive system, neurodevelopment, cancer incidence, obesity, diabetes, asthma and allergy. However, the strength of association is variable. A number of environmental impacts have also been noted, particularly for aquatic ecosystems. However, quantification of these effects beyond assessment of the presence or absence of risk is lacking.
Impact assessment	Information on the population at risk, incidence of disease, etc., is readily available in Europe and the USA. The key difficulty for the impact assessment lies in determination of the attributable fraction of disease for any specific substance. From the toxicological work there will typically be a need to extrapolate information across concentration ranges and often between species.
Valuation of impacts	In most cases, health impacts are valued using at least the direct costs associated with medical care. In some, productivity losses are also added in. However, in rather few cases is account taken of disutility, even though this accounts for the largest share of impacts when it is taken into account (see, e.g. Olsson et al. (2014[5])). Amongst the US studies there is a tendency to value disutility by reference to QALY or DALY loss, applying a value of USD 50 000 per QALY or DALY.
Benefits transfer	Processes for benefits transfer (to different countries and over different time periods) seem robustly applied across the studies considered. Inflation of direct healthcare costs has considered rates specific to the health sector. Discount rates of 3% or 4% are used as appropriate in all studies where relevant.
Uncertainty assessment	Several studies provide ranges for effects and their values. However, the actual meaning and validity of these ranges may not be apparent. The ECHA (2017[8]) background document on the proposed restriction of four phthalates provides a good example of uncertainty assessment in the context of CBA.
Stage of assessment	The ECHA (2017[8]) background document on the proposed restriction of four phthalates provides a good example of uncertainty assessment

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From Holland

Table 4.2. Summary of unit values used in the studies reviewed above

All figures in EUR, price years in second row of table

	Trasande (2014[14])	HEAL (2014[19])	Olsson et al. (2014[6])	Trasande et al. (2015[32]) and (2016[36])	Attina et al. (2016[38])	ECHA (2017[8])
Price year	**2008**	**2010**	**2013**	**2010**	**2010**	**2010/12/14**
			Obesity, diabetes			
Childhood obesity	1 650				54 000	
Overweight children					26 000	
Adult obesity	39 000			290 000	215 000	[290 000]
Diabetes		Unspecified		28 000	54 000	[29 600]
			Neurodevelopment			
Autism		12 445		630 000	981 000	[630 000]
ADHD		10 650		77 000	119 000	[90 000]
IQ point loss				9 600	14 500	
Intellectual disability				360 000	1.0 million	
			Reproductive system			
Female infertility						[29 700]
Preterm birth with VLBW infant						[126 000]
Fibroids				2 900	5 200	[3 000]
Endometriosis				8 600	415 000	[8 620]
Male infertility			3 480	7 600	7 800 - 11 000	[8 930]
Cryptorchidism		5 715 - 8 415	34 674	28 000	6 291	[26 000]
Hypospadias		Unspecified	39 617			[6 900]
Human fertility. treatment		4 500 - 51 822				
Reduced semen quality						[7 630]
Low T deaths				320 000	0.33 to 0.62 million	[320 000]
			Cancers			
VSL						[3.5 million]
Statistical case of cancer						[350 000]
Value of cancer morbidity						[410 000]
Breast cancer		Unspecified				
Endometrial cancers		Not quantified				
Thyroid cancer		Not quantified				
Prostate cancer		Unspecified				
Testicular cancer			80 980	124 000	17 000	[81 000]
			Other conditions			
Coronary Heart Disease	33 000					
Allergy episode						[18]
Asthma episode						[50]

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Navrud conclusions and the way forward

- ID health benefits with largest damages for further study–- is that the key criterion?
- Quantification of the impacts through expert elicitation -- why not through new health studies?
- New valuation studies
- Updated BT guidance

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Horizontal Learnings: Comments on "Assessing Economic Valuation of the Benefits of Regulating Chemicals: Lessons Learned from Five Case Studies" by Ståle Navrud

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Prepared for:
Best Practices in Assessing the Social Costs of Selected Chemicals
OECD Workshop
August 30-31, 2017

Contents

- General observations
- Valuing nonfatal health risk reductions: issues and opportunities
  - Willingness to pay
  - Monetized QALYs and DALYs
  - Averted costs (COI)
- Additional references

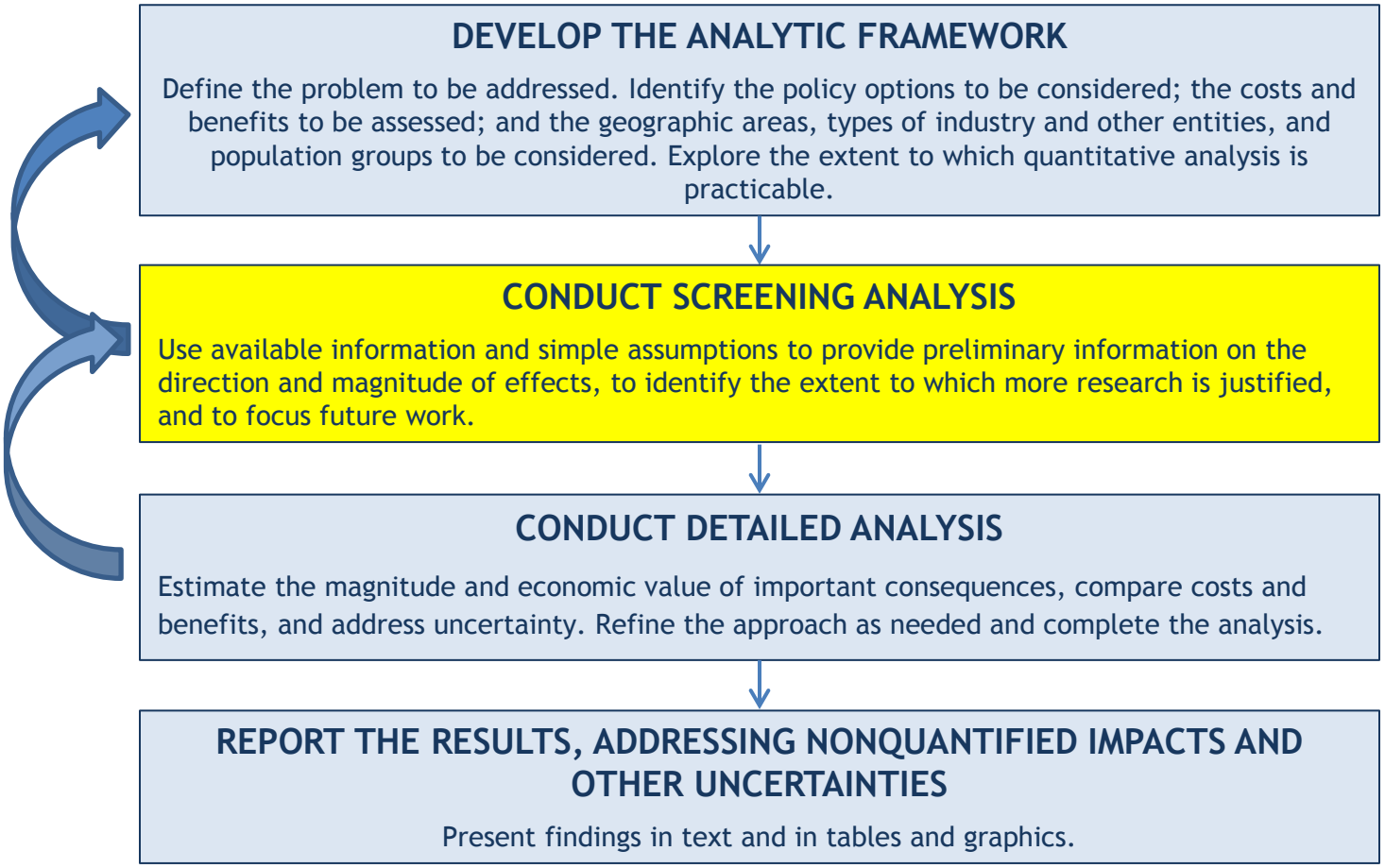
General Observations

- Paper summarizes five case studies, which demonstrate substantial challenges to estimating changes in health and environmental risks, benefit values, and costs.
- Proposed new valuation work is an incredibly important step forward, but…
  - Primary research is expensive, challenging, time-consuming.
  - Every study has advantages and limitations, may need several to triangulate on values.
  - Values likely to vary depending on risk causes as well as consequences and across populations affected; also across marginal and non-marginal changes.
  - New hazards will continue to emerge.

General Observations

- How can we do the best with what we have?
  - Provide best practice guidance, develop proxy values, case study examples, clearinghouses/databases of available research, tools (e.g., USEPA's BenMAP) that are useful across policies.
    - Recognize that we will never have full agreement on methods, but clear communication of assumptions and limitations is essential.
  - Increase training on dealing with limited information, and on clearly communicating results, uncertainties, usefulness.
  - Address nonquantified effects using breakeven or threshold analysis, cost-effectiveness analysis, bounding or "what-if" analysis, as well as qualitative discussion.
  - Conduct retrospective analysis to better understand sources of under- or over-statement and improve analytic approaches.
  - Consider whether level of analysis is proportionate to its usefulness for decision-making.

General Observations



Valuing Nonfatal Risk Reductions

- Approaches use to value nonfatal health risk reductions in case studies:
  - WTP is preferred approach but rarely used due to gaps in primary research.
  - Proxies include averted costs (cost of illness) and monetized QALYs or DALYs.
    - Averted costs (medical costs and lost productivity) applied frequently.
    - QALYs or DALYs reported in some studies; occasionally monetized.

Willingness to Pay

- Lack high-quality, applicable research; lack consensus on approaches for selecting and synthesizing estimates and on use of proxies (averted costs, monetized QALYs or DALYs).
- Opportunities:
  - Prioritize new research based on expected influence on decisions (informal value of information or benefit-cost test).
    - Likely to affect conclusions regarding which policies yield net benefits, which policy has the highest net benefits?
    - Addresses endpoint(s) of interest to decision-makers, other stakeholders?
    - Addresses high stakes policies (large costs or benefits, significant controversy)?
  - Prioritize new research that is applicable across settings.
    - Same or similar survey conducted in different settings (e.g., Krupnick, Alberini, et al. studies).
    - Address multiple risk and population attributes to allow tailoring to different contexts.
  - Provide more guidance on applying available estimates.
    - Tailor benefit transfer guidance to address available research on health outcomes.
    - Include proxy methods for use when suitable WTP estimates of reasonable quality are not available.
  - Consider multiple approaches to synthesizing research.
    - Criteria-driven literature review.
    - Meta-analysis.
    - Structured (formal) expert elicitation.
  - Develop consolidated open access clearinghouse/database for primary research, related reviews, guidance documents, applications.

Averted Costs

- Estimates often outdated, developed for dissimilar contexts and countries, relationship to WTP uncertain (often understate, may overstate at times).
  - What costs are included (medical costs, lost (market and nonmarket) production, other costs) inconsistent.
  - Values likely to vary substantially across countries.
  - Values likely to change significantly over time.
  - Health care and labor markets highly distorted.
  - Possible double-counting if summed with other measures (WTP, monetized QALYs or DALYs).
- Opportunities:
  - Substantial expertise available (health economists, labor economists).
  - Data are relatively easily accessible for numerous endpoints and countries.
    - Investigate country-specific and international data sources (OECD, WHO, World Bank, others).
    - Identify most appropriate sources, options for adjusting across countries and over time.
  - Develop guidance on estimating opportunity costs given market distortions.
    - Recently drafted for U.S. HHS; work needed to extend to other settings.
  - Only include third party costs if summed with other measures (WTP, monetized QALYs or DALYs), unless costs to individual clearly excluded from underlying studies.

Monetized QALYs or DALYs

- QALYs and DALYs are nonmonetary measures that are used extensively in public health and medicine.
  - Measure trade-off between alternative health states and longevity, not between health risks and money that can be spent on other things.
  - Consistent with benefit-cost framework only under restrictive assumptions.
  - Easily accessible, numerous estimates for many health effects.
  - Best practice recommendations available.
- Typically valued using a constant VSLY or value per QALY (or DALY), calculated from a VSL estimate.
  - Use of a constant is inconsistent with theory and available empirical evidence.
  - $50,000 per QALY or DALY is unsupported, estimates derived from VSL are generally much higher.
- Opportunities:
  - Can take advantage of substantial research base; use of a constant for valuation easy to implement.
  - Can adapt available best practice guidance to SEA context.
  - In the near-term, value using a constant derived from a VSL estimate and assess implications of related uncertainties.
  - Over the longer-term, develop a valuation function to better approximate WTP (see Hammitt references for related work).

References

General:

U.S. Department of Health and Human Services 2016. "Guidelines for Regulatory Impact Analysis: U.S. Department of Health and Human Services," prepared by L.A. Robinson, J.K. Hammitt, and J. Baxter under subcontract to Industrial Economics, Incorporated and Mathematica Policy Research. https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis-primer; https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.

Estimating averted costs:

Baxter, J.R., L.A. Robinson, and J.K. Hammitt. 2017. Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices: Final Report. Prepared for Amber Jessup, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (will be posted soon at https://aspe.hhs.gov/reports).

Robinson, L.A., D.B. Rein, J.K. Hammitt, J. S. Wittenborn, and R.M. Wygle. 2017. Estimating Medical Costs for Regulatory Benefit-Cost Analysis: Conceptual Framework and Best Practices: Final Report (pending). Prepared for Amber Jessup, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (will be posted soon at https://aspe.hhs.gov/reports).

Estimating QALYs or DALYs:

Miller, W., L.A. Robinson, and R. Lawrence (eds.). 2006. Valuing Health for Regulatory Cost-Effectiveness Analysis, Washington, DC: National Academies Press. URL

Neumann, P.J. et al. (eds.). 2016a. Cost-Effectiveness in Health and Medicine (Second Edition). New York: Oxford University Press.

Sanders G.D., Neumann P.J., Basu A., et al. 2016. "Recommendations for Conduct, Methodological Practices, and Reporting of Cost-Effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine." JAMA. 2016; 316(10), 1093-1103

Salomon J.A. et al. 2012. "Common Values in Assessing Health Outcomes from Disease and Injury: Disability Weights Measurement Study for the Global Burden of Disease Study 2010." The Lancet 380: 2129-2143. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)61680-8/abstract

Salomon J.A. et al. 2015. Disability Weights for the Global Burden of Disease 2013 Study. The Lancet Global Health 3(11): e712-e723. http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(15)00069-8/abstract

Valuing QALYs:

Hammitt, J.K. 2013. "Admissible Utility Functions for Health, Longevity, and Wealth: Integrating Monetary and Life-Year Measures." Journal of Risk and Uncertainty. 47: 311-325

Hammitt, J.K. 2017. "Valuing Non-fatal Health Risks: Monetary and Health-Utility Measures." Revue Economique 68: 335-356.

Hammitt, J.K. and K. Haninger. 2007. "Willingness to Pay for Food Safety: Sensitivity to Duration and Severity of Illness." American Journal of Agricultural Economics 89(5): 1170-1175.

Hammitt, J.K. and K. Haninger. 2017. "Valuing Nonfatal Health Risk as a Function of Illness Severity and Duration: Benefit Transfer using QALYs." Journal of Environmental Economics and Management 82: 17-38.

Haninger, K. and J.K. Hammitt. 2011. "Diminishing Willingness to Pay per Quality-Adjusted Life Year: Valuing Acute Foodborne Illness." Risk Analysis. 31(9): 1363-1380.

Johnson F.R., E.E. Fries, and H.S. Banzhaf. 1997. "Valuing Morbidity: An Integration of the Willingness-to-Pay and Health-Status Index Literatures." Journal of Health Economics 16: 641-665.

Van Houtven, G. et al. 2006. "Valuing Avoided Morbidity Using Meta-Regression Analysis: What Can Health Status Measures and QALYs Tell Us About WTP?" Health Economics 15: 775-795.

Presentation to OECD workshop,
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Discussion on Conclusions: Cross-cutting conclusions; emerging policy implications; and suggestions for further work

by

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Cross-cutting conclusions

- Ståle Navrud's paper on all five case studies, when coupled with the discussion to date in each of the sessions, confirms the conclusion in my comments on the formaldehyde case study: the economic evidence base is clearly incomplete and in need of correction.

- Equally clear from the discussion to date is that the "pre-economic" evidence base (on the epidemiological and other material impacts of these chemicals) is also incomplete and in need of correction.

Cross-cutting conclusions (continued)

- Re the economic evidence base, my main concern is *not* our current inability to monetise all environmental impacts (*pace* the last session at Helsinki).

- Yes, the assessment of environmental impacts should be further developed. But the same applies in many fields, not in chemicals alone. Importantly, decision-makers are aware of it and often prepared to make allowance for it by admitting qualitative assessments.

Cross-cutting conclusions (continued)

- What stands in need of urgent correction is rather the incidence of departures from best practice, departures that are likely delivering erroneous estimates of the benefits from avoided mortality and morbidity.

- These include not only dated values, limited endpoints and over-reliance on value transfers from US studies but also, and of quantitative importance, incomplete use of WTP-derived VSLs and WTP-derived disutility costs as well as the use of excessive discount rates.

Cross-cutting conclusions (continued)

- These corrections are within the power of economists to deliver. But what of Ståle's conclusion that "the major uncertainty is the lack of dose-response functions rather than monetary estimates of impacts"?

- As argued in my recent studies on air pollution, the better part of our revaluation of its social costs is the result of the revaluation of its epidemiological impacts. How much of the impact of chemicals are we missing as a result of information gaps outside economics?

Emerging policy implications

- Our collective evaluation of the incomplete economic evidence base here in Ottawa provides, I think, sufficient evidence to table an important and positive result before regulators and governments:

- There is clear scope to extend the economic evidence base for chemicals; progress in CBA techniques makes us well-equipped to do it; *ceteris paribus*, such an extension is likely to show higher levels of benefits.

Emerging policy implications (continued)

- But we are also duty-bound to communicate Ståle's point on "the uncertainty in all steps of the IPA/DFA" so as to facilitate "regulatory management decisions under incomplete information and high uncertainty."

- This is important: over-confident assertions based on incomplete scientific evidence have sometimes served to weaken the credibility of environmental regulation, with spill-over effects into fields where the evidence base is much more complete (such as air pollution).

Emerging policy implications (continued)

- The need to address uncertainty does not negate the first point: we have good reason to be confident that we are well-placed to extend the economic evidence base to inform strong (and stronger) regulation.

- The point would be negated only if the uncertainty from information gaps were to be addressed in the wrong way: i.e., by cumulative short-cuts that seek to avoid the task of closing these gaps and end up by abandoning the firm ground of welfare economics.

Suggestions for further work

- So far as concerns the work of economics, my principal suggestion is to prepare (1) new, improved CBAs where possible and as rapidly as possible.

- These should deliver (i) more recent values and (ii) for more complete end-points and (iii) incl. more countries as appropriate – using, *inter alia*, (iv) the latest (Roy-Braathen, 2017) OECD VSL estimates for mortality, (v) WTP disutility estimates for morbidity, and (vi) an economically justified discount rate, justified anew.

Suggestions for further work (continued)

- The strengthening of cost-benefit analysis also needs to pay attention to the cost side of the equation: to develop a well-founded methodology covering at least the main elements of costs, and one that could be used with reasonable consistency across a range of CBAs.

- A well-founded methodology should guard against over-estimation of direct producer costs (partly by factoring in technical progress). But it would also need to account for the external costs of technical substitutes.

Suggestions for further work (continued)

- As a first step, it should surely be possible to extract out of Alistair's paper on formaldehyde, and my comments thereon, a new and more complete calculation of costs and benefits, relative to what is now on the record.

- Such an exercise should provide the clearest example of the quantitative change to the CBA result that would follow from adopting best practice on the basis of the available data – and enable regulators to judge whether and how to prioritise investment in best practice.

Suggestions for further work (continued)

- There remains the question of how to close the gaps in the pre-economic evidence base so as to give us greater confidence in the quantitative data that we as economists are valuing and converting as welfare benefits.

- This will likely require a major collaboration between epidemiologists and economists (cf. the case of air pollution). As a first step, I suggest that any new CBAs, including the update on formaldehyde, proceed by way of including at least one epidemiologist “in the room”.