

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

**ANNEX TO: WORKSHOP REPORT: OECD WORKSHOP ON SOCIOECONOMIC IMPACT
ASSESSMENT OF CHEMICALS MANAGEMENT**

**Experiences, methods and information requirements for quantifying the costs and benefits of regulating
the risks related to chemicals**

**Series on Risk Management
No. 32**

This Annex contains the Presentations from the Workshop on Socioeconomic Impact Assessment of Chemical Management held on 6-8 July 2016 in Helsinki, Finland. The main report is available under the cote ENV/JM/MONO(2016)68.

The complete Annex is available in pdf format only.

JT03407181

Complete document available on OLIS in its original format

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OECD Environment, Health and Safety Publications

Series on Risk Management

No. 32

ANNEX 1 TO:

**WORKSHOP REPORT: OECD WORKSHOP ON SOCIOECONOMIC IMPACT ASSESSMENT
OF CHEMICALS MANAGEMENT**

Experiences, methods and information requirements for quantifying the costs and benefits of
regulating the risks related to chemicals

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 CO-OPERATION AND DEVELOPMENT
Paris 2016

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- No. 10: Proceedings of the OECD Workshop on Sustainable Chemistry, Venice, 15-17 October 1998 (1999)*
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- No.14: Technical Guidance Document on the Use of Socio-Economic Analysis in Chemical Risk Management Decision Making (2002)*
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- No. 16: OECD Guidance Document on Risk Communication for Chemical Risk Management (2002)*
- No. 17: Strategies in the Chemicals Industry and Related Areas; Vienna, Austria, 13-14 November 2003, Part I and Part II: Summary and Conclusions (2004)*
- No. 18: Workshop on Exchanging Information Across a Chemical Product Chain, Stockholm, Sweden, 15-16 June 2004 (2004)*
- No. 19: Results of Survey on Production and Use of PFOs, PFAs and PFOA, related Substances and Products/Mixtures containing these Substances (2005)*
- No. 20: Workshop Report on Consideration of Chemical Safety in Green Procurement, Seoul, Korea,*

8-10 November 2005 (2006)

No. 21: Preliminary Lists of PFOS, PFAS, PFOA, PFCA, their related Compounds and Chemicals that may degrade to PFCA (2006)

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No. 25: Sustainable Chemistry: Evidence on Innovation from Patent Data. (2011)

No. 26: Current Landscape of Alternatives Assessment Practice: A Meta-Review. (2013)

No. 27: Synthesis Paper on Per- And Polyfluorinated Chemicals (Pfc). (2013)

No. 28: Preliminary Analysis of Policy Drivers Influencing Decision-Making in Chemicals Management. (2015)

No. 29: Risk Reduction Approaches for PFASs – A Cross-Country Analysis

No. 30: Working towards a Global Emission Inventory of PFASs: Focus on PFCAs - Status Quo and the Way Forward

No. 31: Synthesis Report from the OECD Workshop on Alternatives Assessment and Substitution of Harmful Chemicals

Other OECD Environment, Health and Safety Publications related to Risk Management:

OECD Proceedings: Sources of Cadmium in the Environment (1996)

OECD Proceedings: Fertilizers as a Source of Cadmium (1996)

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This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication is available electronically, at no charge.

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PRESENTATIONS



BCA: Triumphs and Troubles

Alan Krupnick
Resources for the Future

BCA is ...

Lester Lave, an economist at the Brookings Institution, said that cost-benefit analysis "is a delightful tool for economists because it is complete, flexible and allows you to look at everything."

...[In] many cases, benefit–cost analysis cannot be used to prove that the economic benefits of a decision will exceed or fall short of the costs.... [But it] can provide illuminating evidence for a decision, even if precision cannot be achieved because of limitations on time, resources, or the availability of information. (Arrow et al. 1996, 5)



OECD Workshop: Socioeconomic Impact Assessment of Chemical Management
Helsinki, July 6, 2016



Definition

- Use of a monetary measure of aggregate change in individual well-being from a prospective policy decision/regulation
- Advantages are transparency, possibly accountability, framework for consistent data collection and gap identification, ability to aggregate over dissimilar effects.
- Disadvantages: one dimensional

Who does CBA? (Smith and Braathen, OECD EWP, No. 92)

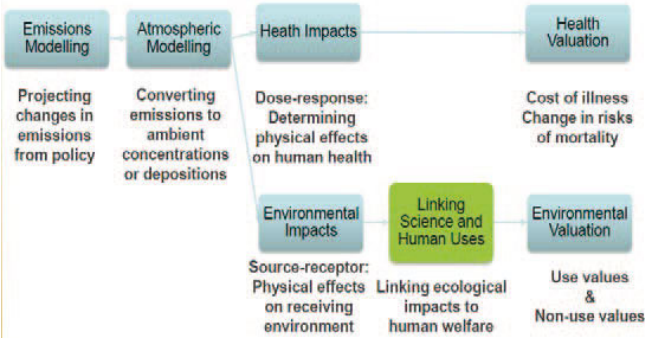
ENV/WKP(2015)13

Table 1. Summary of questionnaire responses

		Transport investments		Energy investments		Other investments		New policy assessments		Ex post assessments	
		#	%	#	%	#	%	#	%	#	%
Are there clear criteria for how to do CBAs?	Yes	18	90%	15	75%	10	77%	15	83%	11	65%
	No	2	10%	5	25%	3	23%	3	17%	6	35%
	Total	20	100%	20	100%	13	100%	18	100%	17	100%
What is the share of cases in the last 3-5 years that have been CB-analysed?	All	3	16%	3	19%	3	25%	4	25%	0	0%
	Most	14	74%	6	38%	5	42%	8	50%	4	27%
	Some	1	5%	3	19%	4	33%	3	19%	6	40%
	A few	1	5%	3	19%	0	0%	1	6%	2	13%
	None	0	0%	1	6%	0	0%	0	0%	3	20%
Total	19	100%	16	100%	12	100%	16	100%	15	100%	



From Science to Policy: The Role of Economics



What makes toxic chemicals special relative to air pollution

Economics implications

- From regulatory perspective: thousands of substances, used in products, banning an option; focus on substitutes
- Endpoints: emphasis on cancer/mutagens/birth defects/serious morbidity
- Latency

Physical/biological science implications

- Multiple exposure points
- Long-lived (particularly in ecosystems)/accumulative
- Synergies across chemicals
- Creation of new chemicals with uncertain effects



EPA RIA for disinfection by-products

- No VSL adjustment for bladder cancer
- Morbidity increment of fatal bladder cancer: medical costs
- Nothing on adverse reproductive and developmental health effects.
- For non-fatal bladder cancers: 1996 (!) study on risk-risk tradeoff with curable lymphoma and death (58.3% of death). \$587K.
- Adjustments for real income growth
- Handling lags in impacts
- Use Monte Carlo simulation to handle uncertainties
- Discount rates: norm at EPA/OMB is 3% and 7%



New TOSCA rule

In proposing and promulgating a rule on a specific chemical, Administrator shall consider and publish a statement on the costs and benefits of the rule. This can be for testing a chemical, banning it, etc.

- Reauthorized TOSCA law says “without consideration of costs” about 50 times.
- Mentions “benefits” twice; focuses on risks
- Mentions costs and benefits together once. But EO would require it anyway.



Outline of Talk

1. What we do well
2. What we need to do better
3. What we mostly ignore
4. What we do that we shouldn't

Some caveats:

- Most of my experience with BCA analyses is U.S.
- Skipped environmental valuation



What we do well or at least agree on

- Market valuation in general
- Focus on linkage: Health endpoints-valuation startpoints
- Options analyses (although sometimes seems contrived); sensitivity analyses
- Adjustments for income growth
- Co-benefits
- Discounting? (sensitivity analyses, hyperbolic discounting)



What we need to do better: mortality valuation

- EU: Braathen et al: ~ \$4 million SP studies
- US: ~\$9 million mostly RP studies
- Cancer (including latency/cessation lags)
- Public vs private context
- Children
- PPP vs. Exchange rate (for transfer)
- Income elasticity of WTP (for transfer)
- A new name: EPA trying out value of a micro risk (e.g., \$8 per 1/1,000,000)
- VSL vs. VSly

Alberini and Scasny (1/16) (draft)

Value of Statistical Life (\$millions CAN\$)

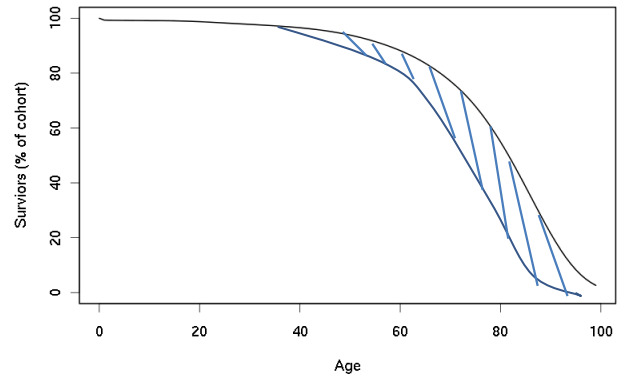
Type	Adult	Parent for Child
Cancer	7.0	8.7
Road Accident	4.7	6.8
Respiratory	5.0	7.8
Add'l if Public	1.8	2.4



VSLY

- Years Life Lost is “probably” a better metric than “lives lost”
 - Need VSLY
- Just as there’s no one VSL, there’s no one VSLY
- Three approaches in literature
 - Amortize VSL – exponential function; need discount rate (~\$300,000)
 - SP (Desaigues et al 2011; Chilton et al, 2004; Cameron and DeShazo, 2013)

Shift in Survival Function



What we need to do better: serious morbidity valuation

- Holy Grail: Choice experiment with sufficient attributes to describe/differentiate between toxic chemicals – do for products with substances and with substitutes
- Do studies for particular endpoints or chemicals
 - ECHA review (2016) of studies in Italy, Czech R, UK and Neth. (skin irritation, kidney failure and disease, fertility and developmental toxicity, cancer). Fertility/Birth defects study in Canada (Scazny and Zverinova, 2016)

Integrating across Morbidity/Mortality and Beyond

- Add morbidity cost to mortality
- Choice experiments with qualitatives
- Choice experiments with quantitatives
- Choice experiments with illness profiles
- Choice experiments with chemical properties



Integrated morbidity/mortality valuation studies

Adamowicz et al (2011)

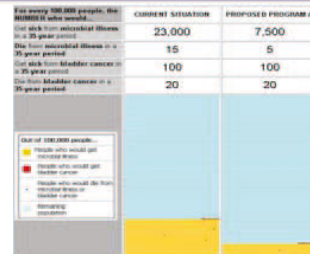


Table 8. Value of Statistical Life and Value of Statistical Illness Calculations

	Conditional Logit Models ^a			WTP Space Models ^a		
	V5	V6	V5 + V6	V5	V6	V5 + V6
Microbial death	17,498,000 (4,510,100) ^b	17,135,000 (4,333,800)	17,634,000 (3,585,000)	20,016,990 (4,988,558)	21,953,310 (3,988,718)	19,677,680 (5,206,360)
Microbial illness	25,188 (4,291)	18,591 (3,322)	24,013 (3,124)	34,269 (4,164,685)	19,330 (3,867,622)	31,248 (26,983)
Cancer death	16,021,000 (4,057,400)	8,538,000 (3,261,100)	13,559,000 (2,785,800)	16,691,720 (5,404,344)	10,927,880 (4,331,812)	15,408,610 (4,628,368)
Cancer illness	2,539,900 (903,860)	4,330,900 (943,830)	2,952,400 (624,130)	3,275,405 (5,978,036)	4,908,321 (4,123,471)	4,113,380 (4,685,878)

Georgiou et al (2015) ppt. WTP to reduce Deca-BDE

	Current Situation	Alternative 1	Alternative 2
Risks of death due to household fires	5 in a million	15 in a million	10 in a million
Relative level of risks of impact on wildlife	High	High	Low
Relative level of risks of impact on human health	High	Low	High
Increase in annual household expenditure	£ 0	£ 50	£ 5

Example: One of the 11,385 randomized choice sets. (Cameron and DeShazo, 2013)

Choose the program that reduces the illness that you most want to avoid. But think carefully about whether the costs are too high for you. If both programs are too expensive, then choose Neither Program.

If you choose "neither program", remember that you could die early from a number of causes, including the ones described below.

	Program A for Heart Disease	Program B for Colon Cancer
Symptoms/ Treatment	Get sick when 71 years old 2 weeks of hospitalization No surgery Moderate pain for remaining life	Get sick when 68 years old 1 month of hospitalization Major surgery Severe pain for 18 months Moderate Pain for 2 years
Recovery/ Life expectancy	Chronic heart condition Die at 79	Recover at 71 Die of something else at 73
Risk Reduction	5% From 40 in 1,000 to 38 in 1,000	50% From 4 in 1,000 to 2 in 1,000
Costs to you	\$15 per month [= \$180 per year]	\$4 per month [= \$48 per year]
Your choice	Reduce my chance of heart disease	Reduce my chance of colon cancer
	Neither Program	

Valuation study for Canada's Chemicals Management Plan (Patterson et al, 2016)

EXHIBIT 1. ATTRIBUTES AND ATTRIBUTE LEVELS

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

Results (\$ per Household per Month)

EXHIBIT 25. CONDITIONAL LOGIT MODEL - IMPLIED WILLINGNESS-TO-PAY TO AVOID ADVERSE EFFECTS OF CHEICALS

Remove chemicals that ...	Implied WTP
... are carcinogenic to humans	\$49.23
... are toxic to non-human organisms	\$41.06
... affect soil quality	\$37.42
... affect water quality	\$37.22
... affect air quality	\$35.76
... are persistent in air water or soil	\$28.83
... have adverse effects on the lungs, heart, or other aspects of the respiratory or circulatory systems in humans	\$26.64
... bioaccumulate	\$25.66
... adversely affect a person's ability to conceive a child by damaging reproductive organs or disrupting physiological processes related to reproduction	\$23.73
... increase the likelihood of birth defects or adversely affect the normal growth and development of a human foetus or child	\$17.54



What we need to do better: market valuation of chemicals policies

Opportunity costs of a ban: market net consumer and producer surplus and non-market value difference (accounting for substitutes)

- Don't know the feasible set of substitutes
- Sometimes don't know the health effects (let alone their value)
- Sometimes there are no approved options



What we mostly ignore

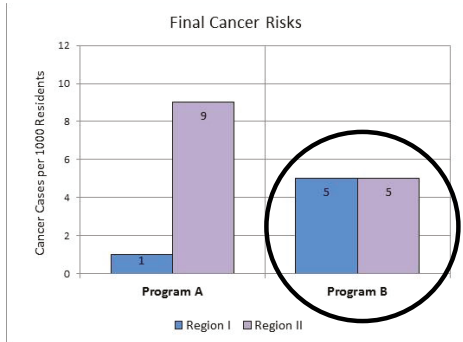
- Equity.
 - Describe
 - Inequality aversion
- Uncertainty In net benefits
- Benefits/costs to other countries:
 - ➔ EPA RIA for CPP: 10/15:



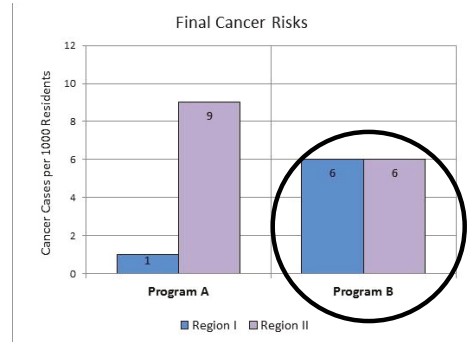
Inequality Aversion (Cropper et al, 2016)

- Assume an individual has a utility function defined over the distribution of health risks in a society.
- The Equally Distributed Equivalent risk (EDE) is the amount of risk which, if equally distributed, yields the same utility as the existing distribution of risk.
- For the Atkinson SWF over bads (Sheriff & Maguire):
 - $EDE = mean\ risk * (1+A')$, where A' is the Atkinson inequality index for health risks
 - A' can be interpreted as the proportionate increase in average risk a person would accept if the remainder were distributed equally





	Program A	Program B
Final risk for Region I	1 in 1000	5 in 1000
Final risk for Region II	9 in 1000	5 in 1000
Total cancer cases per 1000 residents	10	10

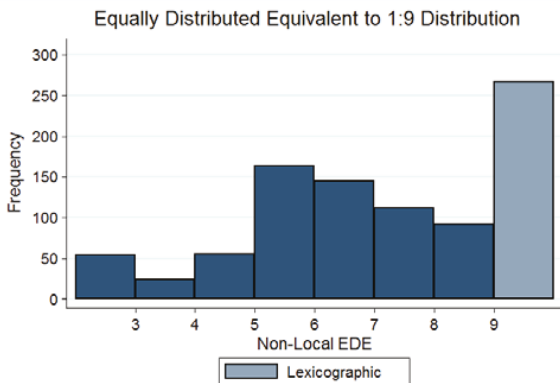


	Program A	Program B
Final risk for Region I	1 in 1000	6 in 1000
Final risk for Region II	9 in 1000	6 in 1000
Total cancer cases per 1000 residents	10	12



Results

Home on the range (Krupnick, Morgenstern, Nelson, 2005)



“A big part of my frustration was that scientists would give me a range. And I would ask, ‘please just tell me at which point you are safe, and we can do that.’ But they would give a range, say from 5 to 25 parts per billion (ppb). And that was often frustrating.”

Christine Todd Whitman, quoted in Environmental Science and Technology Online, April 20, 2005



FIGURE 1
Probability that Policies Produce Net Benefits in 2025
Comparison of Tight and Intermediate NOx Caps

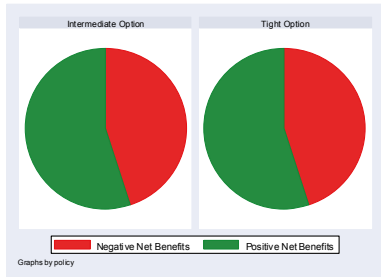


FIGURE 2

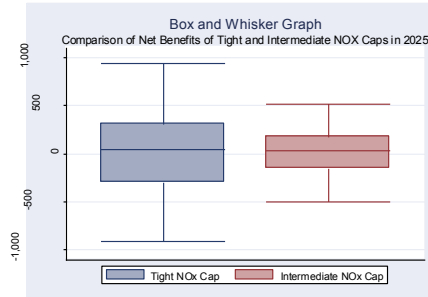


FIGURE 3

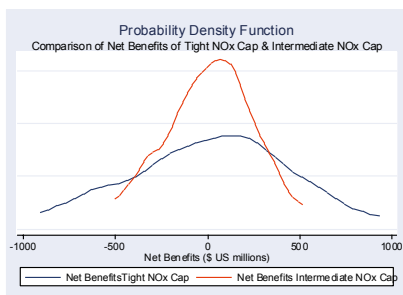
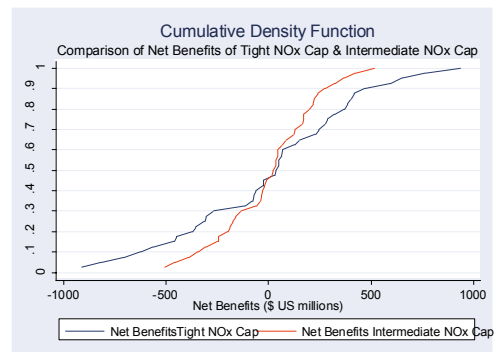
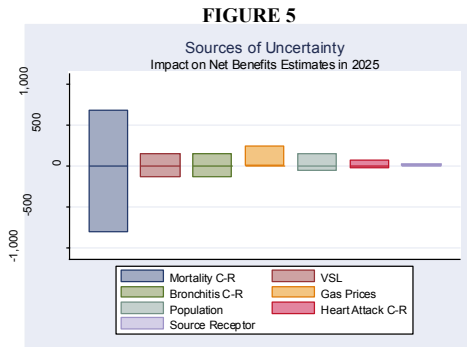


FIGURE 4



Cumulative Density





Communicating uncertainty - conclusions

- Pdf preferred
- CDF did not fare well
- Tables preferred over box and whisker
- Sources of uncertainty not of equal weight
- Preference for CEA or even discussion



RIA for CPP (EPA, 2015)

Table ES-9. Monetized Benefits, Compliance Costs, and Net Benefits Under the Rate-based Illustrative Plan Approach (billions of 2011\$) ^a

	Rate-Based Approach					
	2020		2025		2030	
Climate Benefits ^b						
5% discount rate	\$0.80		\$3.1		\$6.4	
3% discount rate	\$2.8		\$10		\$20	
2.5% discount rate	\$4.1		\$15		\$29	
95th percentile at 3% discount rate	\$8.2		\$31		\$61	
	<u>Air Quality Co-benefits Discount Rate</u>					
	3%	7%	3%	7%	3%	7%
Air Quality Health Co-benefits ^c	\$0.70 to \$1.8	\$0.64 to \$1.7	\$7.4 to \$18	\$6.7 to \$16	\$14 to \$34	\$13 to \$31
Compliance Costs ^d	\$2.5		\$1.0		\$8.4	
Net Benefits ^e	\$1.0 to \$2.1	\$1.0 to \$2.0	\$17 to \$27	\$16 to \$25	\$26 to \$45	\$25 to \$43



Domestic SCC: 7-23% of global value

What “we” do but shouldn’t

- “We do so little, so we better keep doing it.” Arthur Fraas, formerly of OMB
- RP dominant over SP (a US problem)
- Casual approach to “unknown costs”



“Process” recommendations/suggestions

1. Need clear decision rules for CBA and legislative requirements where necessary. EO12291 issue
2. Outside peer review; linking to literature; raising standards to academic levels
3. CBA early in process even dictating info needed (matching RA)
4. Expand set of policy options
5. More money for analysis
6. Emphasize best estimates (not worst cases) of physical consequences and also emphasize CEA in certain cases
7. More retrospective analyses



Triumphs and Troubles

Triumphs

- BCA becoming ever more legitimate within governments
- Health valuation becoming more legitimate – primarily because of huge valuation benefits – environmental community sold
 - BUT: Health science community is a tough sell

Troubles

- Continued Issues with VSL/VSLY in many directions
- Equity
- Institutional Issues
- tribulation



Questions? Contact Krupnick@RFF.org

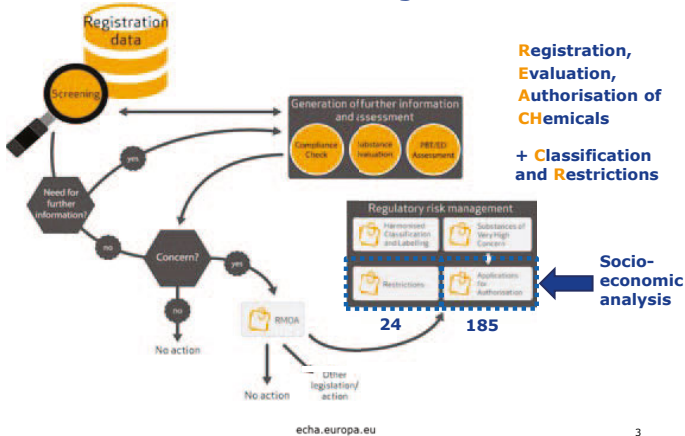
Overview in analysing the costs and benefits of applications of authorisation and restrictions under REACH

Matti Vainio
European Chemicals Agency
Risk Implementation Unit

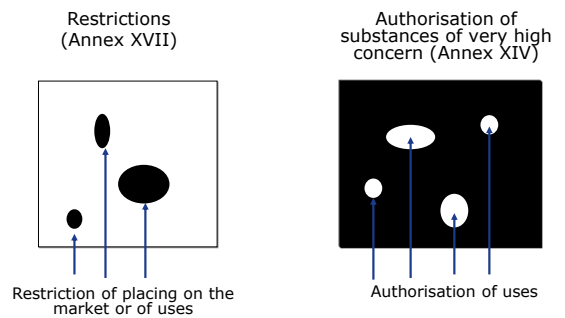
Outline

1. REACH and its processes
2. Costs and benefits of applications for authorisation
3. Costs and benefits of restrictions
4. Conclusions

Risk management in EU's chemicals regulation



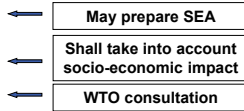
Relationship between Restrictions and Authorisations



SEA in restrictions and authorisations

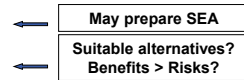
Restrictions (Title VIII)

- Member State (or ECHA) prepare a Restriction dossier
- [SEAC and RAC give opinions](#)
- Commission decides (comitology)



Authorisation (Title VII)

- Substance is placed on Authorisation list (Annex XIV of REACH)
- Companies apply for authorisation
- [SEAC and RAC give opinions](#)
- Commission decides (comitology)



Health and environmental impacts analysed

Adverse health effects

- Premature death: cancer, internal organ failures
- Dermatitis, burns, eye problems and breathing difficulties, decreased lung functioning, fractures,...
- Neurotoxic and neurodevelopmental effects (e.g. decrease in IQ)
- Infertility, birth weight,...

Environmental damages

- Ecosystem's function and services, biodiversity, water quality
- General PBT concern (unknown impacts)

Further aspects

- Avoided legal costs
- Avoided loss of consumer surplus
- Avoided restoration costs



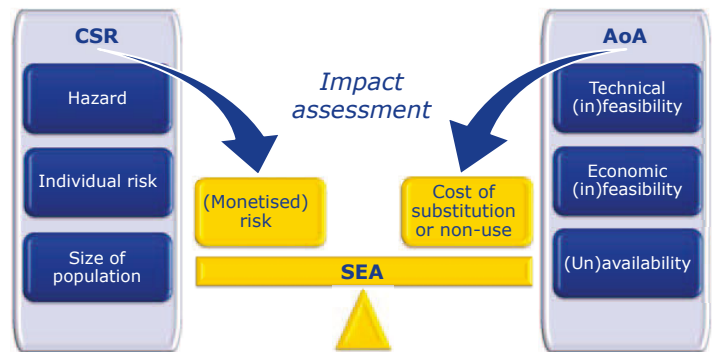
Calculating costs

- Changes in production costs
 - Investment and operating costs
- Change in the characteristics of the good
- Treatment of residual value of capital
- Ensuring that only additional costs are included
- Distinguish between social and private costs
- Recommended discount rate: 4%
- Use either annualised or cumulative cost approach



Source: Appendix I Calculation of compliance costs

Links between Chemical Safety Report (CSR), Analysis of Alternatives (AoA) and SEA



Costs and benefits of applications for authorisation



Why is SEA made in authorisations?

European Commission **needs** SEA information:

- "...authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies."

REACH Article 60(4)

ECHA **shall** formulate draft opinion within 10 months:

- "The draft opinions shall include [...] an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives [...]."

REACH Article 64(4)(b)



185 applications for authorisations have been submitted to date (all with SEA)

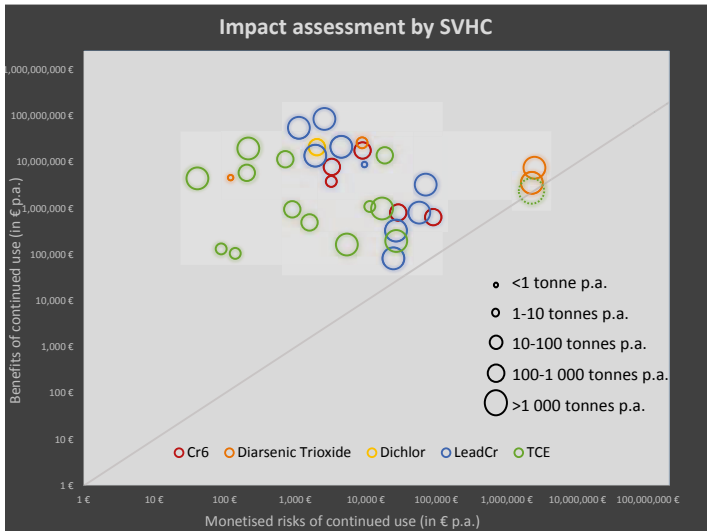
	Submitted applications (applicants)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and per applicant	Commission decisions per use and per applicant
2013	8 (10)	17	1	1	0
2014	19 (33)	38	30	34	2
2015	7 (20)	13	25	51	10
2016	78 (133)	117	5	6	29
Total	112 (196)	185	61	92	41



NUMBER OF APPLICANTS PER COUNTRY

Germany	56	Austria	3
France	27	Ireland	3
UK	21	Belgium	2
Netherlands	21	Hungary	2
Finland	13	Luxembourg	2
Italy	12	Portugal	2
Spain	7	Greece	1
Poland	5	Norway	1
Czech Republic	4	Romania	1
Sweden	4		





Example of interacting AoA and SEA to substitute: Yara – diarsenic trioxide

- **Use:** Decarboxylation step of ammonia production
- **Original proposal:** Complex reconstruction of plant (requiring 7 years) to switch to amino solution
- **AoA:** Substitution possible with Vanadium pentoxide
 - Alternative found in BREFS (BATs);
 - Originally discarded because C2 but process uses non classified Vanadium potassium carbonate
 - Substance much more compatible with existing installation – transition possible in 2.5 years
- **SEA:** Faster substitution = Lower cost and lower monetised health risk

Source: EPPA at workshop on SEA, Brussels 29 June 2016

Costs and benefits of authorisation: preliminary results (work in progress)

- Applicants estimated the average benefit of authorised use at €50m per year
 - SEAC considered that some benefit categories were not relevant (ref. Employment): benefits around €10m per year
- Applicants estimated the average monetised risks of authorized use at €0.14m per year
 - This was considered somewhat lower by RAC and SEAC
- Methodological issues were identified:
 - Many applicants view costs of non use high (cf. employment)...
 - ... but have difficulties in analyzing the impacts for the whole supply chain
 - With dose-response functions made public in advance, monetised risks were estimated...
 - ... still prone to over or under estimations (e.g. man via the environment)

Costs and benefits of restrictions



Why is SEA made in restrictions?

Member States **may** prepare a SEA:

- "The socio-economic impacts of the proposed restriction **may** be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction **may** be compared to its net costs [...]."

REACH Annex XV

ECHA **shall** formulate an opinion:

- "Any [...] decision [of restriction proposal] **shall** take into account the socio-economic impact of the restriction, including the availability of alternatives." REACH Article 68.1

24 restriction proposals submitted (with SEA information)

	Submitted by Member States	Submitted by ECHA	RAC-SEAC opinions	Commission decisions
2009	0	0	0	0
2010	3	1	0	0
2011	1	0	4	0
2012	1	1	1	4
2013	3	1	2	0
2014	4	2	4	3
2015	3	0	6	2
2016	2	2	2	2
Total	17	7	19	11

Restriction: recent and future work

2015

- DecaBDE (ECHA): used in textiles and plastics (September 2015)
- PFOA and related C8 substances (DE): many uses (December 2015)
- BPA (FR): Use in thermal paper (December 2015)

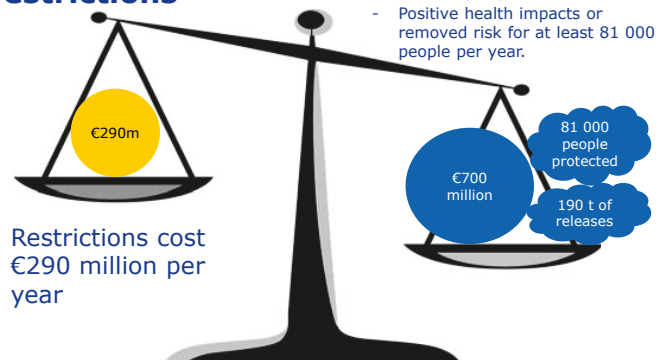
2016

- Methanol (PL): in windshield washing fluid (March 2016)
- D4/D5 (UK): use in cosmetic products washed off with water (June 2016)
- TDFA (DK): use in spray products (ongoing)
- Phthalates (ECHA/DK): use in articles (ongoing)
- DMF (IT): industrial and professional uses inc. articles (submission 7/2016)
- Isocyanates (DE): industrial and professional uses (submission 10/2016)
- Lead (ECHA): stabilisers used in PVC (submission late 2016)

2017

- Lead (ECHA): shot used in wetlands (submission in mid 2017)
- CMRs/sensitisers (ECHA): used in in Tattoo inks and permanent make up (submission late 2017).

Costs vs. benefits of restrictions



- Benefits of restrictions include
- Health impacts equivalent to over €700 million per year, **and**
 - Reduction of 190 tonnes of releases of substances of concern per year, **and**
 - Positive health impacts or removed risk for at least 81 000 people per year.

Experiences

- Some Member States considered the preparation of the restriction proposals too burdensome
 - Getting market information surprisingly (?) difficult
 - Preparing SEA has been a new aspect brought by REACH
 - Restriction Efficiency Task Force addressed these
- Applications for applicants have been a challenge to some
 - Information asymmetry
 - Consultants are learning fast (by doing)
 - Task Force for the workability of Applications is addressing challenges,
 - in particular how manufacturers and importers can apply in a meaningful manner
- ECHA's committees have learned fast (also from each other), increased capacity
 - Developed tools to streamline work (dose-response functions, checklists, opinion trees etc.)

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Conclusions

- Socio-economic analysis is key requirement under REACH—a “living laboratory” of CBA:
 - Over 20 restriction cases
 - Almost 200 applications for authorisation
- Practical methodologies developed
 - Willingness to pay for relevant health endpoints (incl. cancer)
 - Dose-response functions for many SVHC
 - Other practical advice (e.g. on how to treat unemployment)
- Capacity building
 - Seminars, workshops, guidance... for Member States and applicants
 - Risk Assessment and Socio-economic Analysis Committee learn (also from one another)
 - In applications, consultants and advisors cumulate knowledge
 - Network on REACH SEA and Analysis of Alternatives Practitioners (NeRSAP)
- International collaboration

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Thank you!

Credits:

Mark Blainey, Sanna Henrichson, Kalle Kivelä, Elna Liopa, Thierry Nicot, Jukka Peltola, Daniele Pennese, Christoph Rheinberger

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Bisphenol A in Thermal Paper

Experiences from a REACH restriction case

Thea Marcelia Sletten - Norwegian Environment Agency
SEAC Co-Rapporteur

Backdrop on BPA in thermal paper

- BPA is used as a dye developer in thermal paper
- Thermal paper is mostly applied for point-of-sale receipts and self-adhesive labels
- People get exposed to BPA through the handling of point-of-sale receipts
- France found a risk, from BPA in thermal paper, to the unborn child of cashiers and consumers in the EU
 - ➔ Proposed an EU wide restriction



Regretful substitution

Will industry substitute to a safer alternative?

- Three alternatives were evaluated by France (BPS, D8 and Pergafast)
- The cheapest alternative (BPS) was suspected to have similar hazardous properties as BPA
- If all industry actors switched to BPS, no certain risk reduction would be achieved
- No indication of how large part of industry would actually choose a safer alternative, and thus ensure a risk reduction from the restriction



Will industry substitute to a safer alternative?

- In the worst case, all industry actors would choose BPS
- Under this worst case scenario, it would be unlikely that a EU-wide restriction is a proportionate measure
- In the best case, all actors would switch to less hazardous alternatives.
- Best case scenario taken forward for the proportionality assessment



Analysis under information constraints

RAC's method and result

- Data for the relevant endpoints did not allow establishing dose-response relationships
- Alternative approach using a composite DNEL to account for the possible risk to multiple endpoints
- **RAC concluded there was no risk to consumers, but that there was a risks for cashiers (RCR>1).**
- The resulting risks did not relate to one specific endpoint, and the likelihood of observing effects could not be established



SEAC's choice

- The dose-response relationships could not be used for impact assessment
- SEAC had no information regarding the expected impacts, and thus no benefits to be compared with the costs of the restriction.

Two possible ways forward:

- A. Conclude that France had not shown that the cost were proportionate to the risk?
- B. Try to use the information at hand to arrive at a more informed conclusion



Available information

- Cost estimated to be between €43 - €151 million per year, with a central estimate of €86 million per year.
- The population at risk: ~ 80 000 fetuses per year
- Five endpoints representing possible adverse effects
 - Mammary gland
 - Immunotoxicity
 - Female reproductive system
 - Brain and behaviour
 - Metabolism and obesity



Break-even analysis

1. Proposed representative adverse effects for each endpoint and unit costs (WTP) for avoiding said effects
2. Allocated a share of the costs to each endpoint
3. Calculated the necessary number of cases of each adverse effect
4. Used the population at risk to derive corresponding occurrence rates
5. Evaluated the probability of BPA in thermal paper being able to caused the calculated occurrence rates



Results from the break-even analysis

Central estimates for the necessary occurrence rates from BPA in thermal paper, for the costs to be off-set

- Mammary gland: $\sim 10^{-2}$
 - Immunotoxicity: $\sim 10^{-2}$
 - Female reproductive system: $\sim 10^{-2}$
 - Brain and behaviour: $\sim 10^{-1}$
 - Metabolism and obesity: $\sim 10^{-1}$
- With advise from RAC, SEAC concluded that it was unlikely that such high occurrence rates would be caused by BPA in thermal paper



SEAC's final conclusions

- Still remaining large remaining uncertainties
 - Additional considerations
 - The safer alternatives was considered affordable
 - The group at risk was a particular vulnerable one
- The proposed restriction was considered unlikely to be proportionate. However, there may be favorable distributional and affordability considerations.



Lessons learned

- A realistic analysis of alternatives is important to avoid regretful substitution
- Substances for which (some of the) health effects are not well understood are difficult to regulate under the standard benefit-cost paradigm
- Break-even analysis, though the last resort, can be a helpful tool for providing a new perspective on a case
- **Collaboration between risk assessor and economists is necessary to maximize the information utilisation**



Thank you

Backup



Overview of the process



Restriction dossier received

- Risk reduction analysis
- Socio economic analysis



RAC & SEAC scrutiny

- Public consultation
- Discussions and opinion development
- Joint opinion sent to the Commission



Commission decision

- xxx
- xxx

Will industry substitute to safer alternatives?

Proportionality

- Two extreme cases constructed for illustrative purposes

- 1) Worst case scenario: 100% transfer from BPA to BPS

- Close to zero benefits
- Expected costs: €1.4 million per year

- 2) Best case scenario: 0% transfer from BPA to BPS

- RCR for workers between 1 and 2
- Expected costs: € 43 million - €151 million



Results from the break-even analysis

Absolute risk reduction necessary to offset the cost				
Endpoint	Cost division	low cost - high WTP	medium cost - medium WTP	high cost - low WTP
Mammary gland*	20 %	2 %	7 %	162 %
Immunotox	20 %	0.6 %	2 %	5 %
Neurobehavior	20 %	0.4 %	3 %	16 %
Reprotox*	20 %	7 %	20 %	70 %
Metabolic	20 %	4 %	12 %	41 %

→ With advise from RAC, SEAC concluded that it was unlikely that such high occurrence rates would be caused by BPA in thermal paper



Will industry substitute to a safer alternative?

- Evidence from consultation with industry suggested that even though BPS is the cheapest alternative, many actors would nevertheless switch to a more expensive alternative with less hazardous properties.
- No indication of how large part of industry would actually choose a safer alternative, and thus ensure a risk reduction from the restriction



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

OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management

July 6, 2016

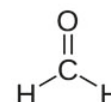
U.S. Environmental Protection Agency

1



Formaldehyde in consumer products

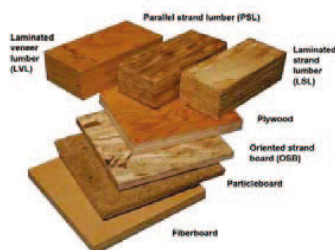
- Formaldehyde is a known human carcinogen. It can also cause eye, nose, and throat irritation, as well as cause respiratory symptoms.
- Many household products emit formaldehyde. These include glues, permanent press fabrics, carpets, antiseptics, medicines, cosmetics, dishwashing liquids, fabric softeners,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



2



Some examples of composite wood products



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.

3



Regulatory development history

- 1980s U.S. Environmental Protection Agency (EPA) began investigating consumer exposure to formaldehyde from composite wood products.
- 2001 California Air Resources Board (CARB) began evaluating methods to reduce formaldehyde emissions from composite wood products.
- 2008 CARB issued Air Toxics Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products.
- 2008 EPA was petitioned to adopt the CARB standards nationally. The Agency began a new investigation into whether action might be appropriate to protect against risks posed by formaldehyde emitted from composite wood products.
- 2010 The Toxic Substances Control Act (TSCA) was amended to establish formaldehyde emission standards for composite wood products that are identical to the CARB standards. Congress directed EPA to consider a number of elements for inclusion in the implementing regulations, many of which are aspects of the CARB program.
- 2013 EPA published a proposed rule for public comment.
- 2016 EPA anticipates publishing a final rule.

4



External Forces: Hurricanes Katrina and Rita

- Hurricane Katrina hit the Gulf Coast in 2005. Hurricane Rita followed in 2008.
- Severe damage to many homes.
- The Federal Emergency Management Agency (FEMA) provided temporary housing: approximately 100,000 trailers.
- Many complaints about formaldehyde levels in these trailers.



5



California Formaldehyde Rule

- The California rule establishes formaldehyde emission limits for 3 types of composite wood panels (hardwood plywood, particleboard and 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.
- Chain of custody requirements for panels and finished goods apply to panel manufacturers, distributors, importers, fabricators, and retailers. Requirements include product labeling and record keeping.
- Requirements apply to products whether they are produced in California, elsewhere in the U.S., or outside the U.S.
- The California rule became a *de facto* national standard in the U.S., and affected production throughout the world.



6



Federal Regulation of Formaldehyde by U.S. EPA

- In 2010, the U.S. Congress passed legislation amending the Toxic Substances Control Act (TSCA).
- The statute directs EPA to implement regulations establishing a national formaldehyde program modeled on the California rule, including identical emission standards.
- EPA published a proposed rule in 2013 and expects to publish a final rule this year. The rule and the supporting analyses are still being developed and undergoing review.

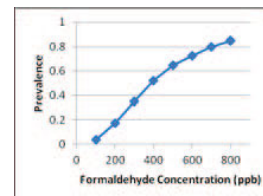


7



Determining dose-response functions to estimate health benefits

- EPA identified 9 categories of health effects associated with formaldehyde exposure.
- Only 2 of these were judged to have sufficient data for quantitative concentration-response modeling in support of the benefits assessment. Other endpoints were discussed qualitatively.
- There are often disputes about the shape of the dose-response curve, particularly at low doses.
- Benefits that can be quantified and monetized often receive more weight in decision-making. Unquantified benefits can lead to sub-optimal rule stringency.



8



Valuing reductions in fatal cancer risk

- EPA generally calculates the benefits of reducing the risk of death using the value of a mortality risk (VMR), which is calculated from the value of a statistical life (VSL).
- EPA's standard VSL estimate is based on a review of relevant wage-risk analyses of labor markets, as well as several contingent valuation studies.
 - The risks in these studies tend to be dominated by deaths associated with accidents or other immediate causes.
 - Thus the VMR reflects the willingness to pay (WTP) to reduce the risk of an immediate, accidental death with no additional complications.
- An individual's WTP does not include costs borne by others, such as medical costs paid by health insurance or government programs.
- So EPA's VMR does not represent the total benefit of reducing the risk of a lengthy illness with significant medical costs (e.g., cancer fatality).
 - As a result, EPA's VMR estimate is likely to underestimate the benefits of avoiding cancer fatalities.
- Ongoing discussion with our Science Advisory Board about how to address this.

9



Benefits of labeling, recordkeeping, and other administrative requirements

- 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.
- Even though many of these provisions were similar or identical to California's requirements, information was not available to quantify how much they contribute to the effectiveness of the rule.
- EPA's analysis quantified costs for many of these provisions, but not benefits.
- In general, the inability to quantify the benefits of many provisions makes options with less stringent requirements look artificially attractive.

U.S. Firms Subject to TSCA Formaldehyde Rule



10



Assessing substitutes

	<u>Simpler</u>	<u>More Complex</u>
Benefits of the Rule	Hazard comparison	Risk comparison Monetization
Costs of the Rule	Purchase price Equipment changes Energy usage Disposal costs	Learning curve Product quality Performance characteristics Technological innovation
Assessment Focus	Individual chemical	Sectors/Processes (multiple chemicals)

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For more information

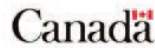
- Formaldehyde rulemaking docket at [Regulations.gov](http://www.regulations.gov)
- Docket number EPA-HQ-OPPT-2012-0018
 - This docket contains the proposed rulemaking, technical support documents, public comments, etc.
 - The Economic Analysis for the proposed rule is at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0484>

12



Doing CBA for CMP Regulations: Canadian perspectives

Michael Donohue, Health Canada
Joe Devlin, Environment and Climate Change Canada
Helsinki, July 2016



Outline

A Canadian perspective on CBA for CMP regulations:

- 1) Outline the cost-benefit analysis (CBA) framework for regulations published by the Government of Canada
- 2) Examine two case studies, which reflect the recent work Health Canada (HC) and Environment and Climate Change Canada (ECCC) have performed under the Chemicals Management Plan (CMP)
- 3) Review the CBA framework, identify some key challenges and questions for improving CBA for CMP regulations

Canada



Population:
36 million

GDP: \$1.8 trillion USD

GDP per capita:
\$52 000 USD

Federal Policies & Tools

When determining whether and how to regulate, departments and agencies are responsible for assessing the benefits and costs of regulatory and non regulatory measures. This analysis should include quantitative measures and, when it is not possible to quantify benefits and costs, qualitative measures.

The Cabinet Directive on Regulatory Management (2012)

Bisphenol A (BPA): A Case Study

The science says:

- Use in Canada has declined significantly, from about 12 kilotonnes per year in 1986, to under 1 kilotonne in 2006.
- There is evidence that **low-level exposure** to BPA particularly at sensitive life cycle stages, may lead to permanent alterations in hormonal, developmental or reproductive capacity.
- In laboratory testing, these effects have occurred within the range of concentrations measured in Canada, indicating that there is potential for adverse effects in populations, particularly close to point sources.

Therefore, it is concluded that Bisphenol A should be classified as a toxic substance, based on threats to human health.

Page 5 – June 29, 2016

Bisphenol A (BPA): A Case Study

What we did about it...

Ban it! Baby bottles containing BPA are no longer allowed to be imported into or sold in Canada.

Page 6 – June 29, 2016

Bisphenol A (BPA): A Case Study

Quantified Costs: \$2.2 million

- Cost to industry: \$0. Industry has already phased it out.
- Cost to consumers: \$2.2 million PV, if they buy new baby bottles to replace existing ones

Page 7 – June 29, 2016

Bisphenol A (BPA): A Case Study

Unquantified Benefits

- Bisphenol A is potentially harmful to the neurological and behavioural development of newborns and infants.
- Given [the health science], it is considered appropriate to apply a precautionary approach when characterizing risk. The prohibition will eliminate the risk from this source altogether.
- Health Canada is proceeding with the prohibition as it is considered the most effective option to reduce the exposure to bisphenol A to newborns and infants.

Total benefits to this initiative are expected to justify the costs.

Page 8 – June 29, 2016

Mercury: A Case Study

The science says:

- Canadian mercury emissions have already been reduced by roughly **90%** since the 1970s through aggressive action to curb industrial emissions.
- Methyl mercury, a very harmful organic substance, is of particular concern since it can build up in living organisms through their surrounding environments as it moves up the food chain.
- **Human exposure** to mercury can cause brain, nerve, kidney, lung or cardiovascular damage, or — in extreme cases — coma or death. Exposure can be quantified as the risk of the percentage (%) releases to air.

Page 9 – June 29, 2016

Mercury: A Case Study

What we did about it...

Prohibited the manufacture and import of all products containing mercury (with some exemptions and permits where applicable) as of 2015.

Page 10 – June 29, 2016

Mercury: A Case Study

Quantified Costs: \$9 million (over 19 years; 2014-2032)

- Estimated increased cost of products with more expensive inputs: \$5.5 million
- Administrative costs: \$1.4 million
- Costs to government: \$2.1 million

Page 11 – June 29, 2016

Mercury: A Case Study

Quantified Health Benefits: \$18 million

Assuming that there is no lower threshold with respect to the **negative impacts** of mercury on brain development, these authors estimate benefits of \$10,000 to \$11,000 per kg of emissions avoided.

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.

Total benefits of this regulation are expected to justify the costs.

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Summary: CBA Framework



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Quantitative Risk Assessment

Challenges

Although a qualitative risk assessment is always performed for regulations under CMP, certain issues persist with quantifying risk...

- The links between reduced human exposure and reduced health risks cannot be quantified in certain cases, due to a lack of data
- Even when willingness-to-pay (WTP) estimates are available, there may be a lack of information on other factors such as the number, location and quality of the receiving environment, which prevents the monetization of total benefits
- The **precautionary principle** is the principle rational for putting regulations in place when there is insufficient evidence or data

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Summary RIAS Table

Regulations	Year	Impact	Risk (Q)	Reduction (Q)	Costs (\$)	Benefits (\$)
PCB	2008	High	✓	✓	✓	✓
2-BE	2006	Medium		✓	✓	
Chromium	2009	Medium	✓	✓	✓	✓
Prohibition	2013	Med		✓	✓	
Mercury	2014	Medium	✓	✓	✓	✓
Prohibition Amendments (2-ME)	2006	Low	✓	✓	✓	✓
PFOS	2008	Low	✓	✓	✓	✓
PBDE	2008	Low			✓	
Phosphorus Amendments	2009	Low		✓	✓	
PCB Amendments	2014	Low		✓	✓	
Prohibition Amendments (HBCD)	2015	Low		✓	✓	
ODSHAR	2015	Low				

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Conclusion(s)

From a Canadian perspective:

- We can almost always estimate costs and quantities
- We can value benefits when we have quantified risks
- We don't always have quantified risks

Questions for Discussion

1. What do we need in order to perform more robust risk analyses?
2. What research could best address data gaps regarding valuation?
3. When can we use CBA alternatives such as cost-effectiveness analysis or break-even analysis?

Thank You!

Comments/Questions?

Special credit to Margot McComb (one of our ECCC economics graduate students) who worked tirelessly and without complaint on 44 versions of this presentation

Appendices

Additional information on CBA work performed under CMP in Canada

CMP Regulations 2006-2010¹

Regulations under CMP (2006-2009)	Abbreviation	Year	Impact
Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-ME)	Prohibition Amendments (2-ME)	2006	Low
2-Butoxyethanol Regulations	2-BE	2006	Medium
Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations	PFOS	2008	Low
Polybrominated Diphenyl Ethers Regulations	PBDE	2008	Low
Polychlorinated Biphenyls Regulations	PCB	2008	High
Chromium Electroplating, Chromium Anodizing and Reverse Etching Regulations	Chromium	2009	Medium
Regulations Amending the Phosphorus Concentration Regulations	Phosphorus Amendments	2009	Low

¹ This table excludes regulatory proposals with only administrative costs as well as SNAc Orders and additions to Schedule 1

CMP Regulations 2011-2015¹

Regulations under CMP (2010-2015)	Abbreviation	Year	Impact
Prohibition of Certain Toxic Substances Regulations, 2012 (BNST)	Prohibition	2013	Medium
Regulations Amending the PCB Regulations and Repealing the Federal Mobile PCB Treatment and Destruction Regulations	PCB Amendments	2014	Low
Products Containing Mercury Regulations	Mercury	2014	Medium
Regulations Amending the Prohibition of Certain Toxic Substances Regulations (HBCD)	Prohibition Amendments (HBCD)	2015	Low
Ozone-depleting Substances and Halocarbon Alternatives Regulations	ODSHAR	2015	Low

¹ This table excludes regulatory proposals with only administrative costs as well as SNAC Orders and additions to Schedule 1

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Monetized Impacts

Regulations	Year	Impact	Benefits (M\$)	Costs (M\$)
PCB	2008	High	317.0	365.0
2-BE	2006	Medium		17.0
Chromium	2009	Medium	58.5	18.8
Prohibition	2013	Medium		20.0
Mercury	2014	Medium	18.0	9.0
Prohibition Amendments (2-ME)	2006	Low	33.4	-3.0
PFOS	2008	Low	6.4	6.0
PBDE	2008	Low		0.2
Phosphorus Amendments	2009	Low		0.2
PCB Amendments ²	2014	Low		-0.1
Prohibition Amendments (HBCD)	2015	Low		2.4
ODSHAR	2015	Low		

² Note: For the purpose of this presentation, cost and benefits for the PCB Amendments are reversed. The PCB Amendments extends an exemption period (costs are to the environment and benefits are to industry).

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Overview – CBA Framework

➤ Three components are crucial to the estimation of benefit impacts:



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Summary of CBA Benefit Estimations

Regulations	Year	Impact	Release	Risk	Benefits (\$)
PCB	2008	High	✓	✓	✓
2-BE	2006	Medium	✓		
Chromium	2009	Medium	✓	✓	✓
Prohibition	2013	Med	✓		
Mercury	2014	Medium	✓	✓	✓
Prohibition Amendments (2-ME)	2006	Low	✓	✓	✓
PFOS	2008	Low	✓	✓	✓
PBDE	2008	Low			
Phosphorus Amendments	2009	Low	✓		
PCB Amendments	2014	Low	✓		
Prohibition Amendments (HBCD)	2015	Low	✓		
ODSHAR	2015	Low			

Topic #1: Quantity

- Regulations under CMP mostly focus on reducing the **release of substances** into the environment
- This environmental discharge is commonly categorized as releases to air, soil and water
- Releases are quantified where possible

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Quantified Release Estimates

Regulations	Impact	Release Reduction Estimates (tonnes)	Elimination Ratio (Regulation/BAU)
PCB	High	1.7	100%
2-BE	Medium	159.0	88%
Chromium	Medium	31.0	4%
Prohibition	Medium	200.0	100%
Mercury	Medium	4.1	68%
Prohibition Amendments (2-ME)	Low	9625.0	100%
PFOS	Low	88.6	100%
PBDE	Low		Preventative Elimination
Phosphorus Amendments	Low	28 400.0	Partial Elimination
PCB Amendments ³	Low		
Prohibition Amendments (HBCD)	Low	0.4	100%
ODSHAR	Low		

³ PCB Amendments cause a release to the environment, rather than a reduction of releases (0.9 kg).

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Topic #2: Risk

- Risk assessments are performed in order to determine the health and environmental risks associated with a specific activity
- A quantitative risk assessment is *critical* to the valuation process in order to link quantity to value
- This is because the **value** of a chemical reduction is related to both the **quantity** of the chemical reduction and the risks posed by **exposure** to the chemical

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Quantified Risk Assessment Completed

Regulations	Year	Impact	Risk Assessment
PCB	2008	High	Yes
2-BE	2006	Medium	
Chromium	2009	Medium	Yes
Prohibition	2013	Medium	
Mercury	2014	Medium	Yes
Prohibition Amendments (2-ME)	2006	Low	Yes
PFOS	2008	Low	Yes
PBDE	2008	Low	
Phosphorus Amendments	2009	Low	
PCB Amendments	2014	Low	
Prohibition Amendments (HBCD)	2015	Low	
ODSHAR	2015	Low	

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Quantitative Risk Assessment Challenges

Prohibition Regulations, 2012

- The willingness-to-pay (WTP) for a marginal improvement in water quality for aquatic species, estimated between \$3.07 to \$6.89 annually, was found based on a meta-analysis of 30+ U.S. studies
- However, total monetized benefits could not be derived from this estimate due to the lack of data on the number, location and quality of receiving environment in Canada

2-Butoxyethanol Regulations

- The links between reduced human exposure and reduced health risks could not be quantified, because of the lack of epidemiological data.

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Topic #3: Value

- The valuation (monetization) of benefits allows for benefits and costs to be compared using a common metric (\$\$\$)
- Benefits are not always monetized in CMP regulations and only selected impacts are monetized
- We have a range of tools for valuing benefits

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Key valuation tools

- 2015 ECCC/HC Willingness-to-Pay study
- Value of a Statistical Life (VSL)
- Environmental Valuation Reference Inventory (EVRI)



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Monetized Benefits

Regulations	Year	Impact	Environment (M\$)	Health (M\$)	Other (M\$)
PCB	2008	High	151.2		
2-BE	2006	Medium			
Chromium	2009	Medium	0.5	58.0	
Prohibition	2013	Medium			
Mercury	2014	Medium		18.0	
Prohibition Amendments (2-ME)	2006	Low		33.4	
PFOS	2008	Low			0.25
PBDE	2008	Low			
Phosphorus Amendments	2009	Low			
PCB Amendments ⁵	2014	Low			
Prohibition Amendments (HBCD)	2015	Low			
ODSHAR	2015	Low			

⁵ Benefits to industry, not the environment, were monetized for PCB Amendments.

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Triage Stage Evaluation

- The Cabinet Directive has developed a triage template to facilitate the early assessment of the expected impacts of regulatory proposals
- *Preliminary cost estimation* is an essential component of this assessment, as it sets out the framework and motivation for the entire CBA (refer to table below)

<input type="checkbox"/> No costs	<input type="checkbox"/> Low costs If less than \$10 million PV or Less than \$1 million annual	<input type="checkbox"/> Medium costs If \$10 million to \$100 million PV or \$1 million to \$10 million annual	<input type="checkbox"/> High costs If greater than \$100 million PV or or greater than \$10 million annual
<input type="checkbox"/> Not quantifiable			

Mercury: A Case Study

- The Products Containing Mercury Regulations (2014) quantify exposure as the percentage of release reductions emitted to the air, since there is lack of scientific evidence regarding the impacts of mercury exposure in landfills
- The sum of avoided releases (21 166 kg) can be broken down between releases to
 - land (80% or 16 882 kg)
 - **air (19% or 4 102 kg)**
 - water (1% or 182 kg)



Costs and benefits of policy instruments to address trichloroethylene

*Presentation at the ECHA/OECD workshop,
Helsinki, July 6 2016*
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1

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FRAM

The Centre for Future Chemical Risk
Assessment and Management at the
University of Gothenburg



2

April 21, 2016 – Sunset date for TCE in the EU

1990ies – Germany - tough emission standards

1996 – Swedish ban on TCE

2000 – Norwegian tax on TCE

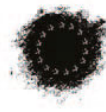
Lessons learned?

8/16/2016

3

European Environment
Doc. No. 10, 200-206 (2001)
ENV. 01.002.001.271

IMPLEMENTATION OF POLICY INSTRUMENTS FOR CHLORINATED SOLVENTS. A COMPARISON OF DESIGN STANDARDS, BANS AND TAXES TO PHASE OUT TRICHLOROETHYLENE



Daniel Slunge¹ and Thomas Sterner²

¹ ERM Scandinavia, Göteborg, Sweden

² Resources for the Future, Washington, and University of Göteborg, Sweden

This paper studies the Swedish
prohibition of trichloroethylene (TCE).
TCE is a common solvent and in some
cases a substitute for solvents such as the
CFCs that were phased out internationally
due to their ozone depletion effect. TCE is

the EU Court of Justice decided in favour
of Sweden's right to have a ban. There are
however clear indications that the ban was
not the best possible policy. It led to
considerable energy being spent on
alternative solutions as a result of the ban.

2016-08-16

Trichloroethylene (TCE) in brief



- A chlorinated solvent mainly used for degreasing in the metal industry and as an intermediate in chemical production
- Total sales in the EU > €100 million per year, used by many small and medium scale enterprises
- Neurotoxic and carcinogenic effects well documented
- Classified as Carcinogenic Category 1B
- Classified as a Substance of Very High Concern and included in Annex XIV ("Authorisation List") of REACH.

2016-08-16

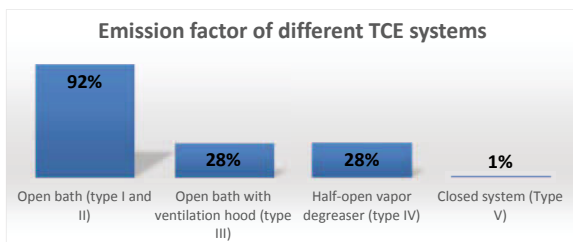
Many alternatives to chlorinated solvents for degreasing metal

- Different combinations of chemicals and mechanical cleaning
- Water-based
- Aqueous cleaners
- Carbon dioxide cleaning
- etc



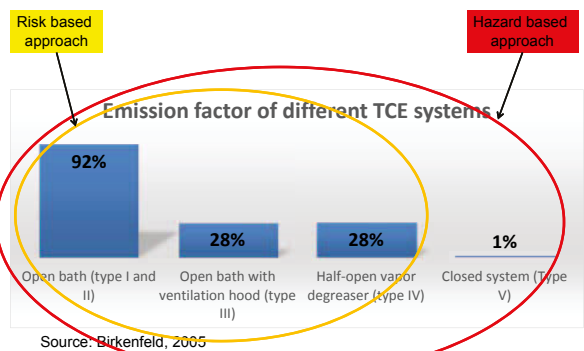
2016-08-16

Emission factor of different TCE systems



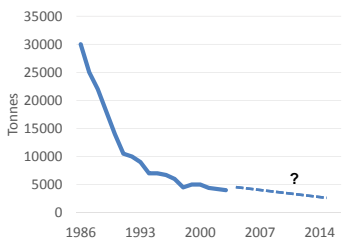
Source: Birkenfeld, 2005

2016-08-16



2016-08-16

Germany – strict emission standards



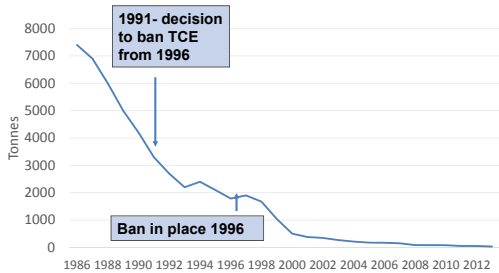
- Large reduction in use in 1990ies when strict emission standards requiring closed systems introduced
- Low damage costs from use
- Incentives for substitution?
- Continued use of TCE after 2003?

2016-08-16

The Swedish Ban against TCE

2016-08-16

Use of TCE in Sweden



2016-08-16

Dagens Industri, November 21, 1994



To the Government Carlsson

We protest!

We are some of several hundred companies who daily use TCE to clean and degrease our products.

Sweden has as the only country in the world decided to ban the use of TCE, despite that this will not lead to any environmental gains and that there are no alternatives available.

Comparable to harakiri.

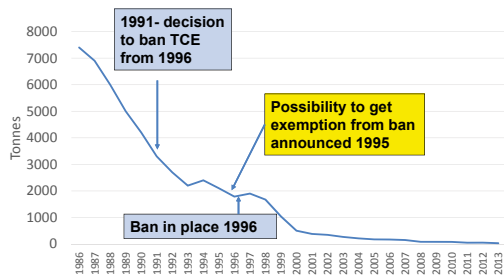
We do not accept an industrial policy which does not allow us to compete with foreign companies on equal grounds.

In a recent survey, more than half of the companies respond that production risks moving abroad or be shut down if the decision to ban TCE is implemented.

Against this background we demand that the

2016-08-16

Use of TCE in Sweden



2016-08-16

Requirements to get exemption from the Swedish ban on TCE

1. Actively search for alternatives
2. No suitable alternatives
3. No unacceptable exposure from use
4. A plan on how to find alternative solutions

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March 2003:
"Anyone who wants get an exemption from the TCE-ban"

103 companies granted exemption from the TCE ban in 2003

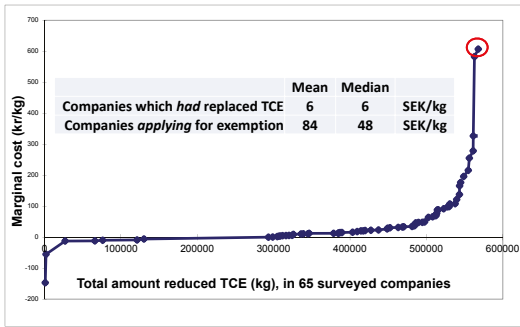
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Swedish TCE ban – 2 Key Problems:

- The reduction in use did not target the companies with largest damage costs
 - Many users with old "open" equipments and high emissions could continue to use TCE several years after the ban
- The reduction in use was not achieved at the lowest possible cost
 - Some companies replaced "closed" equipments at substantial costs
 - Other companies challenged the ban and continued to use TCE, although their cost of reducing TCE would have been low

2016-08-16

Marginal cost of reducing the use of TCE among Swedish companies



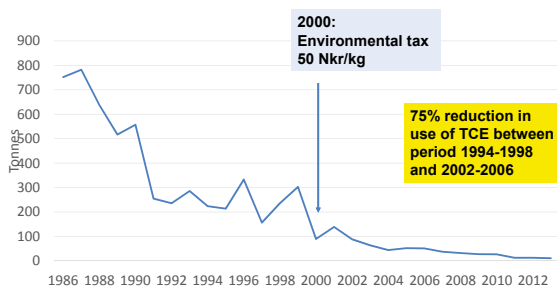
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The Swedish ban against TCE – lessons learned

- Has led to an almost complete phase out of TCE
- Phase out took longer time than expected
- Politically and administratively costly
- Not cost-effective

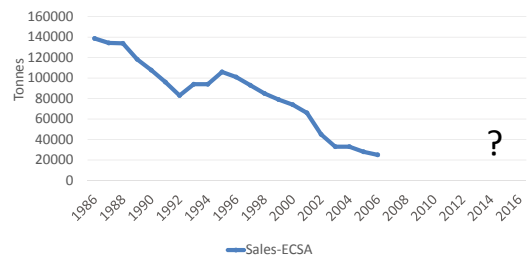
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The Norwegian tax on TCE



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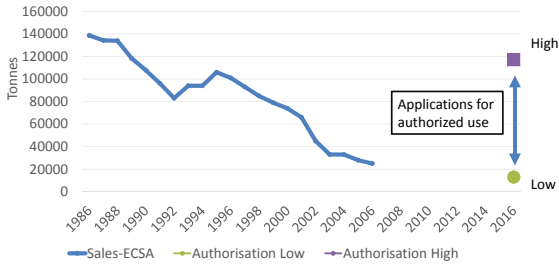
Use of TCE in Europe 1986-2006



Source: ECSA;

2016-08-16

Use of TCE in Europe 1986-2016



Source: ECSA; ECHA

2016-08-16

TCE and REACH

- After the sunset date (21 April 2016) use only allowed with authorization
- The number of TCE using companies that decided to replace TCE and not apply for authorization is not known.
- 19 applications for use of 13 000 -117 000 ton TCE annually
- One applicant applied for authorization for 800 downstream users for 12 years
- Applications reviewed by the ECHA Risk Assessment Committee and the Socio Economic Assessment Committee
- Decisions on authorisation by the European Commission

2016-08-16

www.echa.eu

Adopted opinions and previous consultations on applications for authorisation

This page provides further information on the applications for authorisation that have undergone public consultation. The applications for authorisation are in the public development phase until the final opinion of the Committee for Risk Assessment and Socio-economic Analysis has been adopted and sent to the European Commission. The European Commission's decision-making process can be followed through the consultation register, where further information is available about the REACH Committee's past and upcoming meetings. The European Commission also publishes information about the expected timing of decisions on its website.

1. Applications for authorisation

Case number	Name	EC Number	CAH Number	Applicant(s)	Site name	Status
0019-01	Wichemethalene	201-107-4	79-01-0	Wichem Netherlands Bv	Use of trichloroethylene as a solvent for the removal and recovery of resin from dead ends	Committee decided
0014-02	Trichloroethylene	201-107-4	79-01-0	Wichem Netherlands Bv	Use of trichloroethylene as a solvent in all plants to remove and recycle resin from process water	Committee decided
0010-01	Trichloroethylene	201-107-4	79-01-0	Managroup GmbH	Trichloroethylene used in the manufacturing of polyethylene capillaries for medical purposes	Options allowed
0017-01	Trichloroethylene	201-107-4	79-01-0	INTEK International Limited	Trichloroethylene as an extraction solvent for removal of glycerol and surfactants from the process stream in polyethylene based	Options allowed

Analyzing Stated Costs and Benefits of replacing TCE in the 19 Applications for Authorization under REACH

S.A. Comparison of benefits and risks of continuing Use 1

The analysis finds that the estimated benefits of continuing Use 1 outweigh the associated risks to human health. The benefits of the continued use of TCE are the costs which can be avoided by 130000 tonnes using the PERC alternative. These benefits are estimated to be approximately (PV) 2016-27) and arise due to the estimated costs of the user scenario:

- Capital cost of building new de-waxing production lines which use PERC instead of TCE (PV)
- Higher operating costs of using PERC instead of TCE (PV) and
- Low value-added from new paint production until the new production lines using PERC are operational (PV)

The costs of the risks to human health from continued use of TCE in Use 1 are estimated to be up to 100M in total. A number of scenarios were produced, with a range of benefits estimated at between 11% and 104% (PV). The range reflects uncertainty in relation to worker and general population exposure levels around the Rotterdam site and valuation measures for final cancer.

By comparing the economic benefits of continued use (PV) against the value of risks to human health (100M), it is evident that EU society benefits significantly as net benefits from the continuation of Use 1 cover the great majority. Social, environmental and macroeconomic impacts have been assessed and do not have a material bearing on this outcome. The assessment of the benefits of the substitution of Use 1, which would enable the use of TCE to continue past the Sunset Date, outweighs the risks by several orders of magnitude, and therefore that this substitution is clearly justified from a societal perspective. The conclusion is strongly robust to reasonable sensitivity analysis.

Socioeconomic analysis from one of the applicant companies

Non-disclosure of "confidential information" due to competitiveness reasons makes reviews by academic researchers difficult

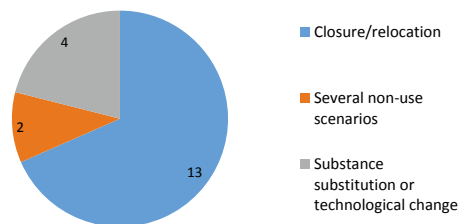
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Large variation in the estimated costs and benefits of phasing out the use of TCE (costs and benefits of non use)

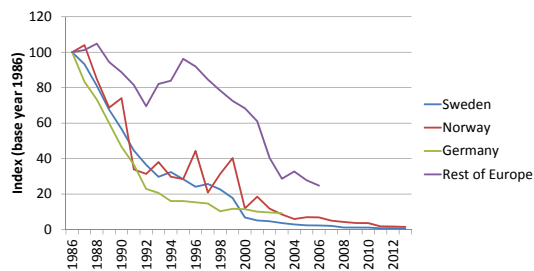
	N	Mean	Median	Min.	Max.
Benefits (Euro, thousands)	19	911	6	0,1	21 000
Costs (Euro, thousands)	10	233 549	74 500	484	1 242 000
Cost/total tonnage (EUR, thousand)	9	203	32	0,09	1 384

Source: Socioeconomic analyses presented by companies seeking authorization for continued use of TCE

Non-use scenarios in socio-economic analyses



Comparison of the rate of reduction of TCE in Europe



Lessons learned / Conclusions

1. Slow process to phase out TCE
2. The enforcement of strict emission standards is crucial to minimize damage costs (negative health effects)
3. A complete ban - the strongest policy instrument in theory – proved difficult to enforce in practice
4. A tax or deposit/refund system can create incentives for a gradual phase out
 - > Tax/fee
 - > REACH Authorisation + Application fee?

Lessons learned / Conclusions (2)

5. Access to information is a key challenge

- Difficult to access data on how much TCE is used and where
- Is it reasonable that data is not accessible for SVHC?

- Companies seeking authorisation have incentives to overestimate replacement costs and to underestimate benefits from reduced use

- Seek alternative sources of information

Work in Progress – Comments and Suggestions Welcome!

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Recent Valuation Research on Environmental and Human Health Impacts linked to Harmful Chemicals

OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management: July 6 – 8, 2016

Health Canada
Michael Donohue

Environment and Climate Change Canada
Wambui Kipusi

CHEMICALS
MANAGEMENT
PLAN
PLAN DE
GESTION DES
PRODUITS CHIMIQUES

Canada

Outline

- Challenges for CBA and the role of valuation
- Recent health valuation projects
- ECCC-HC Valuation Project
- Water Quality Valuation

2

Typical Health & Environmental Benefits Analysis

- Goal usually to:
 - Identify impacts of regulation.
 - Measure impacts of regulation in physical terms.
 - Quantify the economic impact of physical changes using WTP.
- Well established process, highly defensible, used extensively for many scenario (i.e., air pollution).
- Not always possible for chemical management.

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A Key Challenge for Chemical CBAs

- We often know that chemical X is bad for people.
- But we don't know just how bad it is.
- We expect regulation to reduce risks.
- But we can't measure or predict how much the regulation will reduce risks.
- Makes it very hard to quantify the physical impacts of the regulation.
- Without a measurable physical impact, what good does valuation do?

44

Comparing Air and Chemicals

Analytical element	Dimethyl Sulfate	PM2.5 from cars & trucks
Quantification of health risk	Could be a potential health risk, based on tox studies of rodents.	DRFs derived from extensive epidemiological work
Baseline exposure	Very limited	Extensive national monitoring & satellite surveillance
Predicting response to regulation	Unknown	Extensive stakeholder consultation plus a detailed macro economic model
Predicting changes in exposure	Unknown	National emissions monitoring and detailed atmospheric dispersion modelling
Quantification of physical impacts	Not possible	1,400 deaths prevented
Economic valuation	No physical impacts on which to base values	\$7.2 billion in benefits

55

So what to do?

- CBA requires benefits be valued.
- But how to derive values when physical impacts of regulation unclear?
- Or why bother?
- Economic values generally based on WTP. Which requires a good or service that people care about.
- Scientific evidence may exist, but not always a clear link to things that people value.

66

One Approach: Do valuation where the science is strong

- Scientists measure what they can.
- Then economists try to value it.
- Valuation will be difficult if there is no clear link to something the general public understands and cares about.
- Try to use it in CBA, with various assumptions and caveats.

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An Alternative: Valuation now, fill in the science later

- Estimate WTP for some meaningful good or service people value.
- Then do the CBA but with some of the science missing.
- Discuss whether it is likely benefits exceed costs.
- Example:
 - Chemical X is known to cause birth defects.
 - Estimate WTP to avoid birth defects (\$130,000).
 - Estimate cost of regulation (\$13 million).
 - As long as the regulation can prevent at least 100 birth defects, the benefits of the regulation will exceed costs.
 - Talk to scientists and ask them how likely they think it is that the regulation could prevent 100 birth defects.

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Some recent WTP valuation studies

- WTP to avoid a reduction in children's IQ, caused by exposure to lead.
- WTP to increase fertility and lower the risk of birth defects and low birthweight
- WTP of parents to reduce children's mortality risks.
- WTP to avoid assorted negative effects associated with chemicals.
- In some cases, we have tried to value things where the scientific link is clear, even though the good may be hard for an average person to value / associate with.
- In other cases, we've estimated WTP for easily understood outcomes, even though the science is not yet 100% there.

99

Selected WTP estimates from recent work

- VERHI Children's health valuation (Alberini & Scasny):
 - Parental WTP to reduce risks to children is 25% to 40% higher than WTP to reduce risks to adults.
 - Child "premium" depends on cause of death.
- Fertility and birth outcomes (Scasny):
 - Increased fertility WTP of \$75,000 per pregnancy.
 - \$130,000 to avoid minor/cosmetic birth defects
 - \$1 to \$2 million to avoid major birth defects
 - \$250,000 - \$400,000 to avoid very low birthweight
- Lead & IQ valuation (Industrial Economics):
 - \$3,800 to avoid a 1 point drop in IQ
 - \$7,200 to avoid a hyper active child

1010

ECCC-HC Valuation Project

- An Environment and Climate Change Canada (ECCC) – Health Canada (HC) collaborative research and analysis project to:
 - enhance internal capacity to conduct high quality cost benefit analysis,
 - enhance evidence-based decision making and
 - address an existing quantitative analysis gap.
- Objective: develop and implement a stated preference survey to elicit primary data on Canadians' willingness to pay to reduce risks of harm to the environmental and human health from toxic chemicals.
- Study findings to be used in benefits transfer when conducting cost benefit analysis, and to inform risk management actions on toxic chemicals.
- Regulatory and program context
 - Canadian Environmental Protection Act (1999); Other enabling legislation
 - Chemicals Management Plan
- Research team – Industrial Economics Inc. - Henry Roman, Robert Paterson, Michael Welsh, Nora Scherer, Jonathan Bressler, Spencer Shonio; Expert Advisors: James Hammitt and Barbara Kanninen; Survey implementation - Ipsos Reid

1111

The Conceptual Framework

- Choice modeling identified for estimating the value Canadians place on reducing risks of harm to the environment and human health from toxic chemicals, given
 - Chemicals Management Plan (CMP) complexity with many substances and planned actions pre- and post 2020
 - Many attributes and potential impacts. CMP provides a comprehensive approach to assess and manage chemical risks
 - Canadian Environmental Protection Act provisions for chemical risk management
- Incorporates :
 - A consumer (user) choice approach to allow estimation of the marginal willingness to pay to reduce adverse environmental and human health risks linked to harmful chemicals at any stage along the life cycle.
 - Framing a consumer product containing harmful chemicals that may cause damage to the environment, human health or both.
 - Not identifying specific chemicals to allow greater transferability of marginal willingness to pay estimates in benefits transfer analysis.
 - Attributes frame alternative options of commonly purchased products available to survey respondents. Options presented at increasing monthly cost to households.

12

Survey Design Elements

- A national representative stated preference survey incorporating the following:
 - Questionnaire development using 13 focus groups, with Aboriginal population participants.
 - Online English and French web-based delivery of the pilot and final surveys
 - Environmental and human health endpoints/attributes
 - Persistence
 - Bioaccumulation
 - Environmental impacts (air, water, soil)
 - Toxic to non-human organisms
 - Carcinogenic to humans
 - Other potential health effects to humans (reproductive, developmental, respiratory/cardiovascular effects)
 - Differences in exposure by area of residence – six geographical regions; rural verses urban
 - Nine different willingness-to-pay estimates

1313

Attributes and levels included

ATTRIBUTES	LEVELS
Persistence	Persistent Not persistent
Bioaccumulation	Bioaccumulates Does Not Bioaccumulate
Environmental Impacts	No Impacts Impacts Water Quality Impacts Air Quality Impacts Soil Quality
Toxic to Non-Humans	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

1414

Choice questions

Please consider the current and alternative products option 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 ▼		Current Products with Chemical A ▼	Alternative Products Option ▼
Persistence			Persistence	<i>Persistent</i>	<i>Not Persistent</i>
Bioaccumulation			Bioaccumulation	<i>Bioaccumulates</i>	<i>Does Not Bioaccumulate</i>
Environmental Impacts			Environmental Impacts	<i>No Impacts</i>	<i>No Impacts</i>
Toxic to Non-Human Organisms			Toxic to Non-Human Organisms	<i>No effects</i>	<i>No Effects</i>
Carcinogenic to Humans			Carcinogenic to Humans	<i>Carcinogenic</i>	<i>Not Carcinogenic</i>
Other Potential Health Effects on Humans			Other Potential Health Effects on Humans	<i>No Effects</i>	<i>No Effects</i>
Additional Cost Each Month			Additional Cost Each Month	<i>\$0</i>	<i>\$90</i>

Which option would you purchase? (CIRCLE ONE NUMBER)

- I would continue to purchase currently available products
- I would purchase alternative products

1515

Final Questionnaire Elements

- Pre-tested with 300 completed questionnaires; test model highly significant with expected outcomes. No changes to final questionnaire.

Section	Purpose
1. Introductory questions	Acclimatised respondent to survey topic and question formats
2. Attribute definitions	Presented definitions of each attribute in clear, non-technical language
3. Choice scenario	Described choice scenario and presented a series of choice questions (choice cards)
4. Follow-up questions	Debriefing questions – basic demographic information and respondent's views (potential bias)

1616

Survey Implementation

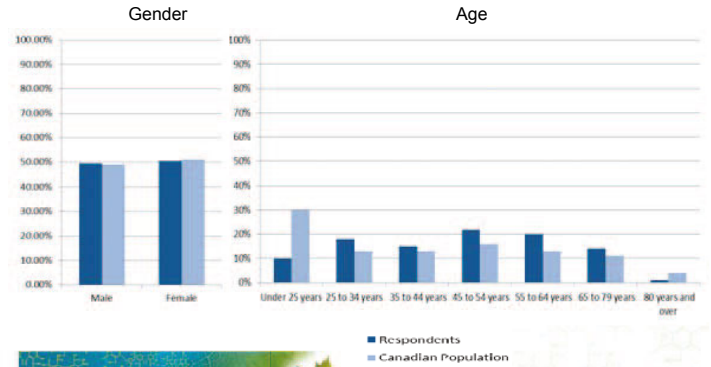
- Questionnaire administered by Ipsos Reid July 7, 2015 through July 17, 2015
- Survey implementation parameters
 - 3,000 completed questionnaires, representative of Canadian population
 - Minimum 500 per geographic area (urban/rural; provincial; Prairies; Atlantic)
 - Two-option card, 40 unique choice cards, seven attributes per choice card
 - Vary cost across choice options, and vary three of remaining six attributes
 - Five choice questions per respondent (randomly assigned without replacement from 40 options)
- Final dataset: 3,174 completed questionnaires used in analysis

FINAL DISPOSITION	NUMBER (%)
Invited, no action	51,452 (84.0%)
Screened out of survey	5,824 (9.5%)
Got to consent screen, did not go further than consent screen	333 (0.5%)
Initiated survey (got past consent screen), did not complete	529 (0.9%)
Completed	3,303 ¹ (5.0%)
Total	61,441 (100%)

Notes: 1) 129 responses were flagged as "fraudulent" by Ipsos, or were removed because of filled quotas. 3,174 responses were used in the analysis (see Chapter 3 for full discussion).

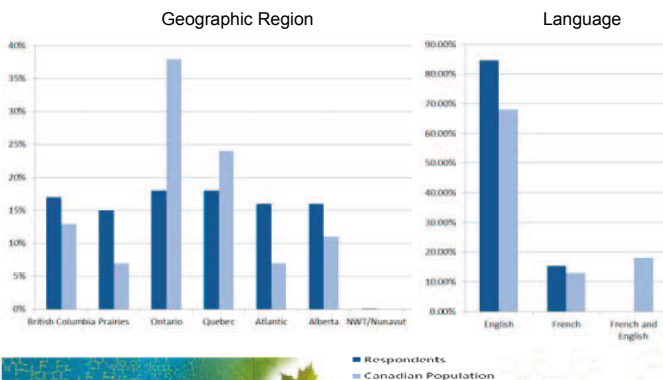
1717

Characteristics of the panel



1818

Characteristics cont.



1919

Summary of Survey Responses

- Section 1 – Introductory Questions:** - Gathered information on respondents' familiarity with chemicals
 - 86% reported information provided in survey about chemicals was similar to what they previously knew about chemicals
 - 47% had taken measures to avoid use of, or exposure to chemicals they believe are harmful
 - 33% had heard of, or experienced instances where chemicals were released to the environment in their vicinity, they believed were harmful
- Section 2 – Attribute questions:** - Asked about respondent's level of concern about each attribute
 - Majority reported being very concerned about attributes in the questionnaire
 - <3% reported "not concerned" about any of the attributes
 - 70% were aware of attributes before taking the survey

2020

Summary of Survey Responses

- Section 3 – Choice Scenario Questions:- Asked how potential risks from chemicals would affect purchasing decisions (including choice scenarios)
 - Five choice scenarios. Attribute and levels for each scenario (randomly assigned)
 - 62% would purchase alternative products
 - 71% reported no other factors (besides the seven listed) influenced choice

QUESTION	FREQUENCY (%)	
	I WOULD CONTINUE TO PURCHASE CURRENTLY AVAILABLE PRODUCTS	I WOULD PURCHASE ALTERNATIVE PRODUCTS
Scenario 1	1,205 (36.5)	2,098 (63.5)
Scenario 2	1,269 (38.4)	2,034 (61.6)
Scenario 3	1,256 (38.0)	2,047 (62.0)
Scenario 4	1,275 (38.6)	2,028 (61.4)
Scenario 5	1,259 (38.1)	2,044 (61.9)
Average	1,253 (37.9)	2,050 (62.1)

Please consider the current and alternative product 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. Which option would you purchase?

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Results of Analysis

- The relative magnitude of the coefficient shows the relative importance of the attribute in the probability of choosing an alternative
- The model is highly significant
- All coefficients are significant and of the expected signs

	Coef.	Std. Err.	Z	P> Z	[95% Conf. Interval]
Number of obs =	31740				
LR chi2(11) =	2204.38				
Log likelihood =	-8593.83				
Prob > chi2 =	0.0000				
CostPerMonth	-0.01516	0.00045	-33.7	0	-0.01604 -0.01428
Persistence	-0.437	0.035795	-12.21	0	-0.50716 -0.36684
Bioaccumulation	-0.38895	0.033183	-11.72	0	-0.45398 -0.32391
WaterQuality	-0.5642	0.051223	-11.01	0	-0.6646 -0.4638
AirQuality	-0.54195	0.044437	-12.2	0	-0.62904 -0.45485
SoilQuality	-0.56713	0.065653	-8.64	0	-0.69581 -0.43846
Toxic_NonHumans	-0.62232	0.031361	-19.84	0	-0.68378 -0.56085
Carcinogenic	-0.7462	0.032509	-22.95	0	-0.80992 -0.68249
RespCardio	-0.40372	0.050566	-7.98	0	-0.50282 -0.30461
Reproductive	-0.35972	0.044033	-8.17	0	-0.44602 -0.27342
Developmental	-0.26581	0.052699	-5.04	0	-0.3691 -0.16253

2222

Estimated Willingness to Pay – Main Effects Model

	COEFFICIENT	IMPLIED WTP
Carcinogenic	-0.7462	\$49.23
Toxic_NonHumans	-0.62232	\$41.06
SoilQuality	-0.56713	\$37.42
WaterQuality	-0.5642	\$37.22
AirQuality	-0.54195	\$35.76
Persistence	-0.437	\$28.83
RespCardio	-0.40372	\$26.64
Bioaccumulation	-0.38895	\$25.66
Reproductive	-0.35972	\$23.73
Developmental	-0.26581	\$17.54
CostPerMonth	-0.01516	N/A

2323

Estimated Willingness to Pay by Residence

	URBAN WTP	RANK	RURAL WTP	RANK	RURAL/URBAN RATIO
Carcinogenic	\$51.13	1	\$38.53	3	0.75
Toxic_NonHumans	\$44.12	2	\$24.12	10	0.55
WaterQuality	\$37.72	3	\$34.24	5	0.91
SoilQuality	\$36.84	4	\$39.70	2	1.08
AirQuality	\$34.80	5	\$41.37	1	1.19
Persistence	\$28.08	6	\$33.10	6	1.18
RespCardio*	\$26.77	7	\$25.57	8	0.96
Bioaccumulation	\$23.96	8	\$35.10	4	1.46
Reproductive	\$23.14	9	\$26.60	7	1.15
Developmental*	\$16.13	10	\$25.08	9	1.55

Urban: Population >10,000; Number of Observations = 27,590
Rural: Population < 10,000; Number of Observations = 4,150; *insignificant estimates

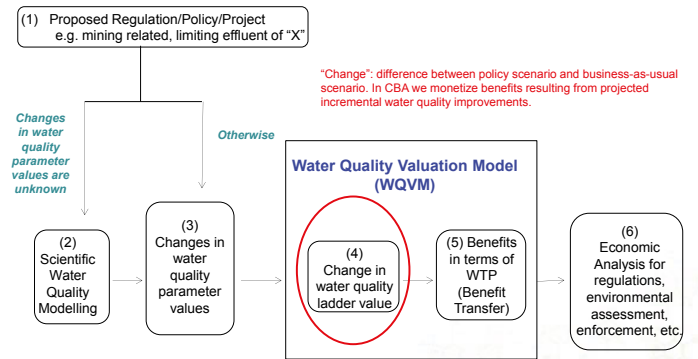
2424

Study Observations

- This study tells us that:
 - Canadians have significant WTP for elimination of harmful attributes in chemicals linked to consumer products
 - WTP is positive for all attributes included – both environmental and human health endpoints
 - WTP is highest for reducing carcinogenic effects from chemicals, followed by toxic-to-nonhuman organisms; lowest for reducing developmental effects
 - WTP differs among rural and urban areas. Rural dwellers' are WTP more to eliminate air and soil quality than carcinogenic effects, and are least WTP to eliminate chemicals toxic to non-human organisms.
 - There are no differences across geographic regions. Some differences based on income.
- What this could be used for:
 - Prioritizing the regulatory actions for different types of chemicals
 - Communicating the benefits of Canada's Chemicals Management Program
- How the results should not be used:
 - The WTP for elimination of all negative attributes of chemicals is not the sum of the individual WTPs
- Next Steps – further analysis in order for results to be useable in CBAs

2525

Water Quality Valuation



26

Discussion and Questions

Michael Donohue – michael.donohue2@canada.ca
 Wambui Kipusi – wambui.kipusi@canada.ca

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Additional Information

2828

Product Examples

Final list of examples of consumer products that contain chemicals, or for which chemicals are used in their production or are released during disposal:

- 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)

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Analysis of Choices

Choices Modeled Using A Conditional Logit Model

$$U_{ij} = \beta_y(y_i - C_j) + \sum_{k=1}^K \beta_k X_{jk} + \varepsilon_{ij}$$

The probability of choosing bundle j over bundle k is the probability that $U_{ij} > U_{ik}$.

Where

$C_j = \$0$ for current products

$X_{jk} = 0$ for all alternative products

$$U_{ij} - U_{ik} = \beta_y(y_i - C_j - (y_i - C_k)) + \sum_{k=1}^K \beta_k X_{jk} + \varepsilon_{ij}$$

$$U_{ij} - U_{ik} = \beta_y(C_k) + \sum_{k=1}^K \beta_k X_{jk} + \varepsilon_{ij}$$

This implies that what matters is the difference in attributes and the difference in cost of the two alternatives.

3030

Interpretation of coefficients

- The sign of the coefficient shows how the probability of selection changes with that variable
 - All non-cost attributes are defined as the presence (1) or absence (0) of that attribute
 - The presence of a possibly adverse environmental/health outcome should decrease the probability of choosing a product with that attribute
 - We would expect the coefficients on non-cost attributes to be negative
 - All else equal, a respondent should be less likely to choose a product with a higher cost
 - We would expect the coefficient on additional cost to be negative

3131

Estimating Willingness to Pay

- The coefficient on an attribute shows how "utility" changes with respect to a unit change in that attribute
 - Think of this as MU/Attribute (marginal utility for that attribute)
- The coefficient on cost tells us how "utility" changes with a \$1 change in price
 - Think of this as MU/\$ (marginal utility of income)
- Dividing the coefficient for an attribute by the coefficient for the cost
 - $[MU/Attribute]/[MU/\$] = \$/Attribute$
 - In this study this is the Willingness to Pay to avoid the presence of that attribute in consumer products

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Estimated Willingness to Pay by Income

	BELOW \$75,000	ABOVE \$75,000	RATIO
Carcinogenic	\$43.62	\$55.58	1.27
Toxic_NonHumans	\$39.97	\$45.97	1.15
SoilQuality	\$33.25	\$40.71	1.22
WaterQuality	\$35.68	\$38.25	1.07
AirQuality	\$38.02	\$34.47	0.91
Persistence	\$28.38	\$27.90	0.98
RespCardio	\$28.12	\$24.41	0.87
Bioaccumulation	\$27.16	\$23.40	0.86
Reproductive	\$21.18	\$25.71	1.21
Developmental	\$16.64	\$23.16	1.39

Number of Observations for Household Income Less than CDN\$ 75,000 = 15,880
 Number of Observations for Household Income Greater than CDN\$ 75,000 = 12,000



Cost benefit analysis in the development of policy – Australia

Dr Sara Broomhall, Director
Chemicals Management and Standards Section



Overview

- Australia's regulatory policy requirements
 - Some elements and requirements for cost benefit analysis
 - Example of persistent chemicals and associated challenges
-

Regulatory Policy Requirements

10 principles

- Regulation should not be the default option for policy makers
 - The policy option offering the greatest net benefit should always be the recommended option
 - Regulation should be only imposed when it can be shown to offer an overall net benefit
-

Regulatory Policy Requirements

7 RIS questions

- What is the problem you are trying to solve?
 - Why is government action needed?
 - What policy options are you considering?
 - What is the likely net benefit of each option?
 - Who will you consult about these options and how will you consult them?
 - What is the best option from those you have considered?
 - How will you implement and evaluate your chosen option?
-

Regulatory Policy Requirements

7 RIS questions

- What is the problem you are trying to solve?
 - Why is government action needed?
 - What policy options are you considering? eg
 - No regulation
 - Self regulation
 - Co-regulation
 - Alternative instruments – information and education, taxes, subsidies, standards, etc
-

Regulatory Policy Requirements

9 Steps in preparing a CBA

Step	Action
1	Specify the set of options.
2	Decide whose costs and benefits count.
3	Identify the impacts and select measurement indicators.
4	Predict the impacts over the life of the proposed regulation.
5	Monetise (attach dollar values to) impacts.
6	Discount future costs and benefits to obtain present values.
7	Compute the net present value of each option.
8	Perform sensitivity analysis. (includes real discount rate of 7 per cent and sensitivity analysis at 3 and 10 per cent)
9	Reach a conclusion.

Cost Benefit Analysis

- We must consider at least three options, one of which must be non-regulatory.
 - A 'do nothing' or 'business as usual' option will usually provide the *base case* against which the incremental costs and benefits of each alternative are determined.
 - Only costs and benefits that would not have occurred in the base case should be included in the CBA.
-

Cost Benefit Analysis

A few observations on costs

- Standard matters - such as cost of alternatives or switching production; costs to meet proposed waste disposal requirements; costs to monitor, etc. Includes govt and community and private sector.
 - 'regulatory burden measurement' – here is where we must quantify only private sector in order to offset
 - Includes administrative compliance costs (eg having to report)
 - Substantive compliance costs – eg operational costs, new staff training
 - delay costs - eg to prepare an application
-

Cost Benefit Analysis

Environmental considerations

- Describing environmental assets, how they benefit the community and how they these benefits are likely to change under different policy options
 - Categories of 'Ecosystem services'
 - a. Provisioning services
 - b. Regulating services
 - c. Cultural services
 - d. Supporting services
-

Cost Benefit Analysis

Quantifying and then valuing endpoints

- Value (not just price)
 - Direct and indirect use values (eg crops and ecosystem services)
 - Non use (eg existence value, bequest value)
 - Revealed preference (eg real estate prices)
 - Stated preference (eg choice modelling)
 - Value transfer/benefit transfer (using studies from other locations)
-

Cost Benefit Analysis

Provisioning services

- Case study: HBCD
 - Direct dose response relationship not possible
 - Approach: estimating possible benefits/avoided costs of reducing HBCD emissions under different scenarios
 - Assumptions:
 - a. Water [HBCD] and fish embryo survival rates based on Australian data for HBCD concentration in sediment
 - b. Assumed linear relationship between embryo loss rate and HBCD concentrations
 - c. Loss rate applied to HBCD estimated emissions to derive estimated loss rate per kg of HBCD
-

Cost Benefit Analysis

- Difficulty in quantifying and in establishing dose response, hence fall back to qualitative discussion.
- Often purely scientific regarding potential risks, but can also consider within the frame of known health costs eg - if a chemical affects liver or reproductive hormones – what are the costs to society of reproductive problems? What are the costs to society of liver disease?
- eg \$60 million a year. If only a tiny fraction, say 0.001% could be avoided due to reduced exposure, then benefits may be positive.
- Could assist in ranking options.

Cost Benefit Analysis

Decision making under uncertainty

- Sources of uncertainty (lack of data or knowledge)
 - The nature of uncertainty
 - a. Resilient strategy
 - b. Adaptive strategy
 - c. Threshold analysis
-

Cost Benefit Analysis

Threshold analysis

- The value to society of an improvement in environmental quality is worth its associated opportunity costs.
 - Minimum value the associated environmental benefit would need to have to justify choice
 - Applicability:
 - Used when concerns about the reliability of valuation estimates
 - Limitations: Subjective decision making
-

Cost Benefit Analysis

- Costs of inaction
 - How to take into account multiple chemicals/efficiencies from considering several at once
 - Precautionary principle
 - Risk communication and risk appetite
-



WHO experiences with economic assessments

Frank George
WHO Regional Office for Europe
European Centre for Environment and Health, Bonn,
Germany



Definition of Health

“Health is a state of complete physical, mental and **social well-being** and not merely the absence of disease or infirmity.”

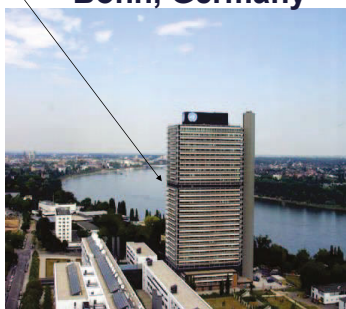
(extract from the constitution of WHO, **1946**)



OECD Helsinki workshop on socioeconomic impact assessment
6-8 July 2016

WHO European Centre for Environment and Health (ECEH)

Bonn, Germany



WHO European Centre for Environment and Health

(established by the 1st Ministerial Conference, Frankfurt, 1989)

Role of ECEH, Bonn

Provide the 53 WHO European Member States with evidence to support policy-making in environment and health

- Organize systematic review of scientific evidence
- Stimulate research on EH priorities
- Analyse environment-related policies and their health impacts
- Provide stewardship for health in multi-sectorial policies



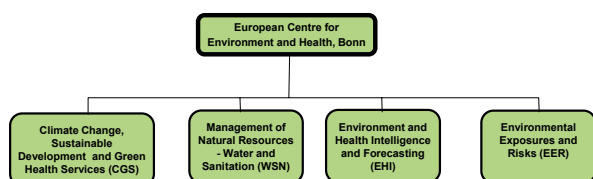
OECD Helsinki workshop on socioeconomic impact assessment
6-8 July 2016



OECD Helsinki workshop on socioeconomic impact assessment
6-8 July 2016

WHO European Region as the only region with an ENVIRONMENT and HEALTH Ministerial Process

1989	1990	1994	1999	2004	2010
First Ministerial Conference Frankfurt	WHO ECEH established	Second Ministerial Conference Helsinki	Third Ministerial Conference London	Fourth Ministerial Conference Budapest	Fifth Ministerial Conference Parma



Foundations of Economic Use in Environmental Health



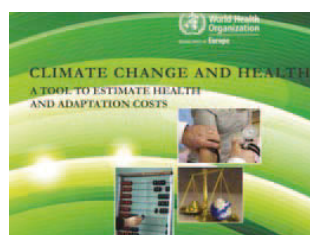
- **Health 2020**
European policy framework supporting action across government and society for health and well-being
- **Health in All Policies**
A healthy economy depends on a healthy population

What is the role of economics in environmental health?"Why WHO"?

- Revealing important links between social and environmental determinants of health
- Advocacy and policy promotion purposes in a context of constrained resources and competing priorities
- Policy evaluation (prospective/retrospective)
- Decision-support tools
- Equity considerations

4 Examples of WHO use of economics

1) Climate change and health economic tool



- Expanding analysis of damage and adaptation beyond physical impact
- Standard techniques (VSL, HCA, COI,...) with traceable indicators and transparent formulas
- Supports adaptation planning in Member States
- Based on review of evidence and inputs from experts in the field

2) Health Economic Assessment Tools (HEAT) for walking and cycling

<http://www.heatwalkingcycling.org>



Goal: facilitate the integration of health in transport appraisals and planning

- Need to make health benefits of cycling and walking “visible” to **transport and urban planners**
- Need to **“speak their language”**
- Importance of **economic analysis** in transport planning

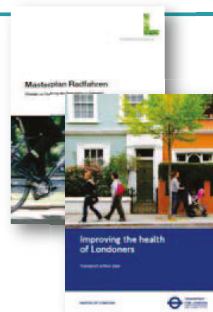


What is HEAT?

An online tool for economic assessment of health benefits of walking or cycling, i.e. the answer to the question:

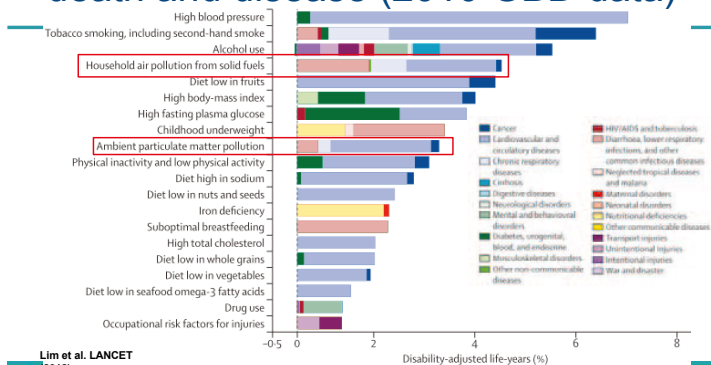
“What is the economic value of the health benefits from a given volume of walking or cycling within a defined population?”

Success: case studies

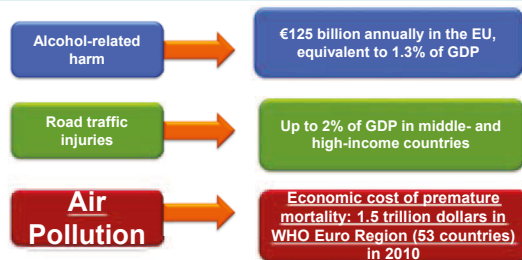


- England
 - Part of official toolbox for the assessment of transport projects (WebTAG)
- Austria
 - Health effects of national cycling masterplan
- USA
 - Evaluation of 4 FHWA nonmotorized transportation pilot projects
- London
 - Action plan, recommendation for using HEAT in business cases
- Barcelona, Modena, Nantes, Kuopio, Pärnu, ...

3) Air Pollution is a leading cause of death and disease (2010 GBD data)



Economic Case for Health Promotion and Disease Prevention



4) An Economic Assessment of Asbestos Bans and Declines in Asbestos Production and Consumption

WHO Regional Office for Europe Conference, Bonn, Germany, 18-19 May 2016
 Assessing the economic costs of the health impacts of environmental and occupational factors: The economic dimension of asbestos

Outline of WHO EURO economic asbestos report (draft 2016, July)

- Overall trends in asbestos production, consumption and bans
- Economic effects of asbestos bans and declines in asbestos production and consumption
- Economic costs of continued production and consumption of asbestos

Potential Costs of Shifting Away from Asbestos

- Costs of substitutes (for asbestos consuming countries)
 - Do substitutes exist?
 - Are they cost effective?
- Potential negative impact on jobs and incomes (for asbestos producing countries)
 - Is there a country-wide or regional impact?
 - If so, how long does it persist?

Summary

- **No observable negative economic impact at the country-level from bans or a decline in asbestos production or consumption**
 - Lack of effect likely reflects the small share that asbestos represents of national economic activity
- **No persistent negative effect at the regional-level**
 - However, available data are limited
 - More study is needed to identify all costs that may be observable only at the regional-level
- **Substantial costs exist to continuing consumption**
 - Health costs will likely be considerable for countries continuing to produce and consume asbestos
 - Remediation and litigation costs may be even greater than health costs, based on experience of past producers/consumers

Key Messages



✓ Good Health is a Human Right !

some argue no need for more (economic) evidence

✓ Economic evidence can be a powerful tool to convince policy-makers in and beyond the health sector (transport, agriculture, energy, economics etc.) – Health in all policies

✓ Problems /Solutions for WHO:

- 1) WHO talks DALYs/QALYs – “life has an indefinite/no price”/ no solution as such
- 2) WHO limited economic expertise / partnering with OECD/EC/WB, universities, think tanks and NGOs
- 3) WHO still lacks a harmonised methodology for estimating economic costs and benefits/Solution and new ideas by this workshop?...

More information

- <http://euro.who.int/ecehbonn>
- <http://www.euro.who.int/en/who-we-are/policy-documents/parma-declaration-on-environment-and-health>

Thank you

- georgef@who.int

OECD workshop on socio-economic impact assessment of chemicals management

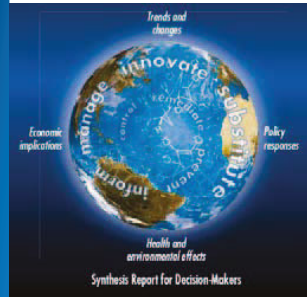
Feedback on the Global Chemicals Outlook and Cost of Inaction Reports Experience

European Chemicals Agency
6-8 July 2016, Helsinki Finland

Pierre Quiblier ,
Programme Officer
Chemicals and Waste Branch,
UNEP/DTIE



The Global Chemicals Outlook



- Provide scientific evidence and information for giving priority to sound management of chemicals as part of sustainable development.
- Make the economic case for investing in sound chemicals management and send a positive message about the economic opportunities that derive from sound management of chemicals
- Elevate chemicals management to the top of the international policy agenda as an essential condition to achieve sustainable development



Chemicals Intensification of the Economies

Table 1: Chemical Production: Predicted Annual Growth Rates, 2012-2020

	Percent change, 2012-2020	
North America	25%	
United States	25%	
Canada	27%	
Mexico	28%	
Latin America	33%	
Brazil	35%	
Other	31%	
Western Europe	24%	
Emerging Europe	35%	
Russia	34%	
Other	36%	
Africa & Middle East	40%	
Asia-Pacific	46%	
Japan	22%	
China	66%	
India	59%	
Australia	23%	
Korea	35%	
Singapore	35%	
Taiwan	39%	
Other	44%	

Source: Percentages calculated based on projections in Thomas Kevin Swift et al., "Mid-Year 2011 Situation & Outlook," American Chemistry Council, June 2011.

1. Shift in production/consumption
2. Trade flows – Penetration of Chemical intensive Products
3. Increasing emissions from major economic development sectors



Cost on National Economy: Unrecognized and Substantial

Direct Implications: Financial costs to the chemicals and related industries:

- Higher insurance costs,
- loss of productivity,
- reputation impacts.

Costs incurred due to asbestos and contaminated drywall, for example, total over **US\$125 billion worldwide** – and the figure is still rising.

COSTS OF ACCIDENTS

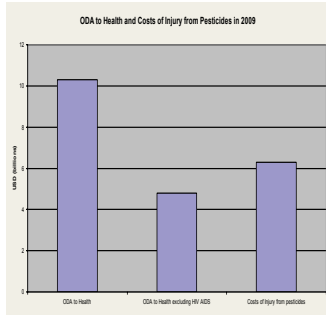
US\$ 19 million reported profit made by Trafigura for the 2006 ship leased "Probo Koala" with a shipment of coker gasoline. Total costs paid out by Trafigura to date for waste dumping incident equal approximately **US\$ 250 million**.

US\$ 600 million to date: treatment of contaminated sludge from the Minamata mercury pollution incident; Over 47,600 people likely to be compensated in the legal process.



Cost on National Economy: Unrecognized and Substantial

External implications and cost of inaction for human health and environment: large with heavy burden on individual and public budgets



A conservative projection of the 2005 estimate to 2009 shows costs of injury due to pesticide poisoning for pesticides users on smallholdings in sub-Saharan Africa to be USD \$6.2 billion. This suggests that the total ODA to general healthcare is exceeded by costs of inaction related to current pesticide use alone.



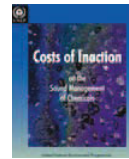
Costs of Inaction Report Objectives

- Raise awareness of the economic benefits of sound management of chemicals
- Advance the integration of chemicals management into national development plans

... by embracing a new approach to the political economy of sustainable development, we will bring the sustainable development paradigm from the margins to the mainstream of the global economic debate.

Thus, both the cost of action and the cost of inaction will become transparent. Only then will the political process be able to summon both the arguments and the political will necessary to act for a sustainable future.

United Nations Secretary-General's High-Level Panel on Global Sustainability (2012)



The Cost of Inaction Report

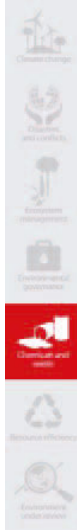
- Baseline Assessment Report on the existing information on Costs of Inaction on Sound Management of Chemicals
- An extrapolation study on the cost of inaction of use of pesticide in small holdings in Sub-saharan Africa



Economic information on environmental effects of chemicals

- More scattered information on environmental effects than for health effects
- few studies focus on the environmental effects of the chemicals
- Environmental effects data relates mostly to water, ecosystem services and biodiversity
- Difficult to disaggregate the environmental effects from chemicals from other causes

To progress we need a better understanding of certain chemical uses or routes of exposure.



Economic information on cost from health effects

Identified examples showed difference in

- Methodologies
- Substances covered
- Health endpoints
- Geographic coverage

Makes it difficult to compare and aggregate into meaningful global or regional estimates

Sufficient information to make an extrapolation study on health cost of pesticides for Sub-Saharan Africa



State of Economic Information for SMC

- The available data on the health, environmental, and development planning effects of harmful chemicals shows high costs of inaction.
- The data is fragmentary with little standardization in methods used.
- little assessment of what findings might mean for other sectors and regions.
- Data was found mainly in prominent areas but little data on these chemicals throughout their life cycles.
- No or limited picture of the future risk scenario.



Cost of Inaction Main messages

- Data and information on the costs of inaction and benefits of action : A key driver for mainstreaming the sound management of chemicals into national development policies
- Need for enhanced financial inputs into sound chemicals management.
- The costs and benefits of chemicals use must in turn be compared with the costs and benefits of sound chemicals management.
- Need to consider new types of strategies that target broad spectrum gains (for example, strategies that span substances and sectors), and system-wide approaches to complement measures defined in national and international legal and institutional infrastructures



Filling the Gaps in knowledge

- Inter-agency cooperation to focus on the costs of ecosystem services due to chemicals.
- A consistent applied guidance of methods specified for chemical effect analysis:
 - better access existing in-country information.
 - build capacity for consistently collecting and analyzing policy relevant data.
- Collection of unpublished/ raw data
- Filling the sectoral evidence



COI Recommendations

- Practical, useable guidance is needed to assess and value the costs and benefits of ecosystem services regarding how these services can be affected by chemicals management.
- focus on economic sectors, specifically agriculture, mining, leather and textiles, and waste management, that are critical to most developing countries experiencing increasing volumes of chemicals and penetration of chemicals intensive products into national economies.
- assess costs of inaction in context of, and relative to:
 - a) the costs of actions to improve sound management of chemicals that are practical and achievable and,
 - b) the benefits of actions



Economic instruments GCO analysis

Table 3. Economic Instruments for the Sound Management of Chemicals

Category	Instruments
Price Instruments	Fees, taxes and user charges on production inputs, emissions, outputs or consumption User-charges on natural resource inputs, i.e. water charges Removal/reduction of perverse subsidies Subsidies or environmental funds for environmentally preferable activities Tax adjustments/breaks Chemical leasing, deposit-refund systems, tax-subsidy, refunded emissions fees
Liability Instruments	Environmental fines Liability systems Extended producer responsibility (EPR)
Procurement Instruments	In-house environmentally preferable procurement (EPP) Guidelines for market preferences
Information Instruments	Labeling for market creation and product differentiation Certification for market creation and product differentiation Environmental reporting Information disclosure Eco-design and green chemistry awards

Ref: Adapted from UNEP Chemicals Branch, An Analysis of Economic Instruments in Sound Chemical Management of Chemicals, Draft, May, 2011.



Economic instruments Strengths and weaknesses

- Can increase safer chemical management, reduce externalities, and improve market efficiency.
- Offer flexibility for industry
- Potentially, generate revenue for public cost recovery,
- However
- Complex and difficult to administer and, in some cases, such as revenue generation
- Can erode as chemical management practices improve (waste or emission fees)
- Not an alternative to legal instruments
- Tend to reduce rather than eliminate hazards



Economic instruments Which one to use?

Which objectives: Change economic behaviors; raise revenue or both?

- Fees on targeted chemical
- Waste disposal fees and user charges
- Site clean-up and spent chemical stockpile management fees
- Equipment installation and operating permit fees and license programmes
- Corporate taxes



Next steps: GCO-II

Three complementary building blocks:

- Part I. Global Context, Trends and Developments
- Part II. Review of Chemical Management Areas of Relevance Beyond 2020
- Part III. Creating an Enabling Environment

To capture the state of scientific, management and policy knowledge to support policy-makers and stakeholders in their assessment of the implementation of the 2020 goal and in deliberating the sound and sustainable management of chemicals and waste beyond 2020.



GCO-II Part III. Creating an Enabling Environment

4 envisaged thematic review papers:

- Cost of inaction methodologies and examples and best practices in developing countries
- Set up regulatory capacity through cost recovery schemes
- Economic Cost benefits analysis to address priority interventions and hotspots issues
- Use of fiscal incentives to change producers and consumers behaviors



Next Steps Links to the African ChemObs

- The main objective of the observatory is to predict, prevent and reduce chemicals risks to human health and the environment and remediate pollution throughout the life cycle of chemicals through costing of inaction and indicating benefits of action.
 - Component 2: Is focused on the development of broad-based action plans to promote sound chemicals management and reduce negative impacts on health and the environment.
 - ✓ Activities include: definition of benefits and cost of action to mitigate risks and justify specific interventions;



Thank you



Experience in air pollution regulation : benefit valuation

Mike Holland

mike.holland@emrc.co.uk

July 6th 2016



Magnitude of quantifiable impacts

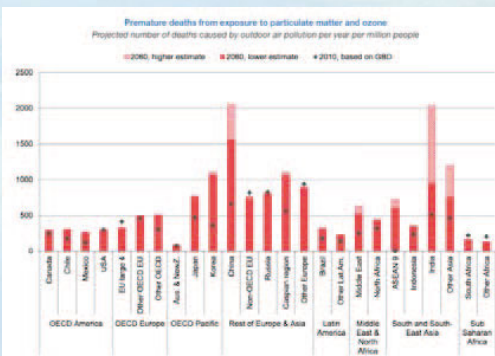
- Air pollution is a major environmental risk factor (results for EU28, 2030, all results annual)

IMPACTS			CLE 2030
Acute Mortality (all ages)	Prem. deaths	O ₃	17,239
Respiratory hospital admissions (>64)	Cases	O ₃	20,060
Cardiovascular hospital admissions (>64)	Cases	O ₃	87,705
Minor Restricted Activity Days (all ages)	Days	O ₃	83,557,315
Chronic Mortality (30yr +) *	Life years lost	PM	2,538,700
Chronic Mortality (30yr +) *	Prem. deaths	PM	303,878
Infant Mortality (0-1yr)	Prem. deaths	PM	394
Chronic Bronchitis (27yr +)	Cases	PM	233,889
Bronchitis in children aged 6 to 12	Cases	PM	732,056
Respiratory Hospital Admissions (All ages)	Cases	PM	100,854
Cardiac Hospital Admissions (>18 years)	Cases	PM	77,180
Restricted Activity Days (all ages)	Days	PM	320,525,771
Asthma symptom days (children 5-19yr)	Days	PM	7,728,256
Lost working days (15-64 years)	Days	PM	76,102,105

2

Global trends (OECD CIRCLE study)

- Substantial increase in impacts to 2060 in many world regions



See OECD CIRCLE study: <http://www.oecd.org/environment/the-economic-consequences-of-outdoor-air-pollution-9789264257474-en.htm>

Current state of air pollution benefits assessment

Table 1. Annual benefits of moving from the CLE to the MTRF scenario in 2025 and 2030 across the EU28, €million/year, 2005 prices.

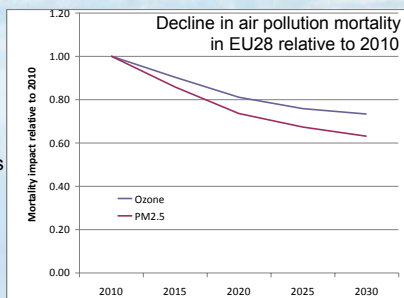
Endpoint	CLE – MTRF, 2025	CLE – MTRF, 2030
Particulate matter		
Chronic Mortality (All ages) median VOLY	42,605	41,623
Infant Mortality (0-1yr) median VSL	198	185
Morbidity	16,187	16,388
Ozone		
Acute Mortality (All ages) median VOLY	161	160
Morbidity	595	599
Total health benefits		
Mortality only (median VOLY, median VSL for infant mortality)	42,424	41,968
Mortality and morbidity (median VOLY, median VSL for infant mortality)	57,996	57,759
Range	57,966 – 198,377	57,759 – 207,054

EU Clean Air Policy Package analysis, <http://ec.europa.eu/environment/air/pdf/TSAP%20CBA.pdf>

4

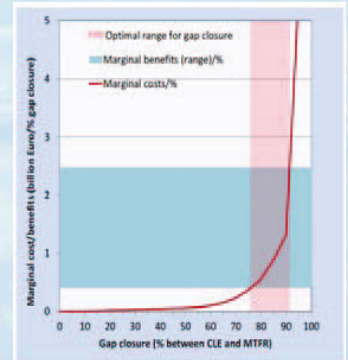
Problem or opportunity?

- Bad news:
 - Air pollution has a significant impact on health
- Good news:
 - We know air pollution is a major risk factor
 - We are reducing it
 - We know we can reduce it further
 - Co-benefits with climate, transport and other actions
- Is action worthwhile?



Current state of air pollution benefits assessment

- Comparison of marginal costs and benefits for EU28
- Justification for 70%+ gap closure between:
 - Current legislation
 - Maximum abatement



EU Clean Air Policy Package analysis,
<http://ec.europa.eu/environment/air/pdf/TSAP%20CBA.pdf>

6

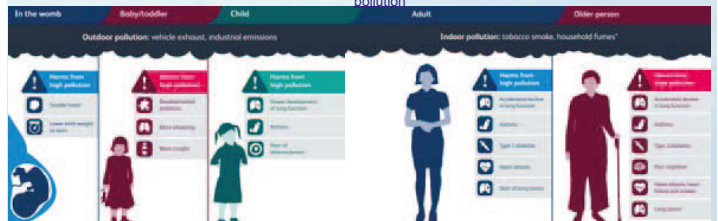
Some issues for quantification and monetisation

1. Identifying impacts
2. Understanding mortality
3. Matching impacts to values
4. Including healthcare costs as a separate component
5. Marginal valuation and large impacts

7

1. Identifying impacts How complete is quantification?

- Link to many diseases including:
 - Cancer
 - Asthma
 - Stroke
 - Heart disease
 - Diabetes
 - Obesity
 - Dementia
 - <https://www.rcplondon.ac.uk/projects/outputs/every-breath-we-take-lifelong-impact-air-pollution>



1. Identifying impacts Extending HIA for metal emissions

- Nedellec and Rabl (2016) Risk Analysis

c) Mercury.

Threshold = $6,7E-03$ mg_{Ue}/kg_{body}/day [EPA 2001] and $f_{inc} = 0.44$

Endpoint	Cases/kg _{Ue}	Undiscounted, no threshold	Lag [yr]	Discount factor	Discounted, no threshold	Discounted, with threshold
Mortality	0.56	23,303	10	0.68	15,743	6,945
IQ loss	1.42	4,257	0	1	4,257	1,878
Total €/kg_{Ue}		27,560			20,000	8,824
<i>ExternE [2008]</i>						3,400

9

2. Understanding mortality Why is this important?

- What are we valuing?
- What causes the death?
 - Ischaemic heart disease
 - Genetics
 - Diet
 - Exercise
 - Air pollution
 - Smoking
 - Diabetes
 - Ageing
 - ...



2. Understanding mortality Ways of expressing mortality

Table 1. COMEAP results for effects of outdoor PM_{2.5} exposure on mortality for the UK²

Measure of mortality	Impact
Number of attributable deaths	28,861
Attributable deaths per 100,000 aged over 30 years	75
Burden on total survival (life-years lost)	340,000
Difference in life expectancy for the 2008 cohort (days)	
Females	194
Males	182

COMEAP – UK Dept of Health Committee on the Medical Effects of Air Pollutants
Table highlights different ways of representing mortality impacts of air pollution
Averages at ~12 years of lost life expectancy per equivalent attributable death

11

2. Understanding mortality Interpretation of mortality estimates

- COMEAP:
 - Estimates of deaths linked to air pollution are a statistical construct
 - Air pollution has some role in bringing forward the deaths of a (much) larger number of people than the 29,000 COMEAP estimate
 - The 29,000 figure is more accurately interpreted as an **'equivalent attributable deaths'** than simply 'deaths'

12

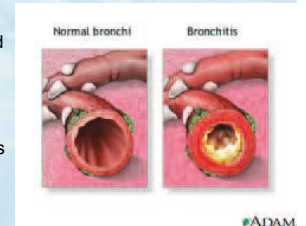
2. Understanding mortality Valuation methods

- Value against deaths
 - Value of statistical life (VSL, VPF, ...)
 - Extensive literature
 - Well suited to 'equivalent attributable deaths' / long term exposure
 - Application to short term exposure deaths?
 - Inconsistent with health economics
- Value against life expectancy
 - Value of a life year (VOLY)
 - Behavioural questions?
 - Limited literature
 - More consistent with health economics

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3. Matching impacts to values Example: Bronchitis and PM

- Definition of bronchitis for epidemiology
 - Cough or production of phlegm daily for at least 3 months of the year for at least the last 2 years
 - Does not distinguish severity
 - Identifies additional cases but not worsened cases
- Definition of bronchitis for valuation
 - Early studies focused on severe effects
 - Later studies considered less severe effects
 - But what is the average?
 - What is the effect of air pollution
 - Just recruit new cases?
 - Worsen existing disease?
 - How can you aggregate results?



#ADAM

COMEAP report on chronic bronchitis available at:
<https://www.gov.uk/government/publications/comeap-long-term-exposure-to-air-pollution-and-chronic-bronchitis>

14

4. Including health care costs as a separate component

- What is included in WTP estimates?
 - Just utility via pain, suffering, lost life expectancy?
 - Or also healthcare costs?
 - Productivity?
- Survey design
- Possible US-Europe differences?
 - Payment methods for health care



5. Marginal valuation and large impacts

- Question raised for OECD CIRCLE study
 - Is VSL based on valuation of marginal changes in risk applicable to (e.g.) total burden calculations?
- Value specifies time (e.g. WTP to avoid a risk of x in the next 3 years)
- Individual actions involve marginal change in risk
- Bias against action on large impacts?

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Conclusions

- Air pollution effects on health now routinely quantified and monetised
- Important questions considered here:
 - How complete are estimates of impacts?
 - How do we define 'death'?
 - Do valuations match quantified impacts?
 - Should healthcare be included as a separate component?
 - Applicable of marginal values to large changes
- Important questions not addressed here
 - Attribution of effects
 - Value transfer (elasticity, etc)
 - ...

The Cost of Air Pollution: Method, Results, Conclusions

by
Dr. Rana Roy
Consulting Economist

Introduction

- This presentation reports on – rather, extracts from – a series of recent studies I have authored/co-authored (incl. OECD, 2014; WHO, OECD, 2015; Roy, 2016; Roy, Braathen, 2016; and the on-going work of the newly-founded Global BCA Working Group).
- It extracts from this to highlight some key features of the evolving method, the results and the conclusions of our calculation of the cost of air pollution.

2

Introduction (continued)

- Air pollution is, in the words of WHO, “the world’s largest single environmental health risk”. As at 2013, the global death toll from HAP was c. 3 million; the global death toll from AAP c. 3 million ... *and rising*.
- But our subject today – what is relevant to this forum – is not air pollution *per se* but rather the progress gained in the calculation of its cost and its potential spill-overs to other areas of socioeconomic assessment.

3

Method

- Let’s start with first principles. What precisely do we mean by the “cost” of mortalities or morbidities or environmental impacts other than on human health?
- Economics supplies a clear answer. “Value”, aka “utility”, refers to the valuations that individuals place on the objects they desire – incl. consumption, leisure, health and life – and which they are obliged to trade-off at the margin. “Cost” is a measure of their loss.

4

Method (continued)

- Following Jacques Drèze, economics today possesses a standard method for calculating the cost of mortalities – that is, for calculating the loss of the valued object, life – at the level of society as a whole.
- This centres on the “value of statistical life” (VSL), or the marginal rate of substitution between consumption and a reduction in the risk of dying, as derived from aggregating individuals’ “willingness to pay” (WTP).

5

Method (continued)

- A simple logic. Each individual has an expected utility function, EU, relating the utility of consumption over a given period, $U(y)$, and the risk of dying in that period, r , of the form: $EU(y, r) = (1 - r) U(y)$.
- The WTP to maintain the same expected utility in reducing risk from r to r' is the solution to the equation: $EU(y - WTP, r') = EU(y, r)$.
- VSL is thus the marginal rate of substitution between consumption and the reduction in the risk of dying, such that: $VSL = \delta WTP / \delta r$.

6

Method (continued)

- A simple search mechanism. As in OECD, 2012: “[A] survey finds an average WTP of USD 30 for a reduction in the annual risk of dying from air pollution from 3 in 100 000 to 2 in 100 000. This means that each individual is willing to pay USD 30 to have this 1 in 100 000 reduction in risk. In this example, for every 100 000 people, one death would be prevented with this risk reduction. Summing the individual WTP values of USD 30 over 100 000 people gives the VSL value – USD 3 million in this case.”

7

Defining method (continued)

- And thence: the cost of the impact under study is the VSL value \times the number of premature deaths attributed to it; the benefit of a mitigating action is the VSL value \times the number of premature deaths avoided.
- Work to be done in standardising the calculation of the cost of morbidities and other impacts. But NB: all evidence suggests that mortalities are the larger part of the cost of air pollution. (Cf. US EPA, 2011; Holland, 2014; OECD, 2014; WHO, OECD, 2015; Hunt, 2016).

8

Method (continued)

- For value transfer in global calculations: I start with the OECD (2012) meta-analysis of VSL studies yielding the base value of 3 million USD for the OECD world in year 2005. And a simple formula to translate this into values for selected countries (accounting for income differences) and in the selected year (accounting for income growth):
$$\text{VSL}_{C_{2010}} = \text{VSL}_{\text{OECD}_{2005}} \times (Y_{C_{2005}}/Y_{\text{OECD}_{2005}})^{\beta} \times (1 + \% \Delta P + \% \Delta Y)^{\beta}$$
- ... but with an income elasticity beta of 0.8 for OECD- and 1.0 for non-OECD countries (Roy, Braathen, 2016).

9

Results

- The results of applying a cost calculation using VSL values to the data on air pollution in the Global Burden of Disease evidence base (GBD 2010 and now GBD 2013): *millions of deaths => cost of trillions of dollars (USD).*
- In our latest calculation of the cost of AAP (APMP + AOP) for the 6 major EMEs known as the BRIICS plus the 34 member-countries of the OECD (Roy, Braathen, 2016): 2.3 million deaths => cost of 3.4 trillion USD.

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Results (continued)

- Importantly: whilst the sum of deaths from AAP has fallen in the OECD countries taken together, the fall has been too modest to suppress a rise in the burden of its cost. As incomes rise, so too does the willingness to pay to reduce the risk of dying and, therewith, the cost of deaths from air pollution for any given number of deaths.
- In the BRIICS as well as in the rest of the world, the sum of deaths from AAP continues to rise. And, of course, so too does the burden of its cost.

11

Conclusions

- At one level, the conclusion from these results is clear. If the cost of air pollution runs into trillions of dollars, the benefits from ambitious policies to mitigate air pollution are likely to outstrip by far the cost of the said policies.
- And so it has proved: witness the United States EPA's 2011 estimate of a BCR of 31:1 in its *ex post* evaluation of the 1990 Clean Air Act Amendments – or the European Commission's 2013 estimate of a BCR of 42:1 in its *ex ante* evaluation of its proposed Clean Air Package.

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Conclusions (continued)

- At another level, the conclusion to be drawn is more sobering. For the present availability of extraordinarily high BCRs is also evidence of a past policy failure – a failure to enact policies with ordinarily positive BCRs.
- There is a message here for economists. To make our output more readily usable (as the Global BCA Working Group aims to do). And also to communicate its simple essential meaning. Hence, my return to first principles.



Social Costs of Morbidity Impacts of Air Pollution

Alistair Hunt & Julia Ferguson (plus Fintan Hurley)
6 July 2016
ECHA, Helsinki

[OECD Workshop on socio-economic impact assessment of chemicals management](#)

ecaasph@bath.ac.uk

1

Outline of Talk

- Purpose of OECD Research Project
- Defining the social cost components of air pollution-induced health impacts
- Recommended unit values for specific health end-points for use by OECD
- Lessons for impact assessment of chemicals management

2

Purpose of Research

Purpose: Inform the development, by the OECD, of improved estimates of the social costs of human morbidity impacts resulting from air pollution

Component Tasks

- **Develop a core set of health end-points to be covered when estimating the costs of morbidity (Hurley, IOM)**
 - Identify a consistent and comprehensive "core" set of health endpoints for the assessment of the morbidity costs of air pollution.
 - Define the social cost components of air-pollution induced health impacts
- **Review of current partial or comprehensive estimates of the cost of morbidity from air pollution and suggested values for use by OECD**

06/07/16

3

Defining the social cost components of air pollution-induced health impacts

Cost Category	Description of Cost Category
Resource costs	<i>Avertive expenditures</i> , e.g., staying inside to avoid air pollution
	<i>Mitigating expenditures</i> , including the direct medical and non-medical costs associated with treatment for the health impact
Plus	
Opportunity costs	Costs related to loss of productivity and/or leisure time due to the health impact
Plus	
Disutility costs	Pain, suffering, discomfort and anxiety linked to the illness
<u>Equals</u>	
Economic value of avoiding the health impact	

Economic theory suggests aggregate costs will be minimised: implies balancing these cost components

Checklist of potential over-lapping cost components

		Secondary cost			
		Disutility	Productivity costs	Averting costs	Medical costs
Original cost	Disutility	n/a	√	√	√
	Productivity costs	-	n/a	-	-
	Averting costs	√	√	n/a	√
	Medical costs	√	√	√	n/a

Original cost indicates the cost component intended for measurement,

Secondary cost indicates components with which it may potentially overlap.

For example, a questionnaire that asks an individual to state her WTP to avoid disutility cost component needs to be designed so that she does not include financial as well as non-financial concerns in her assessment of her loss of welfare.



Health end-points considered for Valuation: Selection Process

- Pollutant-health combinations where a real (causal) relationship is supported by current scientific evidence, as assessed by expert groups
- Identified pollutant-outcome pairs that had been used in quantification in at least one of three sources.
- In practice, aimed for pollutant-health combinations that had been selected
 - (a) both by US EPA and by the European Commission; or
 - (b) selected by WHO for Global Burden of Disease.

06/07/16

6

Health end-points considered for Valuation (Social Welfare Cost)

Chronic bronchitis – unit value per new case;

Hospital admissions (Respiratory & Cardiovascular) – unit value per new case;

Work-loss days – unit value per day;

Restricted activity days – unit value per day;

Acute lower respiratory infections (ALRI) in children aged less than 5 years – unit value per new case.

Acute bronchitis in children – unit value per new case.

Method for deriving monetary values for avoiding health end-points

- Consistent with values needed to undertake social cost-benefit analysis, these values measure the effect on social welfare, in monetary terms.
 - The component costs that constitute each unit value were derived from peer-reviewed literature, plus other literature: in AQ context & other contexts
- Selection criteria:
- quantity;
 - transferability;
 - quality



Method for deriving monetary values for avoiding health end-points (2)

- Studies compiled into geographical areas:
 - N. America
 - Europe
 - China & India
 - Other
- 10 – 20 studies for each health end-point, though very disparate
- 90% of studies from OECD countries



Results: Example Compilation Table – Chronic Bronchitis

Study/ date/ Location; Pollution type; Methodology type; Peer-reviewed or not	Value per new case (mean/median; range). Original currency year; USD ₂₀₁₀	Comments
Primary valuation studies – North America		
Viscusi et al. (1991); United States; Contingent valuation – Willingness to pay Peer-reviewed	Chronic bronchitis: USD ₁₉₈₇ : 457 000 – 960 000 Median values for alternative risk-risk and risk-money trade-offs. USD ₂₀₁₀ : 877 440 – 1 843 200.	WTP Disutility; 389 respondents. Survey did not mention other cost components though these might have been considered by respondent. 13 dimensions of CB described (see Annex 3); focused on a severe definition of CB.
Krupnick & Cropper (1992); United States; Contingent valuation – Willingness to pay Peer-reviewed	Chronic: USD ₁₉₉₁ : 460 000 – 1 060 000 Median values for alternative risk-risk trade-offs USD ₂₀₁₀ : 883 200 – 2 035 200.	WTP Disutility; used Viscusi questionnaire to derive WTP from respondents familiar with illness (see Annex 3). Respondents were asked whether loss of income was consideration but explicitly asked respondents to exclude resource costs in questionnaire.

Suggested unit values for selected morbidity end-points USD₂₀₁₀

Health end-point	Central unit value	Range (lower – higher)
Cases of chronic bronchitis	334 750	41 700 – 889 800
Hospital admission cases	2 000	600 – 3 300
Work loss days	Country-specific (e.g. US \$130)	Country-specific
Restricted activity days & Minor restricted activity days	RAD: 170 MRAD: 62	RAD: 41 – 268 MRAD: 53 – 70
Acute lower respiratory infections in children aged < 5 years	464	301– 511
Acute bronchitis in children	464	301– 511

Aggregate Morbidity Valuation: fixed % of Mortality?

- Marking up mortality costs (valued using VSL methods) by 10%-15% would give a quantified estimate which, despite its simplicity, looks to be in the right ballpark
- But:
 - beware of preferred valuation metrics (e.g. VSL, VOLY)
 - Be alert to context specificity (e.g. different pollutant mixes & concentrations)



Lessons for impact assessment of chemicals management


- Depth of evidence base – on both epidemiology and valuation – allows this type of informal meta-analysis
 - Even so, (poor) quality and (low) quantity of some evidence ensures that uncertainty parameterisation remains high
- Health impact valuation of chemicals need not be afraid of proceeding without perfect evidence base




Socio-economic analysis in REACH – from a NGO perspective

Vito Buonsante, Client Earth
Sonja Haider, ChemSec
OECD workshop, July 2016



 @clientearth www.clientearth.org

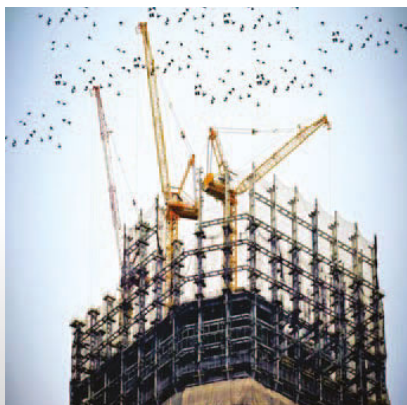



 @chemsec www.chemsec.org

SEA in REACH

...

- Relative importance of SEA vs the Analysis of Alternatives
- Flexible perspective of Technical and Economic Feasibility
- Include a wider perspective on costs and benefits in the socioeconomic analysis
- Do not disfavour users and producers of alternatives

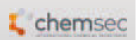


REACH § 55

Aim of authorisation and considerations for substitution

...

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.



Assessment of alternatives

...

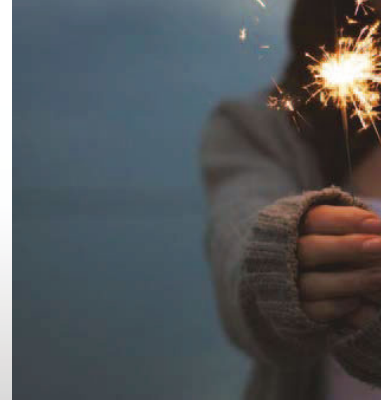
- Assessment of alternatives is key for REACH to fulfill its aims
- Assessment of alternatives is a mandatory element in REACH (authorisation and restrictions)
- SEA are not mandatory [and have a residual role]



Missed opportunities

...

- Adaption to changes is underestimated in performance of products and to initial higher prices
- The concept of economic feasibility of alternatives is rigid, difficult to match and does not drive innovation
- Burden of proof is on the applicant-not on the the alternative providers



Too much emphasis on SEA

...

- Anyone providing a "good business case" should not be granted authorisation
- If a suitable substitute exists in the SEA route no authorisation can be given, regardless of how high the socio-economic benefits are (§ 60.4)
- Given this- SEA gets too much focus in the process



SEA's bias to present

...

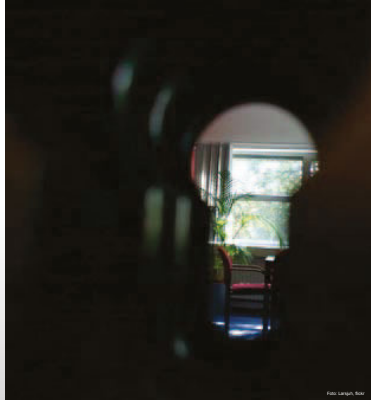
- The future is not less important than the present
- Lack of adaptability
- Qualitative assessments missing
- Too big focus on costs, little on benefits
- Lack of precaution
- ...



See the Bigger Picture

...

- Broadening the picture by inclusion of economical effects on
 - Alternative producers
 - Alternative users
- Examples:
 - Lead chromates in pigments
 - DEHP



Cap on costs for society

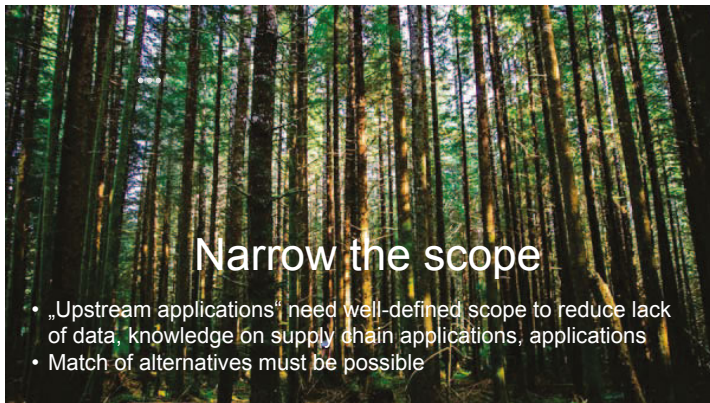
...

- „Benefits outweigh the risks“ – Which amount of costs has a society accept to bear?
- Anyone providing a “good business case” should not be granted authorisation
- If a suitable substitute exists in the SEA route no authorisation can be given, regardless of how high the socio-economic benefits are (§ 60.4)
- Example: Chromium Trioxide, CTAC



Narrow the scope

- „Upstream applications“ need well-defined scope to reduce lack of data, knowledge on supply chain applications, applications
- Match of alternatives must be possible



Positive Effects of Authorisation

...

- Innovation potential
- Safer and healthier materials and products
- Phasing-out of hazardous chemicals and their negative effects
- Transparency in supply chains and for end consumers



Summary

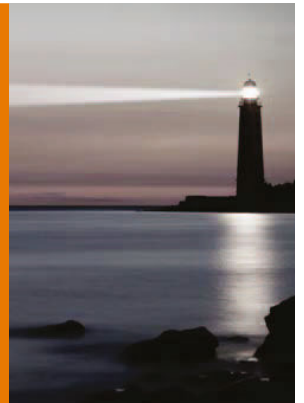
...

- Flexible perspective of Technical and Economic Feasibility
- Assessment of alternatives
- Recognition of adaptability
- Future generations matter
- Broaden the picture of SEA
- Size of societal costs matter
- Well-defined scope allows a match with existing alternatives



**Thank you
for listening**

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Socioeconomic Impact Assessment of Chemicals Management: An Industry Perspective

William F. Carroll, Jr., Ph.D
Indiana University
Carroll Applied Science, LLC

Three Practices

- ▶ Scientific Method
- ▶ Continuous Improvement
- ▶ Strategic Planning, Goal-Setting and Metrics

Three Practices

- ▶ Scientific Method
 - Hypothesis, Experiment, Data Evaluation (Repeat)
- ▶ Continuous Improvement
- ▶ Strategic Planning, Goal-Setting and Metrics

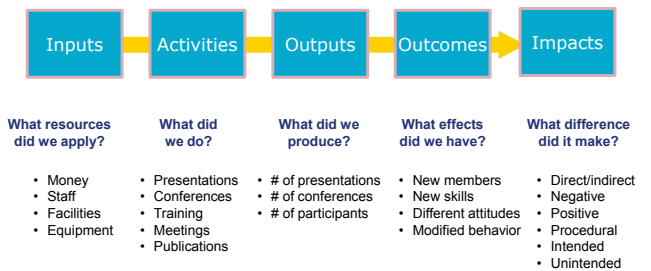
Three Practices

- ▶ Scientific Method
 - Hypothesis, Experiment, Data Evaluation (Repeat)
- ▶ Continuous Improvement
 - Responsible Care® Environmental, Health, Safety and Security (EHS&S) management system
 - Plan-Do-Check-Act (Repeat)
- ▶ Strategic Planning, Goal-Setting and Metrics

Three Practices

- ▶ Scientific Method
 - Hypothesis, Experiment, Data Evaluation (Repeat)
- ▶ Continuous Improvement
 - Responsible Care® Environmental, Health, Safety and Security (EHS&S) management system
 - Plan–Do–Check–Act (Repeat)
- ▶ Strategic Planning, Goal–Setting and Metrics
 - SMART Goals
 - Specific, Measureable, Achievable, Relevant and Time–Bound
 - Milestones, Metrics to Match

Performance Measurement Model



© ACS Leadership Development Systems
Adapted from: Hatry, H.P. *Performance measurement: Getting results* (2006)

The Marketplace as Ecosystem

- ▶ Le Chatelier's Principle
- ▶ Pharmaceutical Testing and Regulation
- ▶ Engineering Principles and Execution

Mercatus Institute

- ▶ Involve Non–Agency Stakeholders
- ▶ Choose the Right Scope
- ▶ Focus on Outcomes *and* Outputs

**Regulatory Studies Center,
George Washington University**

- ▶ Clearly Identify and Quantify Directional Goals
- ▶ Plan Prospectively for Information Collection
- ▶ Clear linkages between standards and outcomes

**What Gets Measured,
Gets Managed**



Chemical Risk Assessment and Translation to Socio-Economic Assessments

Background Paper 1 Presentation for OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management

7 July 2016

Weihsueh A. Chiu, PhD
Texas A&M University

Conflict of Interest Statement

- The author declares no relevant conflicts of interest with respect to the content of this presentation
- This presentation does not reflect the official views of the OCED, U.S. EPA, the State of Texas, or any other organization or third party, and contains personal opinions of the author

1

2

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- Fred Wright, NC State
- Lauren Zeise, California EPA

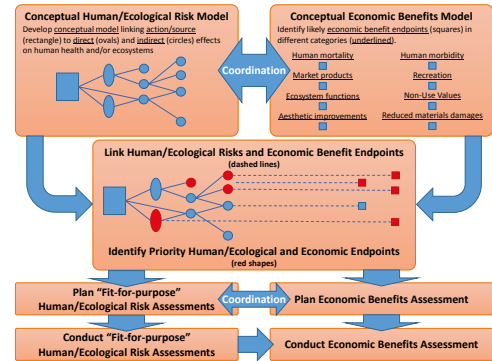
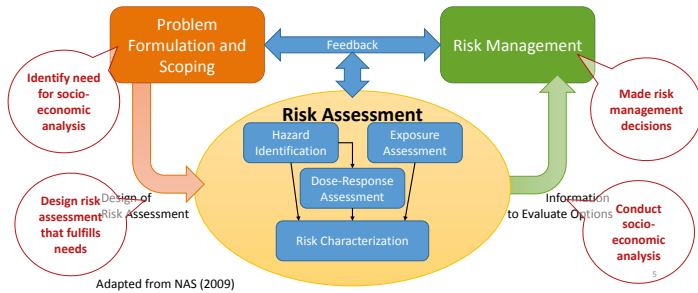
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Outline

- **Framing the Problem:**
Need to Adopt/Adapt Existing Risk Assessments for Use in Socio-Economic Analyses
- **Identifying the Gaps:**
 - Risk assessment information needed for socio-economic analyses
 - Information contained in "typical" chemical risk assessments
- **Bridging the Gaps:**
Challenges, Opportunities, and Recommendations

4

Risk-Based Decision-Making: Developing “Fit for Purpose” Risk Assessments Supporting Socio-Economic Analyses



Realities of expanding application of socio-economic analyses

- Most existing (and ongoing) chemical risk assessments are not designed to support socio-economic analyses.
- In most cases, there will not be the time or resources to iteratively “redo” chemical risk assessments to support socio-economic analyses.
- Economists need approaches to “adopt/adapt” existing risk assessments.

Outline

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Challenges, Opportunities, and Recommendations

Key needs for supporting typical socio-economic analyses

- **Exposure assessment**
 - Expected or central tendency values
 - Impact of risk management alternatives
- **Hazard identification**
 - Conclusion regarding causality
 - Economically-meaning endpoints
 - Non-overlapping endpoints
- **Dose-response assessment**
 - Functional relationship with exposure and time
 - Effects expressed as incidence or severity
 - Expected or central tendency values
- **Risk Characterization**
 - Change in incidence and severity of each endpoint under each alternative (including baseline), as a function of time
 - Expected or central tendency values

Comparison of human health risk assessments

U.S. National Ambient Air Quality Standards for Lead

Purpose: Selecting among alternative air pollution standards for lead.

- Baseline standard of 1.5 µg/m³
- Proposed standards of 0.1, 0.15, 0.2, 0.3, 0.4, or 0.5 µg/m³

Used directly in socio-economic benefit-cost analysis.

EU Risk Assessment Report for Hexabromocyclododecane (HBCD)

Purpose: Determining whether measures to address risks of exposure to HBCD are needed.

- Need for further information or testing
- Need for risk reduction measures to limit risks

Potential for use in socio-economic benefit-cost analysis?

Exposure Assessment

U.S. National Ambient Air Quality Standards for Lead

Blood lead levels in population of concern:

- Estimated annual mean air lead concentrations under different standards
- Estimated mean blood lead levels in children age<7 under different standards

Suitable for supporting socio-economic analyses?

- ✓ Expected or central tendency values
- ✓ Impact of risk management alternatives

EU Risk Assessment Report for Hexabromocyclododecane (HBCD)

Aggregate, multi-source, multi-pathway exposure estimates:

- Separate estimates for occupational workers and general public
- Estimated both “reasonable worst case” and “typical” exposure estimates

- ✓ Expected or central tendency values
- ~ **Impact of risk management alternatives**

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Key needs for supporting typical socio-economic analyses

Exposure Assessment

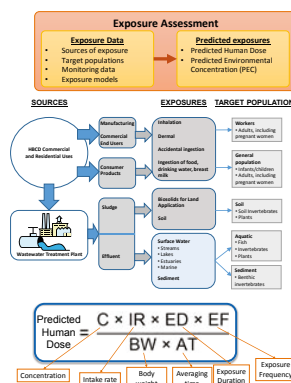
- Expected or central tendency values

Many include both “reasonable worst case” and “typical” exposure estimates.

- Impact of risk management alternatives

Many include enough information to re-estimate exposure under risk management alternatives.

12



Hazard Identification

U.S. National Ambient Air Quality Standards for Lead

Health endpoints associated with lead exposure:

- “The overall weight of the available evidence provides clear substantiation of neurocognitive decrements being associated in young children with blood-Pb...”

EU Risk Assessment Report for Hexabromocyclododecane (HBCD)

Toxicological effects of HBCD exposure:

- “...proposed to base the NOEL for repeated dose toxicity on ... liver weight increase. Enzyme induction is a likely cause to the liver weight increase, and enzyme induction is clearly relevant also to humans.”
- Effects on thyroid and pituitary – confidence in causality less clear.

Suitable for supporting socio-economic analyses?

- ✓ Conclusion regarding causality
- ✓ Economically-meaning endpoints
- ✓ Non-overlapping endpoints

- ~ Conclusion regarding causality
- ~ Economically-meaning endpoints
- ~ Non-overlapping endpoints

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Key needs for supporting typical socio-economic analyses

• Hazard identification

- Conclusion regarding causality

Conclusions regarding causality are not always clearly stated.

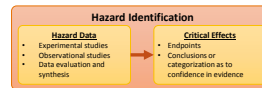
- Economically-meaning endpoints

Many endpoints not directly economically meaningful.

- Non-overlapping endpoints

Limited to discussing endpoints that are “secondary” to other endpoints.

14



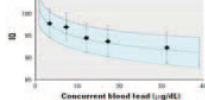
Hazard identification categories

- Carcinogenic to Humans
- Likely to be Carcinogenic to Humans
- Suggestive Evidence of Carcinogenic Potential
- Inadequate Information to Assess Carcinogenic Potential
- Not Likely to be Carcinogenic to Humans

Dose-response Assessment

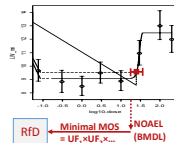
U.S. National Ambient Air Quality Standards for Lead

- Mean IQ loss in children under 7 as a function of blood lead



EU Risk Assessment Report for Hexabromocyclododecane (HBCD)

- NOEL (BMDL) = 22.9 mg/kg-d for 5% increased liver weight
- Uncertainty factors to define “minimal Margin of Safety”

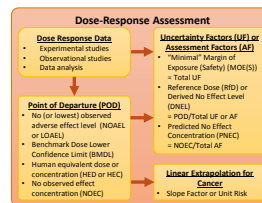
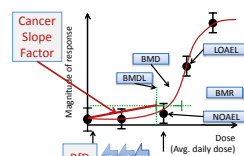


Suitable for supporting socio-economic analyses?

- ✓ Functional relationship with exposure and time
- ✓ Effects expressed as incidence or severity
- ✓ Expected or central tendency values

- ~ Functional relationship with exposure and time
- ✓ Effects expressed as incidence or severity
- ~ Expected or central tendency values

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Key needs for supporting typical socio-economic analyses

• Dose-Response

- Functional relationship with exposure and time

Only routinely estimated for cancer (linear relationship).

- Effects expressed as incidence or severity

Only for cancer or when BMD modeling is conducted.

- Expected or central tendency values

Central tendency values available from BMD modeling, but lacking for Uncertainty Factors.

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Risk Characterization

U.S. National Ambient Air Quality Standards for Lead

- Total IQ points in population gained under alternative standards:
 - 0.5 µg/m³: 230,000
 - 0.4 µg/m³: 230,000
 - 0.3 µg/m³: 270,000
 - 0.2 µg/m³: 360,000
 - 0.15 µg/m³: 400,000
 - 0.1 µg/m³: 510,000

Suitable for supporting socio-economic analyses?

- ✓ Change in incidence and severity of each endpoint under each alternative (including baseline), as a function of time
- ✓ Expected or central tendency values

EU Risk Assessment Report for Hexabromocyclododecane (HBCD)

- Is ratio between NOAEL (BMDL) and Exposure larger than the minimal MOS?
 - Yes: "There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already."
 - No: "There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account."

- ✗ Change in incidence and severity of each endpoint under each alternative (including baseline), as a function of time
- ✗ Expected or central tendency values

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Key needs for supporting typical socio-economic analyses

• Risk Characterization

- Change in incidence and severity of each endpoint under each alternative (including baseline), as a function of time

Only routinely available for cancer (linear relationships with dose and time).

- Expected or central tendency values

Not generally available due to lack thereof in dose-response assessment.

Risk Characterization

Margin of Exposure (Safety)
[Human]

MOE(S) = POD/Predicted Human Dose

- "Acceptable" risk if MOE(S) ≥ "minimal" MOE(S)
- "Unacceptable" risk if MOE(S) < "minimal" MOE(S)

Hazard Quotient (HQ) or Risk Characterization Quotient (RCR)
[Human]

HQ or RCR = Predicted Human Dose/RfD

- "Acceptable" risk if HQ or RCR ≤ 1
- "Unacceptable" risk if HQ or RCR > 1

Excess Risk for Cancer
[Human]

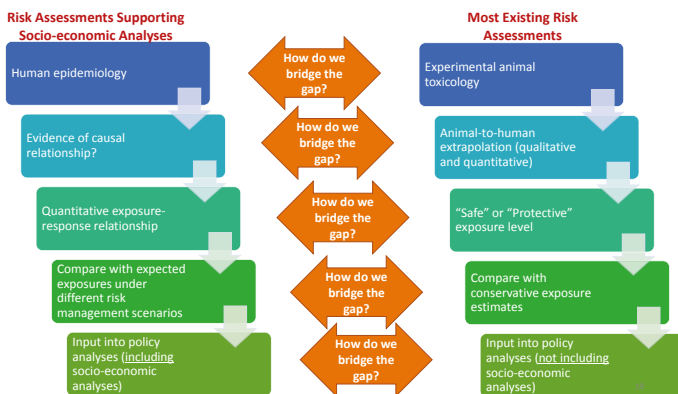
Excess Risk = Predicted Human Dose × Slope Factor or Unit Risk

- "Acceptable" risk if < Benchmark risk (e.g., 10⁻⁶, 10⁻⁵, or 10⁻⁴)
- "Unacceptable" risk > Benchmark risk

Risk Quotient
[Ecological]

Risk Quotient = PEC/PNEC

- "Acceptable" risk if PEC/PNEC ≤ 1
- "Unacceptable" risk if PEC/PNEC > 1



Outline

- Framing the Problem:**
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Challenges, Opportunities, and Recommendations

Feasibility of Adopting/Adapting Existing Exposure Assessments

- **Central tendency values: FEASIBLE**
 - Already exist for many risk assessments
 - Can derive using standard references for “central tendency” exposure parameters
 - Additional refinement: characterizing and distinguishing between uncertainty and variability
- **Impact of risk management alternatives: FEASIBLE**
 - Will always need to tailor the exposure assessment to the risk management alternatives being considered
 - Extensive experience already exists in the community

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Feasibility of Adopting/Adapting Existing Hazard Identifications

- **Conclusion regarding causality: FEASIBLE** (see next slide)
 - Facilitated by trend towards adopting formal causal frameworks like those used at U.S. EPA, WHO/IARC, U.S. NTP.
 - Can assign probability (or range of probabilities) of causation, depending on the risk assessment conclusions (Trasande et al. 2015).
- **Economically-meaning endpoints: FEASIBLE SOMETIMES**
 - Facilitated by trend towards endpoint-by-endpoint causal determinations
 - Often challenged by uncertainty in animal-to-human concordance
 - Short term, focus on endpoints with unambiguous human counterpart
 - Medium-/longer-term, develop economic valuations for “sub-clinical” and more “ambiguous” endpoints.
- **Non-overlapping endpoints: FEASIBLE SOMETIMES**
 - Facilitated by trend towards using more mechanistic / Adverse Outcome Pathway data
 - Short term, not likely issue given limited economically meaningful endpoints.
 - Medium-/longer-term, develop quantitative models of endpoint relationships.

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Convergence of causal frameworks ... and probabilistic hazard identification?

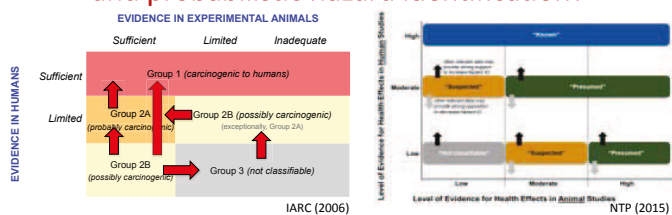


TABLE 4-5 Example Conversion of Quantitative Output to Qualitative Categorical Judgments

Classical Classical X is a Carcinogen	Categorical Judgment
> 90%	Carcinogen in humans
> 50% to > 70%	Likely to be carcinogen in humans
> 10% to > 50%	Suggestive evidence of carcinogenicity
< 10% to > 10%	Inadequate information
< 1%	Not likely to be carcinogen in humans

Adapted from NAS (2014)

Table 1. Framework for Evaluating Probability of Causation

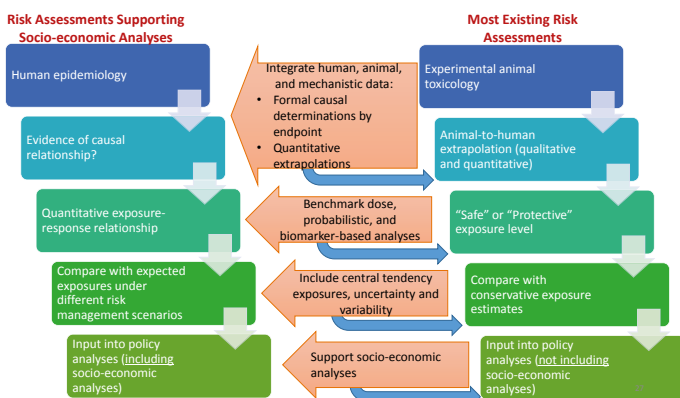
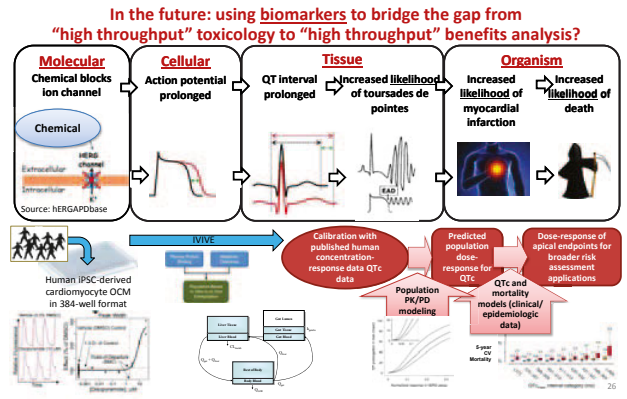
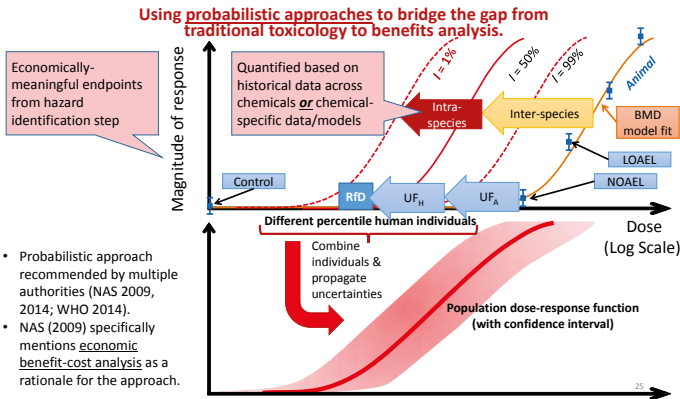
Epidemiological Evaluation	Toxicological Evaluation		
	Strong (Group 1)	Moderate (Group 2A)	Weak (Group 2B)
High (> 100-100%)	High (> 80%)	Medium (40-60%)	Low (20-30%)
Moderate (High 70-80%)	Medium (40-60%)	Low (20-30%)	Very Low (0-10%)
Low (Medium 40-60%)	Low (20-30%)	Very Low (0-10%)	Very Low (0-10%)
Very Low (Low 20-30%)	Very Low (0-10%)	Very Low (0-10%)	Very Low (0-10%)

Trasande et al. (2015)

Feasibility of Adopting/Adapting Existing Dose-Response Assessments

- **Functional relationship with exposure and time:**
 - **Effects expressed as incidence or severity:**
 - **Expected or central tendency values:**
- } FEASIBLE AND INTER-RELATED
- **Replacing LOAEL/NOAEL/BMDL with a function describing the dose-response data**
 - Facilitated by trend towards using benchmark dose modeling (which requires a quantal or continuous endpoint) rather than LOAEL/NOAEL.
 - In short term, can extract the underlying model fits or re-analyze the data to fit a model curve
 - In longer term, can incorporate additional sources of uncertainty, such as model uncertainty
 - **Prediction of extrapolated human population dose-response function**
 - Already done for cancer endpoints, assuming linearity.
 - For non-cancer effects, enabled by probabilistic approach to replace fixed uncertainty factors (recent Harmonized Guidance by WHO/IPCS includes probabilistic “default” distributions for immediate implementation).
 - In short term, will need to re-analyze data to derive predicted dose-response function, using default distributions.
 - In medium-/longer term, can utilize chemical-specific data and eventually quantitative biomarker-based models.

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Conclusions and Recommendations

- Existing “typical” risk assessments leave a number of critical gaps if they need to be “repurposed” for use in socio-economic analyses.
- Many current, recommended risk assessment methodologies facilitate better translation for socio-economic analyses.
 - Methods have not yet become “common” risk assessment practice.
 - “Bridging analyses” will be necessary in the short- and medium-term.
 - Need for multidisciplinary collaboration.
- Case studies demonstrating “bridging analyses” may provide valuable experience and facilitate uptake.
- Further progress possible with economic valuations of “subclinical” endpoints and “ambiguous” risks.

Overview

Review of Chiu, “Chemical Risk Assessment and Translation to Socioeconomic Assessments”

Leonardo Trasande, MD, MPP
NYU School of Medicine

- Strong review of basic steps to chemical risk assessment
 - Comment for emphasis that “risk” implies probability when these are more typically impact assessments
 - Four case studies of risk assessment as used in socioeconomic analyses (HBCD human and ecological; DCM and PFOA)

Main findings

- Most methods poorly adapted to look at entirety of exposure-response function
 - Focused instead on points of departure (Probabilistic Dose-Response Framework an alternative)
 - Heavily reliant on animal data with crucial assumptions about extrapolation to humans (internal dose, species variability)

Main findings

- Methods weak for non-cancer endpoints
- Work from “central tendency” of exposure
 - Fail to consider high-exposure or otherwise vulnerable populations
- Not all end points monetize readily
 - Toxicology needs to adapt better to health and economic outcomes
- Causal framework rigid
 - Misapplied notions of Bradford Hill

Other concerns

- Toxicology studies are limited foundation for imputing effects
 - Small sample size (limited power)
 - Limited and wide range of doses
 - PBPK models not proven to have good fit for many exposures
 - Old assays (e.g., uterotrophic) crude and insensitive
 - Also cannot be extrapolated to humans readily

Other concerns

- Integrated Probabilistic Risk Assessment and Probabilistic Dose-Response Frameworks may particularly compound error from toxicology studies
 - Extrapolating from toxicology studies to assume a distribution of margins of exposure for humans
 - Assumes variability in exposure and response can be modeled in humans (assuming interspecies and intraspecies factors)

Case in point: Triclosan

- IPRA from REACH: 4,894 men could have reproductive deficits based on the decreased vas deferens weights observed in rats
- Extrapolations from human data suggest missed 282,000 girls per year with earlier pubertal development and 428,000 cases per year with increased total T₃ hormone levels

Radka et al in preparation

Other concerns

- Nonmonotonicity, nonlinearity
 - Even newest methods fail to account for this reality
- "Good laboratory practice" (GLP) hardly represents a proper or even gold standard for laboratory studies, with concerns including:
 - Contamination of negative controls
 - Responsiveness to positive controls
 - Dissection techniques.
 - Flaws in many GLP studies have been identified, yet regulatory agencies rely upon these flawed studies.

Myers JP, et al. *Environ Health Perspect* 2009;117:309-15; vom Saal FS et al. *Toxicol Sci* 2010;118:612-3; vom Saal FS, *Environ Health Perspect* 2010;118:A60.

Caution about newer methods

- Flaws in ToxCast have recently been exposed in detecting synthetic chemical obesogens
Janesick et al EHP 2016
- Thyroid, sex steroids are not the only hormonal systems
- Subclinical effects matter (decrements within euthyroid range associated with adverse neurodevelopmental outcomes, e.g. autism and ADHD).
Bellanger et al JCEM 2015

Models are only as good as their inputs

- If toxicology data are flawed, then burden of disease and cost estimates are meaningless.
- Strengths of lead, mercury, air pollution risk assessments derived from strong human and animal data.

Needed improvements

- Stronger pre-market data and follow-up toxicology studies
- Clinical and subclinically relevant endpoints
- Powered, independent peer-reviewed studies
- Careful consideration of endocrine system

Way forward?

- We're not getting anywhere by singling out disciplines
 - Risk assessors, toxicologists, economists epidemiologists can all be blamed for working in silos and failing to provide robust data
 - Socioeconomic analyses are only as good as primary disease/disability estimates (i.e., worry about the money later)
 - Subclinical endpoints are valuable to society (e.g., IQ, Body Mass Index, Blood Pressure, Time to Pregnancy)

Modeling disease burden

- Suggest epidemiologic evidence as first choice for extrapolation
- If toxicologic studies used, cannot simply rely on safety factor for threshold
 - Presumption of steeper exposure-response relationship (with sensitivity analyses), or adapt probabilistic range for main effects in entire population
 - Could still adapt probabilistic ranges for individual-level variability

Modeling disease burden for EDCs

Epidemiologists, toxicologists and economists all served on expert panels

IPCC framework for probability of causation; WHO GRADE Working Group criteria for grading epidemiology; Danish EPA criteria for grading toxicology

- Fifteen exposure-outcome relationships → Monte Carlo simulations yielded median of €163 billion
 - <5% of EDCs considered
 - Breast cancer and many other conditions not included
 - Only considered published costs associated with these chronic conditions
 - COI approach misses substantial welfare costs

Trasande et al JCEM 2015; Andrology 2016

Benefits and costs of replacing BPA

- Potential cost of one BPA alternative, oleoresin = \$0.022 per can
 - 100 billion aluminum cans are produced annually
 - 100 billion x \$0.022 = **\$2.2 billion**
- Potential benefit of replacing BPA with lining free of health effects = **\$1.74 billion**
 - Does not include other effects (cognitive, asthma, breast cancer)
- Sensitivity analyses suggest as high as \$13.8 billion

Trasande Health Affairs 2014

Context for the GBD

- GBD meant to provide common framework for comparing investments in health
- Environmental health interventions reverse externalities, and do not require health ministry expenditures
- Strict causal framework correct for health ministry investment decisions, but not for regulatory decisions in environmental health

Beware the DALY

- Because DALY values have been estimated only for intellectual disability, approach taken in GBD would include DALY losses only from the 3,290 annual cases in the EU found to suffer intellectual disability attributable to PBDE exposure and 59,300 for organophosphates.
 - For the EU, costs from intellectual disability alone were calculated at more modest amounts of €1.2 billion and €21.4 billion, respectively.
 - The more inclusive approach yielded estimates of €9.6 billion and €146 billion, respectively.

Measuring the true chemical GBD

- Quasi-representative biomonitoring from selected countries
 - Current estimate of childhood lead costs: 98.6 million IQ points lost, \$134.7 million international dollars = 4.03% of GDP PPP Attina and Trasande EHP 2013
 - Based on data from five African countries (South Africa, Nigeria, Kenya, Botswana, Uganda)
 - Measurements of biomarkers in populations of concern (adult men, women of childbearing age, children)
 - Suggest not limiting to POPs (phthalate, bisphenol, organophosphates, Hg, Pb, As, Cd)

Summary

- Beware toxicology as input to socioeconomic modeling
- Engage broadly with health scientists
- Embrace probability throughout (causation, reference level, exposure response relationship)
- Disease burden first, counterfactuals, costs last
- COI first, WTP later

Measuring the Economic Value of Chemicals on Ecological System and Human Health

Anna Alberini

University of Maryland

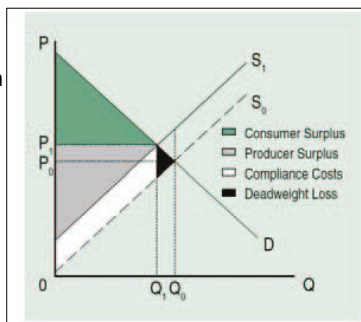
OECD-ECHA Workshop, Helsinki, 6-8 July 2016

Regulating Chemicals

- Chemicals – contained in products, released into the environment
- Should they be regulated?
- Cost-benefit analysis
 - An input into decisionmaking about regulation
 - Convert the various “positive” and “negative” effects of proposed regulation into one metric: euro or dollars
 - Regulation makes sense if benefits > costs
 - Not easy

Costs

- Expenses incurred or resources diverted from other uses to comply with the regulations
- Value of reduction in output
- Limited to one or two markets (partial equilibrium analysis)...
- ...or economy-wide (general equilibrium analysis)



Source: US EPA, Guidelines to Economic Analyses (2012).

Benefits

Benefits = The beneficiaries' Willingness to Pay for the regulation or the policy

How do we estimate benefits?

- List likely physical or market effects (compared to no-policy baseline), beneficiaries
- Attach a monetary value to each unit of these effects
- Seek valuation method appropriate for each such effect
- Methods
 - Market methods
 - Non-market methods

Types of Benefits

Environmental benefits

- Losses/gains to fisheries, agriculture, manufacturing, etc.
 - To producers
 - To consumers (higher prices, lower output)
- Recreation
- Aesthetics (visibility, odors, noise, etc.)
- Non-use values
- Avoided costs of supplying alternate ecosystem services

Human health

- Illnesses and fatalities due to
 - occupational exposure (workers)
 - environmental exposure (general public)
 - Consumption of products containing the chemicals (consumers)

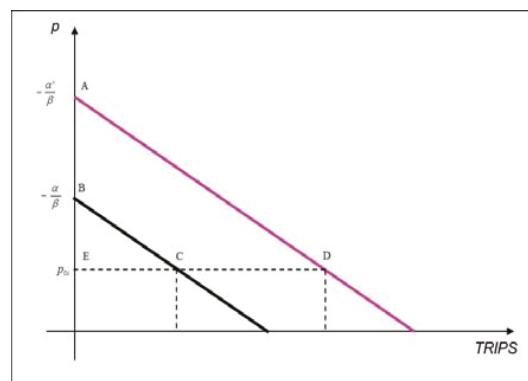
Productivity effects

- Work days lost to illness
- Worker reduced productivity even if at work

Non-market methods

- Travel cost method (TCM)
 - Suitable for recreation sites
 - Only use values
 - Single-site visitation models v. discrete choice models
- Hedonics
- Stated preference methods

TCM: Single-site models



Weak complementarity assumption

TCM: Discrete choice models

- Based on random utility model
- Sites are described by attributes, including environmental quality
- Explicitly allow for trading off attributes, substitution between sites
- Can estimate the WTP for a change in one attribute and/or the WTP for an entire "modified site"

Where shall we go fishing?

Handwritten notes comparing two fishing sites, B and C. Site B has a cost of €15, a boat, a catch of two fish, and good water quality. Site C has a cost of €25, a boat, a catch of three fish, and very good water quality.

Site	Cost	Boat	Catch	H ₂ O quality
B	€15	YES	☒☒	good
C	€25	YES	☒☒☒	v. good

Hedonic pricing methods

- The price of a good is explained by the levels of its attributes
- Housing prices (or rents) should depend on structural characteristics of the home, location, environmental quality at the site
- Regression equation:

$$(\ln)P_i = \mathbf{x}_i\boldsymbol{\beta} + E_i\gamma + \varepsilon_i$$

Hedonic pricing methods (2)

- Use coefficient on environmental quality to see how housing values increase if environmental quality is improved
- Can be applied to other goods (e.g., cars, wages, etc.)
- Difficulties:
 - Environmental quality likely to be correlated with other, unobserved attributes of the neighborhood that influence price
 - If so, we may attribute to environmental quality effects that are really due to something else
 - Look for exogenous "shocks" (e.g., Davis, 2004) or repeat sales
 - Conventional housing price hedonics capture value of environmental quality only if environmental quality doesn't change the decision to sell the home (Guignet, 2014)

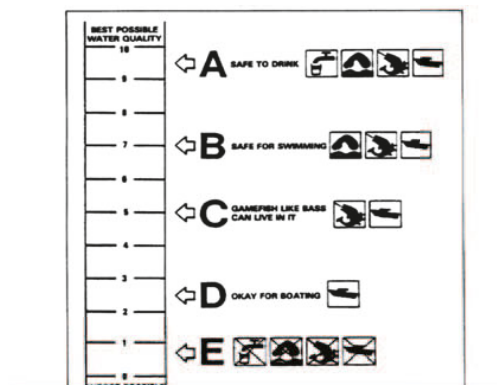
Stated preference methods

- Based on surveys of members of the public
- Ask people what they would do, or how much they would pay, under hypothetical but well specified circumstances
- Suitable for a wide variety of goods, contexts, changes in environmental quality (including any not experienced before)
- Sometimes criticized because they are hypothetical

Stated preference methods (2)

- Contingent valuation
 - “Would you pay X euro for...?” yes/no
- Contingent behavior
 - “Would you continue buying/going or stop altogether if the price was X euro?”
- Discrete choice experiments
 - “Which would you choose—A, B, or neither?”

The Water Quality Ladder (Mitchell and Carson, 1993)



Valuing effects of chemicals on human health

- Types of effects
 - Morbidity
 - Mortality
- Description of effects
 - Duration or frequency (acute v. chronic)
 - Severity (bed disability day, work loss day, restricted activity day)
 - Affected parties (children, elderly, sensitive individuals)

A Simple Model for Morbidity

- Individual or household utility depends on consumption, leisure time, and sick days: $U(X,L,D)$
- Dose-response function: $D=D(P,A)$
- Choose consumption and leisure time to maximize utility, subject to budget constraint
- Budget constraint states that...
 - we spend what we earn
 - sick days reduce work time (and hence income) *and* create medical expenditures
 - plus we spend money on averting activities (self-protection)

What is the WTP to reduce pollution?

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

Slope of the dose response function

Work income lost to illness

Averting expenditures

Value of the disutility and discomfort of illness

Cost of illness

WTP to pay to avoid a sick day

Assumptions

- Pollution enters in the utility function only via its effect on sick days
- Work time is flexible
- The specific nature of the chemical is not important. All that matters is the effect of pollution or chemicals on sick days.

Is this model suited for chemicals?

- Yes and no
- Yes: if the chemicals cause minor symptoms without lasting consequences (e.g., itchy eyes, headaches, ...)
- No: if the chemicals cause serious chronic illnesses (e.g., diabetes), neurological and developmental problems in babies and infants, irreversible reproductive system effects

Chemicals with neurological and developmental effects

- | | |
|--|---|
| <ul style="list-style-type: none">• Lead, mercury, heavy metals• Effects on babies, infants, children• Exposures to high levels → physical and neurological effects → cognitive difficulties, reduced school attendance → lower educational attendance → lower wages | <ul style="list-style-type: none">• Damage from chemical = (Lifetime wage differential + additional costs) × attributable cases• Landrigan et al. (2002), Grosse et al. (2002), Drake (2016), Trasande (2016)• Misses the disutility and suffering of individual and parents• A lower bound to true damage |
|--|---|

Landrigan's figures

- Average lead level in blood in 5-year-olds: 2.7 µg/dL, which is predicted to reduce IQ by 0.675 points
- 1 IQ point lost → 2.39% loss in lifetime earnings
- So 0.675 IQ points lost = 1.61% loss in lifetime earnings
- ...or USD 21,014 for boys and USD 12,394 for girls
- Nationwide USD 27.8 billion (boys) and USD 15.6 billion (girls) (1997 USD)

Loss of productivity

- In air pollution context, loss of productivity is because of work loss days
 - ...and in the air pollution context,
 - Zivin et al. (2011) with agricultural workers
 - Chang et al. (2014) with workers at a pear-packing plant
- find lower productivity *at work* on high pollution days
- Can chemicals have similar effects?

Mortality effects

- Exposure to chemicals via the environment or use of products linked to increase mortality risks (cancer, effects on cardiovascular system, kidneys, liver, etc.)
- Diabetes and shorter life expectancy
- Benefits of regulation:
 - Expected lives saved × Value of a Statistical Life (VSL)
 - or
 - Expected life-years saved × Value of a Statistical Life year (VOLY)

What is the Value of a Statistical Life? (a.k.a. Value of a Prevented Fatality)

- A summary measure of how much someone is prepared to pay to reduce his risk of dying by a small amount
- Grounded in economic theory
- If I am willing to pay 500 euro to reduce risk by 1/10,000 (=0.0001), the VSL is $500 \times 10,000 = 5,000,000$ euro
- Values used by agencies in policy analyses:
 - US EPA USD 7.4 million (2006 dollars)
 - DG-Environment central value EUR 1.5 million
 - OECD recommends a base value USD 3.6 million for EU-27

How is the VSL estimated?

Compensating wage studies

$$w_i = \beta_0 + x_i\beta_1 + p_i\beta_2 + q_i\beta_3 + (q_i \times WC_i)\beta_4 + \varepsilon_i$$

- VSL inferred from the coefficient on fatal risks
- Econometric difficulties, measurement of risks, assumption that workers actually know their risks, heterogeneity and self-protection

Hedonic regressions for other goods

- Car prices depend on car characteristics, including safety
- Home prices change when environmental risks are discovered

Consumer expenditures on safety equipment

Stated preference studies

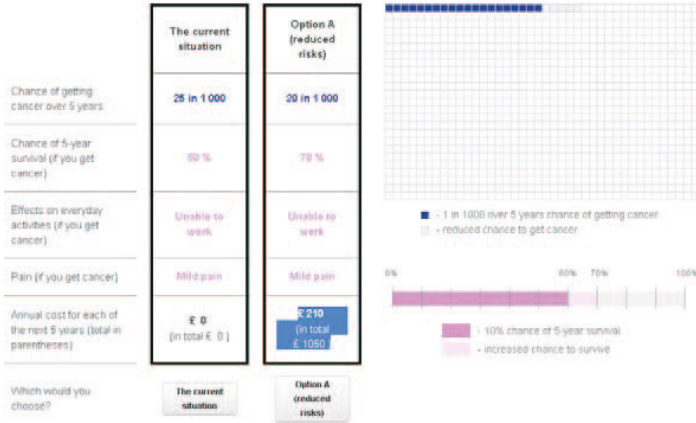
Can we apply existing estimates of the VSL to the effects of chemicals?

- Only if we presume that VSL figures from workplace or transportation accident context can be applied to chemicals
- Must adjust for latency—risk reductions from regulating certain chemicals now likely to occur in the future
- Is the cancer VSL higher?

Cancer risks

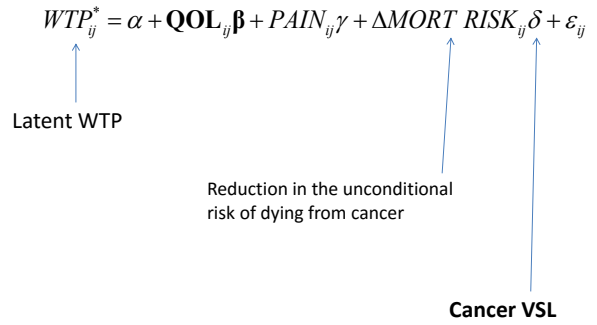
- Risk assessments estimate excess lifetime *cancer risks*, i.e., number of cases of cancer
- Useful to separate the Value of a Statistical Case of Cancer (VSCC) (just getting cancer, being ill and receiving treatment) from the cancer VSL (dying from it)
- Avoid double counting

Alberini and Scasny (2015): Example Choice Card



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Estimating the VSL -- The Model



The Model (cont'd)

But

$$\Delta MORT RISK = \Delta R \cdot (1 - S_0) + R_0 \cdot \Delta S - \Delta R \cdot \Delta S$$

Where

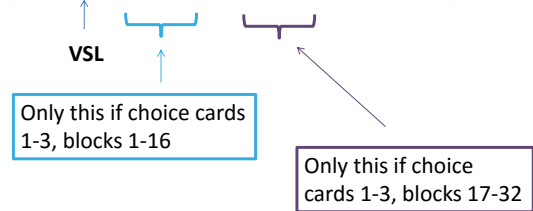
ΔR =reduction in the risk of cancer ΔS =increase in the chance of surviving cancer
 R_0 =baseline risk of cancer S_0 =baseline chance of surviving cancer

So...

$$WTP_{ij}^* = \dots + \delta \cdot [\Delta R \cdot (1 - S_0) + R_0 \cdot \Delta S - \Delta R \cdot \Delta S] + \varepsilon_{ij}$$

Estimating the VSL

$$WTP_{ij}^* = \dots + \delta \cdot [\Delta R \cdot (1 - S_0) + R_0 \cdot \Delta S - \Delta R \cdot \Delta S] + \varepsilon_{ij}$$



Estimating the VSCC

$$WTP_{ij}^* = \dots + \delta \cdot [\Delta R \cdot (1 - S_0) + R_0 \cdot \Delta S - \Delta R \cdot \Delta S] + \varepsilon_{ij}$$

So...

$$VSCC = \frac{\partial WTP^*}{\partial \Delta R} = \delta(1 - S_0) - \delta \Delta S$$

- The VSCC declines with the size of the improvement in the chance of survival
- If $\Delta S=0$ (choice cards 1-3, blocks 1-16), then $VSCC=VSL \times (1-S_0)$

The Data: Sample Sizes

Country	Pilot	Main wave
Czech Republic	148	1 145
United Kingdom	128	733
Netherlands	-	910
Italy	-	824
Total	276	3 612

Key Results — t stats in parentheses

	(A): Blocks 1-16 Choice cards 1-3 Only $\Delta R \neq 0$ Nobs: 3483	(B): Blocks 17-32 Choice cards 1-3 $\Delta S \neq 0$ Nobs: 3759	(C): All blocks, all choice cards Nobs: 16873
QOL=1 dummy	-0.1343 (-1.067)	0.1625 (1.269)	-0.0486 (-1.175)
QOL=2 dummy	0.0026 (0.018)	0.1762 (1.107)	-0.0892 (-1.918)
QOL=3 dummy	-0.1701 (-1.148)	0.1357 (0.827)	-0.1756 (-4.083)
Moderate pain dummy	0.1246 (1.311)	0.0867 (0.977)	0.0190 (0.620)
Δ MORTRISK	15023.027 (8.070)	6136.54 (10.175)	5324.53 (30.271)
Cost	-0.00265 (-9.223)	-0.00325 (-7.938)	-0.00249 (-25.181)
Implied VSL (mill. PPP euro)	5.676 (s.e. 0.866)	1.887 (s.e. 0.284)	2.144 (0.102)
Implied VSCC (mill. PPP euro)	0.551 (s.e. 0.084)	n/a	Varies with ΔS

VSCC from all choice cards, all blocks

Value of $\Delta S=0$	VSCC (million PPP euro)
No change	0.339 (s.e. 0.035)
5% at 5 years	0.266 (s.e. 0.025)
10% at 5 years	0.198 (s.e. 0.021)
20% at 5 years	0.073 (s.e. 0.032)

Chemicals as emerging pollutants

- How should valuation be done when the effects of chemicals are unknown or only tentative?

Points for discussion

1. Responses in related markets have been observed even when causation had not been established (Davis, 2004) or chemicals are not identified (e.g., fracking)
2. The public has consistently demonstrated to be willing to switch to and pay more for safer products
 - Survey of the Canadian public by Industrial Economics (2015)
 - CAD 49 a month to switch to non-carcinogenic products, and CAD 17 – 35 a month to avoid adverse effects on soil, air or water.

Discussion 2

4. When the effects of a chemical are uncertain, we say that they are “ambiguous.”

6. Ambiguity may arise when people are told conflicting information on such effects.

Discussion 3

7. Fox and Tversky (1995) warn that ambiguity aversion may arise when people are comparing ambiguous and clear risky prospects, but diminishes or disappears when risky prospects are evaluated in isolation.

8. Ambiguity aversion would lead to attaching a lower value to an ambiguous risky prospect than to a comparable but clear risk prospect.

9. But do these claims carry over to when the human or environmental effects are ambiguous?

Discussion 4

10. Theoretical work by Treich (2010) and Courbage and Rey (2015) about the VSL and ambiguity aversion

- Effect of ambiguity aversion on VSL cannot be signed (Courbage and Rey)
- Ambiguity premium likely to be small (Treich)

11. Empirical work: WTP to reduce or eliminate health risks not affected by ambiguity, whether or not in isolation (Goldberg et al., 2009; baby formula contaminated with pathogens).

12. Nature of the chemical unlikely to influence WTP much.

In conclusion...

- Various methods for estimating the benefits of reducing exposure to chemicals via the environment or consumer products
- All methods have \pm s
- Many benefits are...
 - underinvestigated (productivity, reproductive health or birth defects)
 - require major updates (e.g., Landrigan figures with lead and IQ; chronic bronchitis, see Alistair Hunt)
 - miss out important components of WTP (suffering and disutility)

Conclusions (2)

- But my reading of the evidence is that ambiguity and the specific chemical or its source are unlikely to make a big difference on the WTP for the symptoms/effects
- Difficulties with..
 - valuing probabilistic outcomes
 - Valuing multiple/simultaneous/cumulative chemical exposures
- Recommend research on the above, but also going ahead with applying WTP figures to chemicals regulations

Thank you!

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Reproductive health effects

- Ex ante v. ex post
- Scasny and Zverinova (2014) for ECHA
 - Ex ante
 - Stated preference study to value an increase in the probability of conception
 - Vitamins (private good) or chemical-free product (public good)
- Value of a Statistical Pregnancy (VSP):
 - 40,000 euro (private good)
 - 33,000 euro (public good)
 - 40,000 euro (public good but respondents who intend to have a child)
- Controlling for possible co-benefits, the VSP is
 - 25,000 euro
 - 11,000 euro
 - 20,000 euro
- The same survey also elicits WTP to reduce the risk of low birth weight and birth defects

Value of a Statistical Life

- Well-grounded in economic theory
- In a static model expected utility model,

$$VSL = \frac{\partial WTP}{\partial R} = \frac{U(y) - V(y)}{(1 - R) \cdot U'(y) + R \cdot V'(y)}$$

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

Anna Alberini and Milan Scasny

Research Questions

- What VSCC and cancer VSL figures should be used in EU/ECHA policy analyses?
- How important are quality of life and pain in explaining the willingness to pay to reduce cancer mortality risks?
- In stated preference studies
 - Can respondents handle several quantitative attributes (here, two probabilities and one cost)?
 - How do qualitative attributes fare?

Approach

- Stated Preferences
- In each choice card, the respondent must choose between an alternative that reduces risks (at a cost) and the status quo =
- = dichotomous-choice (DC) contingent valuation (CV) questions
- Total of 7 DC CV questions per respondent

What Good Are We Valuing?

- Reduction in the risk of dying from cancer
- This risk is the product of
 - Risk of getting cancer
 - Risk of dying from cancer, conditional on getting cancer in the first place
- Generic cancer (no mention of organs affected, type, etc.)
- Description of quality of life impacts and pain

Attributes and Levels

Reduction in the chance of getting cancer within the next 5 years	0 (baseline), 2, 3, 5 in 1000 over 5 years
Chance of survival at 5 years (if you get cancer)	60% (baseline), 65%, 70% and 80%
Effects on everyday activities (if you get cancer)	Fully active No heavy physical work Unable to work Confined to bed half of the time
Pain (if you get cancer) during treatment, recovery, or any other times	Mild pain Moderate pain
Cost (euro)	110 225 370 540

Estimation details

- We don't observe the actual WTP
- We only have yes/no responses to each choice card
- Probit model – RHS is augmented with COST
- Random effects probit to allow for correlated responses
- In earlier slides, QoL and Pain are additive—in alternate specifications, they can be entered as interactions with the reduction in the risk of dying
- Country fixed effects always included

**Example Benefit-Cost Analysis:
Rule for Mercury from Power Plants, US EPA**

Category of benefits or costs	Annual benefits of the final rule in 2016 (3% discount rate)(2007 USD)
Total monetized benefits	USD 37 to USD 90 billion
Partial Hg-related benefits (consumption of fish and its effects through maternal exposure)	USD 0.004 to USD 0.006 billion
PM _{2.5} -related co-benefits (mortality, non-fatal illnesses, hospitalizations, restricted activity days)	USD 36 to USD 89 billion
Climate related co-benefits	USD 0.36 billion
Total social costs	USD 9.6 billion
Net benefits	USD 27 to USD 100 billion
Non-monetized benefits	Include visibility in class I areas; other neurological and health effects of Hg exposure; health effects of ozone; ecosystem effects; health effects from commercial and non-freshwater fish

**Comments on Professor Alberini's paper,
"Measuring the Economic Value of the Effects of Chemicals
on Ecological Systems and Human Health"**

by
Dr. Rana Roy
Consulting Economist

Overview

- To begin with the positive. This paper is ambitiously comprehensive in its coverage. The body of the paper, the sum of Sections 2-6, covers more or less all of the ground that needs to be covered in such a summary.
- Moreover, I find myself in agreement with most of the *detailed* judgment calls arrived at in the discussion of the pros and cons of the various "valuation methods" and of their exact ways and means.

2

Overview (continued)

- My difficulty here is that the paper is "polite to a fault". That is: too tolerant of what are, arguably, cul-de-sacs; too cautious in acknowledging what are, arguably, breakthroughs to the open road; insufficiently ambitious in arriving at an *overall* judgement of rival paths of development in socioeconomic assessment.
- And, thus, too hesitant as a guide to progressing the task of measuring the economic value of the effects of chemicals on ecological systems and human health.

3

Overview (continued)

- Of course, I may be wrong. It may be that my response reflects an over-sensitivity to the paper's choice of locutions. Such as: "it *may become* necessary to use non-market valuation methods" and "it is *also possible* to ask people to report ... their willingness to pay" (emphasis added in both cases).
- But if I am right, it may be worthwhile to articulate where (and why) I think additional judgements are required in order to progress policy-relevant research.

4

Excessive tolerance

- Let me highlight two specific instances where the paper is too tolerant of what I consider cul-de-sacs. The first is the discussion of the hedonic housing price approach to assess damage to air, soil, water (8-10).
- I agree with all the points made on the problems of measurement. But is there not a more inherent problem of method? Should we seek values for social costs and benefits by seeking to refine our search in *this* market – a market riddled with market failure?

5

Excessive tolerance (continued)

- The second is the use of compensating wage studies of the labour market so as to estimate VSLs (21-23).
- Once again, I agree with all the detailed points made here – from the theoretical problem of excluding labour market non-participants to the empirical findings on the relation of risks to wage premia. And once again, there is a more basic question to be asked. Is the labour market the source from which we should seek and find the most accurate VSL values?

6

Excessive caution

- *Per contra*, the paper seems to me to be excessively cautious in recording progress where there is progress to record.
- The paper states (23): “Finally, it is possible to estimate the VSL using stated preference studies.” Surely, it is more than possible? Is it not worthwhile to record that the OECD-initiated work on VSLs – the work I presented here yesterday – has now been adopted, adapted and developed by the WHO, the World Bank and the Global BCA Working Group?

7

Excessive caution (continued)

- *Mutatis mutandis*, the same applies to the OECD-initiated work on morbidities – presented here by Alastair Hunt. Taken together, these impacts on human health, mortalities and morbidities, have been found in several major studies to account for 80-90% of the calculable costs of air pollution. If, as the paper states (36), “it is suspected that the human health benefits are likely to account for the majority of the benefits of regulating chemicals”, is it not worth focussing a little more on the achieved progress on the valuation of these impacts?

8

An alternative starting point?

- An alternative starting point, in Section 1, based on a fuller exposition of the principles of welfare economics, would have delivered a first-order distinction between methods grounded in these principles and other methods – and treated the detailed problems of measurement, the exact ways and means, in the light of this distinction.
- And prioritised stated preference VSLs (independently of its origins in Jacques Drèze's work on road safety. Cf. consumer surplus and its origins in Jules Dupuit.)

9

An alternative conclusion

- Now it is *not* the discussant's prerogative to recommend his own starting point. Rather, the point is that the body of evidence in the paper itself – as well as evidence available elsewhere – suggests an alternative conclusion.
- Surely there is evidence enough to suggest, in Section 7, that the task of measuring the economic value of the effects of chemicals could build on gains achieved in measuring the value of mortalities and morbidities so as to proceed rapidly to measure all other relevant effects?

10

Methods and information requirements for health impact valuation: Discussion

Mike Holland

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July 7th 2016



Completeness

- Tension between risk assessment and socio-economic assessment
 - RA: Is a risk present?
 - SEA: What is the aggregate cost of impacts?

2

Availability of literature

- Limited
- For many health effects, single studies
 - How well do they link to quantified health impacts?
 - How completely do they describe associated values?
 - Can we infer reliability via comparison of values across different impacts?

3

Understanding impacts

- Completeness
- Unfamiliar impacts
- Examples
 - Productivity
 - Cancers
 - IQ loss

4

Capturing the value of unfamiliar impacts

- Low birth weight
- Acceptance of partial value as full value
 - IQ loss valued via loss of earnings
- Diabetes
 - Illness, + mortality component
- Differentiating impacts by severity
 - Chronic bronchitis
 - To what extent does an agent initiate disease?
 - To what extent does an agent worsen disease?

5

Effects on productivity

- Air pollution effects:
 - Ostro et al: lost work days
 - Valuation can account for direct costs (wages of absent workers and replacement staff, lost production), and indirect costs (poorer quality of work).
 - CBI data used in European assessment – extrapolation?
 - Hanna and Oliva: reduced labour supply
 - Zivin et al, Chang et al: reduced productivity in the workplace, 'presenteeism'

6

Value of a statistical case of cancer (VSCC)

- Separation of morbidity and mortality
- Differentiation by pain and quality of life?
 - impacts of treatment
 - course of disease
 - ...
 - Burden on surveyed population?

7

NESHAP mercury rule

- National Emission Standard for Hazardous Air Pollutants
 - Justification largely via cobenefits (PM reduction)
 - Efficiency ?

8

Handling uncertainty

- No discussion in the paper, beyond recognising presence of uncertainty
- Useful approaches?
 - Scientifically valid
 - Understandable by non-experts

Discussion of: *Measuring the Economic Value of the Effects of Chemicals on Ecological Systems and Human Health*

Christoph Rheinberger
European Chemicals Agency
Risk Implementation Unit

Summary

- Paper presents concise summary of economic valuation of non-market goods
- Technical focus seems appropriate for stock-taking, but more details could be discussed w.r.t. to equilibrium sorting models, incentive compatibility,...
- Health valuation is discussed from the perspective of an environmental economist, whereas health economic approaches are only touched upon
- Take home messages should be stronger

Regulator's perspective on WTP values

- Why is the regulator so interested in WTP values?
- Some thoughts about WTP in day-2-day regulatory work focussing on value of statistical life
- Very important to quantify negative externalities of chemicals use most of which affect health & environ.
- Three competing VSL philosophies:
 - VSL based on meta-analysis of labor market studies
 - VSL based on meta-analysis of stated preference studies
 - VSL based on topical, large-scale stated preference studies

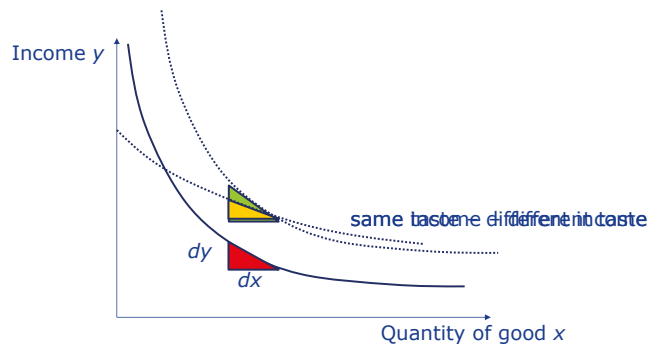
Problems everywhere?

- Labor market studies: generalizability?
- Stated preferences: PGs and incentive compatibility?
- Meta-analyses: too many sources for biases?
- Topical studies: internal and external validity?
 - None of these methods is a priori superior
 - Context matters
 - Biases small compared to those in risk assessment

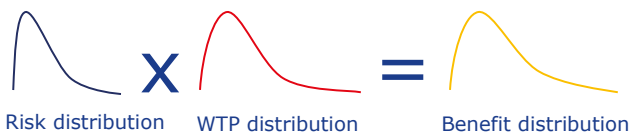
Central value vs distribution

- Policy makers endorse single values, but...
- ...world is complex, single values will never be right
- regulator needs to trade off, keeping in mind both theoretical arguments and communication w/ public
- Why WTP distributions still might be better than endorsed single numbers:
 - avoids certainty illusion in ex ante analysis
 - captures preference heterogeneity across people
 - facilitates sensitivity analysis

Preference heterogeneity in WTP



Sensitivity analysis with distributions



→ No problem to derive "best estimate" for policy analysis

→ Multiplication of 2 lognormals, i.e. can derive any percentile numerically without being a math wizard

Conclusions

- Paper is excellent starting point to reasoning about chemicals impact valuation
- Need for more applied research, especially on environmental impacts
- Paper could stress more that regulator's need to assess both most likely impact & uncertainty bounds
- Exact WTP figure might not be too decisive if consistently applied for ranking policy alternatives
- Important interface between risk assessment and monetization, requires move toward **probabilistic framework for chemicals health impact assessment**



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Possibilities and challenges in transfer and generalization of monetary estimates for environmental and health benefits of regulating chemicals

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Contents

- Value transfer (VT) /Benefit Transfer
 - Definition and Requirements
- Policy Use and Acceptable transfer error
- VT methods
- VT Guidelines
- Possibilities and Challenges
- Tentative approaches to Value Benefits of Chemicals Regulatory Frameworks

Value transfer (VT) / Benefit Transfer

- Transfer economic value of public good from *study* site (primary valuation study) to *policy* site; (often termed *benefit* transfer, but both benefits and costs can be transferred)
- Increased use of cost-benefit analysis (CBA), and lack time and money to conduct new primary study on policy site
→ Use VT, but are transfer errors acceptable?

Transfer Error (TE)

- Percent difference between the transferred (WTP_T) and policy site primary estimate (WTP_P)

$$TE = \frac{|WTP_T - WTP_P|}{WTP_P}$$

Transfer Error – Example Environmental impacts/ecosystem services

- Lindhjem & Navrud (2007) test the reliability of meta analysis (MA) of non-timber benefits of forests for international VT
 - Mean transfer error MA-VT: 47-126 %
while simple unit VT: 62- 86 %
 - More MA of primary studies from other countries and other environmental goods needed before final conclusion can be drawn on MA for VT of environmental impacts
 - Does VT provide sufficient accuracy for policy use ?

Acceptable Transfer Errors

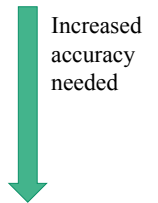
Need higher level of accuracy in NRDA than for CBA, since NRDA is directly used to determine the compensation to be paid by the identified polluter

What is the acceptable transfer error level for CBA ?

- Depends on the decision-making situation;
- If Costs and Benefits are close; higher accuracy is needed in order to decide whether $B > C$ ($NPV > 0$)

Policy use of monetary estimates of environmental and health impacts of chemicals

- **Raising awareness** of social costs
- **Cost-Benefit Analysis (CBA)** of measures and regulatory frameworks
- **Environmental Accounting** (adjusting national accounts)
- **Environmental Costing** for regulation
- **Natural Resource Damage Assessment (NRDA)** (calculating compensation payments after acute releases of chemicals)



Four basic requirements for valid VT:

- 1) Complete, searchable and accessible **database** of domestic and foreign valuation studies (to transfer values from)
- 2) Guidelines for **assessing quality of primary valuation studies**
- 3) **Value transfer techniques**
- 4) **Value transfer guidelines**

1) Valuation Databases- examples

- **International**
 - EVRI – Environmental Valuation Reference Inventory
www.evri.ca (4490 studies; includes public health impacts)
 - ENVALUE (Australia and International)
 - RED - Review of Externality Data
 - BeTa – Benefits Table
 - NOAA’s databases on Marine and Coastal resources (Coastal recreation and Coral Reef Valuation etc.)
- **National**
 - New Zealand NMDB
 - ValueBase ^{SWE}
 - UK Defra Environmental Valuation Source List
 - USDA NRCS (Natural Resource Conservation Service)
 - US Recreational Value Database, Ecosystem Val.; Coastal Res.

2) Quality assesment of primary valuation studies

- **Quality assesment** of candidate studies; both published and unpublished studies (including «Grey literature» in terms of M.Sc.-theses, research reports), using check lists like e.g Söderquist, T and Å. Soutukorva (2006): *An instrument for assessing the quality of environmental valuation studies*. Report, Swedish Environmental Protection Agency
<https://www.naturvardsverket.se/Documents/publikationer/620-1252-5.pdf>

3) Value Transfer methods

1. Unit Value Transfer

- Simple (naïve) unit transfer
 - use value: Consumer surplus/activity day
 - non-use value: WTP/houshold/year
 - mortality: VSL (VOLY)
 - morbidity: WTP per symptom day/episode
- Unit transfer with income adjustments
- International transfer: PPP-adjusted exchange rates

2. Value Function Transfer (from *one* similar study)

- **Meta-analysis** (Value function from *many* studies with different scope in terms of size of the environmental /health impact and different baselines (and fr environmental goods: availability of substitute sites, habitats vs. single species, ecosystem services, recreational use vs. non-use)

Unit value transfer with income adjustment

Adjusted benefit estimate B_p' at the policy site:

$$B_p' = B_s (Y_p / Y_s)^\beta$$

B_s primary benefit estimate (e.g. WTP) from study site,
 Y_s, Y_p income levels at the study and policy site, respectively
 β income elasticity of WTP for public goods (0.3-1.0 range)

Jacobsen & Hanley (2007) found that GDP per capita (i.e wealth in society) was a better predictor of WTP than respondent’s income (i.e. Individual wealth) in a meta analysis of 46 CV studies of WTP for nature conservation

Value function (VF) and Meta analysis (MA)

$$\text{VF: } WTP_{ij} = b_0 + b_1 G_j + b_2 H_{ij} + e$$

WTP_{ij} = willingness-to-pay of household i at site j ,
 G_j = set of characteristics of public good at site j ,
 H_{ij} = set of characteristics of household i at site j

$$\text{MA: } WTP_s = b_0 + b_1 G_j + b_2 H_{ij} + b_3 C_s + e$$

WTP_{ij} = mean willingness-to-pay/household of study s
 C_s = set of methodological characteristics of study s
 n = number of studies (but also several estimates from each study)

Meta analyses (MA) of Biodiversity - examples

- **Rereational use values of ecosystems (TC and CV)**
 - Rosenberger and Loomis (2003), US studies
 - Shrestha and Loomis (2003), US studies
 - Zandersen and Tol (2005) (9 European countries)
- **Non-use values (mainly CV)**
 - Loomis & White (1996) Rare and endangered species
 - Brouwer et al (1999), Brander et al (2006), and Ghermandi (2007) - Wetlands
 - Brander et al (2007) - Coral reefs
 - Nijkamp et al (2007) - Biodiversity and Habitat Services
 - Jacobsen and Hanley (2007)- Biodiversity; 46 CV studies worldwide
 - Lindhjem (2006); and Lindhjem and Navrud (2007)
 - MA and VT based on MA of 30 studies in Norway, Sweden and Finland; non-use values of coniferous forests
 - Tuan and Lindhjem 2008: Biodiversity in Asia and Oceania

Meta Analyses (MA) of Mortality (VSL) - examples

- OECD (2012), Lindhjem et al (2013) – MA of Stated Preference (SP) studies
- Viscusi and Aldy (2003) – MA of Revealed Preference (RP) studies

Validity tests - transfer errors

- Average transfer error for spatial value transfers both *within and across* countries tends to be in the range of 25% - 40% for morbidity endpoints (Navrud, 2004, Ready and Navrud 2006 – Special issue of *Ecological Economics* on VT)
- Individual transfers could have errors as high as 100 % or more.
- *Function transfer* should perform better than *unit value* transfer, but do not always in practise.
- *Meta analyses* can be helpful, but should be limited in scope (no. of studies included) in terms of similar type health/environmental impact valued and state-of-the-art valuation method

4) Value Transfer Guidelines*

- 1) *Identify the change in the environmental good to be valued at the policy site*
 - (i) Type of environmental and health impact
 - (ii) Describe baseline, magnitude and direction of change
- 2) *Identify the affected population at the policy site*
- 3) *Conduct a literature review to identify relevant primary studies (from the EVRI database or specific databases like OECD Stated Preference valuation studies of VSL).*

* Navrud (2006): *Benefit Transfer Guidelines. Report to Danish Environmental Protection Agency*; and Bateman et al (2009): *Valuing Environmental Impacts: Practical Guidelines for the Use of Value Transfer in Policy and Project Appraisal. Value Transfer Guidelines. Report to UK Defra.*

VT Guidelines (cont.)

- 4) *Assessing the quality of study site values for transfer*
 - (i) Scientific soundness; the transfer estimates are only as good as the methodology and assumptions employed in the original, primary studies
 - (ii) Relevance; primary studies should be similar and applicable to the “new” context
 - (iii) Richness in detail; primary studies should provide a detailed dataset and accompanying information

VT Guidelines (cont.)

- 5) *Select and summarize the data available from the study site(s)*
- 6) *Transfer value estimate from study site(s) to policy site*
 - (i) Determine the transfer unit
 - (ii) Determine the transfer method for spatial transfer
 - (iii) Determine the transfer method for temporal transfer
- 7) *Calculating total benefits or costs*
- 8) *Assessment of uncertainty and acceptable transfer errors (and sensitivity analysis for size of «affected population»)*

Criteria for Judging Similarity

- I) **Characteristics of the good**
 - Similar good? (e.g similar type forest/water body, similar use and/or non-use value components; similar recreational activities, similar ecosystem services, mortality risk change, morbidity endpoint)
 - Similar *baseline, size and direction* of change in the public good valued?
 - To avoid scaling up and down values according to the size of the area, involving strict assumptions in terms of e.g. constant value per ha of use and/or non-use values; rather consider foreign study sites with nearly similar size than domestic study sites with a very different scale. The same applies to the baseline and the direction of the change. However, the general recommendation is to choose a domestic study site as close as possible geographically).
 - Similar *availability of substitute* sites? (For use values: recreational sites; For non-use values: National parks and other preserved areas and the ecosystem services they contain)
 - Similar natural resource management regimes/public health care systems ?

Criteria for Judging Similarity (cont.)

II) Population characteristics

- Similar average *income* level (and income distribution)? (If not, income adjustments should be made when performing the value transfer)
- Similar *gender, age and educational* composition?
- Similar *size* of affected population? Expected similar *distance decay*, if any, in non-use values?
- Similar rights to using areas for recreation?
- Similar attitudes to preservation of forests, water, agricultural landscape, mortality risk, morbidity episodes etc. ? (attitudinal and cultural factors)

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Four categories of "Similarity" between Study Site and Policy Site

Category	Level of fit between study and policy sites	Percentage transfer error
1	Perfect Fit	± 20
2	Acceptable fit	± 50
3	Poor fit	± 100
4	No fit	Discard study for this VT ²²

Environmental Impact - Scaling up over size of:

1) Affected Population

- uniqueness – local, regional or national importance and population
- take account of availability of substitutes and their quality
- distance decay in WTP
- aggregate over households rather than individuals (to avoid overestimating WTP)

2) Ecosystem

- *unit of valuation* needed for policy making (e.g. ha of an ecosystem) is not the same as those directly meaningful to ecologists; or how people think about biodiversity and ecosystem services (which is what determines the unit used in Stated Preference surveys)
- discrete changes valued (providing average values per unit of area), while marginal values needed
- Marginal values are not constant; and baseline quality/quantity matters.
- Aggregate at ecosystem level (not at the level of individual species)

Meta Analytic Transfer and Scaling Up of Environmental Impacts

- MA could be potentially very useful when scaling up due to the variability in size, quality, ecosystem services, baseline quality, availability of substitutes, etc of primary studies included.
- Depend on the number of explanatory variables and explanatory power of the estimated Meta-analytic regression model (which could be improved if the scope of the analysis is narrowed in terms of domestic vs. international studies, valuation methods included, definition of ecosystem etc.)

Scaling up over the size of the ecosystem

- Avoid another Constanza et al exercise
- Lindhjem (2006) in a MA of 30 studies in Norway, Sweden and Finland of mainly non-use values of coniferous forests
 - **WTP does not vary with size** of forest area
 - transfers and scaling up-exercises using value pr. ha will be biased
 - Need to test validity of meta-analytic VT (and construct more primary studies with VT in mind)

Challenges (and possibilities) in Value Transfer for Chemicals

- 1) **Ability to translate risk assessments to health and environmental endpoints** for valuation and value transfer.
- 2) **Lack of primary valuation studies** for value transfer for each identified endpoint
- 3) **Frequent need for international value transfer** in a situation with a limited number of primary studies internationally

Main Challenges (cont.)

- 4) Addressing the “**scaling issue**”, when there are few primary studies and a need to scale the result from the primary study up or down
- 5) **Temporal transfer**, both in terms of transferring values over time from existing primary studies, but also when predicting future values in CBAs with a time horizon of many decades. Account for increased income, changing preferences and scarcity of public goods

Main Challenges (cont.)

- 6) Addressing the “**adding-up**”-issue. Moving from benefit assessment of regulating one chemical to also address a larger groups of chemicals covered by regulations like REACH, one need to take account of possible interactions between these chemicals in all stages of the damage function /impact pathway approach

Is it possible to transfer/generalise from assessment of one or a few chemicals to evaluate regulatory frameworks like REACH?

- **NO**
- In theory: Use damage function/approach (DFA) for each chemical, as done for air pollutants in CBA of air quality regulations
But: lack dose-response functions for many chemicals and health and environmental impacts
- Environment /Health Canada Choice Experiment of environmental and health risk characteristics of chemicals in general → fit for their regulatory CBAs, but not for VT/DFA approach for individual chemicals

Tentative Approaches to Value Benefits of Chemicals Regulatory Frameworks

- 1) **Improve existing assessments of individual chemicals**
 - i) better spatial and temporal value transfer,
 - ii) cover more health endpoints (morbidity)
 - iii) cover more cost components (loss in well-being; now COI and Productivity loss),
 - iv) better utilisation of risk assessments to establish causal relationships
 - v) identify which parts of damage function where more research could provide the «highest benefits» in terms of more comprehensive and accurate assessment

Tentative approaches (cont.)

- 2) **Utilize the extensive literature on lost DALY (and QALY) for many chemicals in Global Burden of Disease Assessments;** and combine the aggregate impacts in terms of DALYs multiplied by Value of a Life Year (VOLY) **but** questions about the theoretical foundation and reliability and relevance of combining QALY/DALY numbers with VOLY, and reliability and relevance of VOLY estimates.

Conclusion

- **Learn from the Damage Function Approach work on air pollutants** (e.g. ExternE-project series www.externe.info), which is a result of extensive and long term research efforts
- For chemicals; large knowledge gaps in dose-response functions and impact assessment, as well as valuation of relevant health endpoints (new morbidity endpoints; acute and chronic) and environmental endpoints («translated» into ecosystem service impacts). **But** start now conducting **new primary valuation studies** of expected endpoints **designed for VT**



General Comments

Some comments on Stale Navrud's paper

Alistair Hunt
7.7.2016
ECHA, Helsinki

[OECD Workshop on socio-economic impact assessment of chemicals management](#)

- Comprehensive and generic
- Provides clear guidance to process of VT
- Outlines need for sufficient studies to transfer from

Specific Comments 1

- Reiterate need for new studies,
 - targeted at priority areas
 - Duplication is OK: see next slide
 - Focus on improving knowledge of populations affected: spatial + demographics; temporal

	Quantity	Quality	COI Data	Signif. Ext costs
Premature mortality (chronic)	M	M	M	H
Premature mortality (acute)	M	M	M	M
Respiratory hospital admission	M	M	H	H
Cerebro-vascular hospital admission	M	M	H	H
Cancer (lung) (fatal/non-fatal)	L	L	M	H
Chronic bronchitis	L	L	M	H
Restricted activity days	M	M	H	H
Minor RADs	M	M	M	M
Chronic cough	M	M	M	M
Congestive heart failure	M	M	M	M
Asthma attacks	M	M	M	M
Lower respiratory symptoms	M	M	M	M
Cough	M	M	M	M
Bronchodilator usage	L	L	M	M
Atopy, conjunctival irritation, Allergy/Irritant	L	L	L	L
Ischemic heart disease / myocardial infarction	M	M	H	M
Hypertension	M	M	H	M
Cognitive impairment	L	L	M	M
Hearing impairment	L	L	M	L
Skin cancer	L	L	M	H
Leukaemia	L	L	M	M
Osteoporosis	L	L	M	L
Renal dysfunction	L	L	M	L
Anaemia	L	L	M	L
Neuro-devt. disorders	L	L	M	M

Columns indicate 1) relevant health impacts that have been valued 2) quantity and 3) quality of studies, 4) the extent to which cost of illness data exists, and 5) a broad indication of the significance of each health end-point relative to others in existing RIAs.

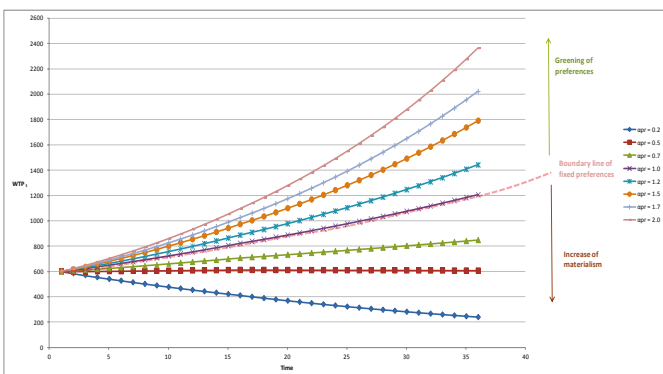
Specific Comments 2

- Analyst's CBAs
 - Primary vs Value Transfer
 - Depends on time & resources available
 - What is the expectation of reducing error bars, given:
 - Necessary complexity of primary study
 - State of existing evidence base to transfer from
 - Unit VT vs Function VT vs Meta-analysis VT
 - Depends on available expertise and evidence base
 - Importance of the value in question in the CBA?
 - Likely significance of specific health/env impacts in costs/benefits

Specific Comments 3

- Temporal considerations: see experience in CC economics literature
- Bulk of the discussion about future generations focuses on how much to discount rate, less on what to discount.
- $\alpha_{tot} = \alpha_{inc} + \alpha_{sc} + \alpha_{pr}$
- where α_{tot} is the total growth rate of WTP; α_{inc} the income growth factor; α_{sc} the environmental depletion (or scarcity) factor; α_{pr} the changing preferences factor.
- Scenario A: Stable preferences; Scenario B: Green preferences; Scenario C: Materialistic preferences

The effect of α_{pr} on future WTP values



Skourtos et. al 2016

Pointers for discussion

- Is there the possibility of shared databases of primary studies?
- What possibilities are there for sharing expertise in VT practice?

Quantifying Regulatory Efficacy

*OECD Workshop on Socioeconomic
Impact Assessment of Chemicals
Management*

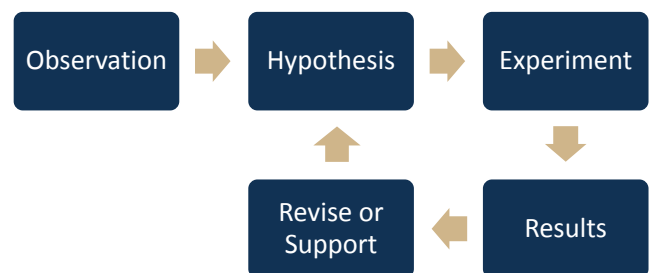
Agenda

- Why evaluate efficacy of regulation?
- How does evaluation fit in the regulatory process?
- Why is evaluation so challenging?
- Methods for better regulatory evaluation
- Improving incentives for robust evaluation
- Discussion

Why evaluate?

- Feedback is important
- Systems mindset
- Inform existing regulations
 - Delivering expected results?
 - Revise or rescind?
- Inform future regulations/policies
 - Improve ex ante analysis
 - Understand *causal* relationships

Scientific method



Regulatory process

- Regulatory impact assessment (ex ante)
 - Hypothesize causal links between action & outcome
 - Assess risks (models, assumptions)
 - Identify alternative actions to manage risks
 - Estimate benefits, costs & distributional effects
- Public engagement (ex ante)
- Implementation
- Ex post evaluation?

Challenges

Ex-ante analysis

- Well-established principles & procedures
- Challenging methodologically
 - Assumptions and models
 - Hypothesize outcomes

Ex-post analysis

- Procedures less well-established
- Challenging methodologically
 - Counterfactual?
 - Opportunity costs?
 - Measuring actual reduction in risks
- Incentives lacking

Responding to Methodological Challenges

- Plan for retrospective review at outset
- Design rules to allow natural experiments
- Lay out theory of change
- Determine proper scope
- Measure causal relationship

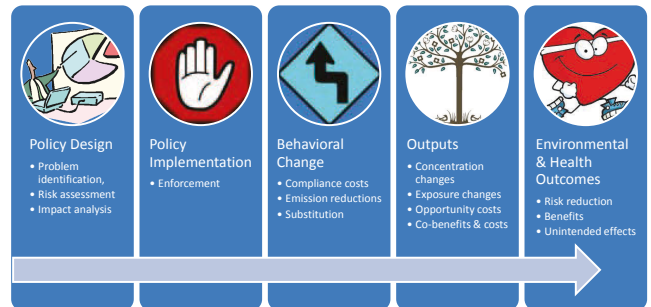
Plan for review at the outset

- Problem to be solved
- Criteria for measuring success
- Causal logic model
- Time frame

Design to enhance learning

- Randomized controlled experiment
- Variation facilitates natural experiments
 - Pilots or trials
 - Different compliance thresholds or timing
 - Differences across jurisdictions

Illustrative Causal Model



Scope

- Specific regulation vs. program-wide
- Outputs vs. outcomes
- Quantified benefits & costs
- Other factors
 - Innovation
 - Flexibility
 - Distribution

Measure causal relationship

- Quasi-experimental approaches
 - Over time
 - Across jurisdictions
- Statistical tests
 - Is X informative about Y?
 - Does X precede Y?
 - Does ΔX explain ΔY ?
 - What do non-parametric methods show?
 - Effect of X w/ other variables held constant

Responding to Incentive Challenges

- Condition new regulation on ex post learning
- Institutionalize independent review
- Change default rules
- Reallocate resources

Conclusions

- Evaluation & feedback important
 - Identify underperforming (or overly costly) rules
 - Improve future policy
 - Modify *ex ante* assumptions
 - Calibrate risk assessments
 - Improve causal predictions of health benefits & other regulatory effects
- Solutions must address methods & incentives

Regulatory Studies Center

THE GEORGE WASHINGTON UNIVERSITY

Contact: Susan E. Dudley
@RegStudies
RegulatoryStudies@gwu.edu
Regulatorystudies.gwu.edu

Background paper – retrospective analysis

Sonja Haider, ChemSec
OECD workshop, July 2016



Challenges

- Chemicals – a complex issue (cocktail effect, effects in later generations, etc.)
- Effects of hazardous chemicals often underestimated and it takes decades to regulate them
- Multiple factors for health effects
- Paralysis by analysis?
- Who covers the costs?
- Implementation of results?

Positive Effects

- Adjustments to reality
- Increased effectiveness
- Learning for the future
- Goals and indicators specified, quantified, clear and verifiable



Negative Effects

- Uncertainty for businesses
- Disruption of structures in implementation, enforcement, in different countries
- Increased bureaucratic burden on authorities (no change of burden of proof possible)
- Delays implementation (e.g. RMOA for SVHCs)
- Open government – only when comments having an effect (150.000 PC on TTIP)
- It's politics, stupid



Already in place?

...


- REACH review
- REFIT
- Changes in implementation

Does it deliver?



Thank you!

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OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management

6-8 July 2016

Discussion: BP#4 'Quantifying regulatory efficacy of risk management activities'

Kevin Flowers
EU Commission (ENV B2: Sustainable Chemicals)



EU's Better Regulation Programme

- Integrated ex-ante and ex-post assessment
- Transparency and stakeholder engagement
- Regulatory Scrutiny Board



EU's Better Regulation Programme

- Integrated ex-ante and ex-post assessment
- Transparency and stakeholder engagement
- Regulatory Scrutiny Board



EU's Better Regulation Programme

"Better regulation is not about "more" or "less" EU rules, or undermining our high social and environmental standards, our health or our fundamental rights. Better regulation is about making sure we deliver on the ambitious policy goals we have set ourselves in the most efficient way."

Frans Timmermans
EU Commission First Vice-President





Ex-Ante: 'Impact Assessments'

- Identifying the problem
- Defining the objectives
- Developing the main policy options
- Analysing the impacts
- Comparing the options
- Outlining future monitoring and evaluation



Ex-Post: 'Evaluations' & 'Fitness Checks'

- Effectiveness
- Efficiency
- Coherency
- Relevance
- EU Value-added



Chemicals policy & legislation: dealing pragmatically with the 'blackbox & complexity' challenge

- Genetics
- Lifestyles
- Chemicals
- Habitat Degradation
- Etc.

The Black Box ?

Health, Environmental & Single Market End-Point Impacts



Some considerations

- SEA/IA = safety valve to help avoid disproportionate costs
- Smooth & cost-effective e.g.
 - Agreed criteria: VOSL, discount rate, etc.,
- Reporting: keep sight of the 'physical' impacts
- Intervention logic (impact pathways) – avoid 'blackboxes'
- EU Commission Impact Assessments (IAs):
 - Rarely arrive at a neat 'cost-benefit' outcome
 - Present what is known, what can be calculated, what is less certain (but possible scale/implications)
 - 'Political' decision





Some considerations

- Transparency is an asset
- Institutional set-up and process:
 - Encourage dialogue and compromise
 - Avoid confrontational decision-making situations
- Chemical impact aspects: standardisation? Help reduce SEA costs.....

....how do we design the SEA process and outcomes so they are not just the preserve of the SEA expert but can be coordinated and used by 'normal' policy decision-makers



Last but not least - beware the 'cost bias'

- Businesses are well set up to identify, collate and assess costs that they incur
- The environment has no 'cost accounting' system
- Human health costs are only partially captured



TATA STEEL



REACH and chromates
 - strategic and economic challenges
 for Tata Steel as
 international operating company

Hans Dommershuijzen
 OECD conference
 6 – 8 July 2016

Together we make the difference

REACH and chromates

1	Introduction – Tata and Tata Steel
2	Authorisation of chromium trioxide
3	Three main situations
3.1	User of critical chrome coated article used in manufacture
3.2	Development of alternative with unique performance requirement
3.3	Conversion ongoing, some applications critical
4	Three authorisation scenarios
5	Final remarks

1.1 Introduction - Tata and Tata Steel



Tata

- Tata Group established in 1868
- Tata businesses span 7 major industry sectors
- Total revenues over \$ 100 billion
- Tata Steel Ltd acquired Corus Group plc in 2007 and rebranded to Tata Steel in 2010



Tata Steel

- Top 12 global steel producer
- Annual crude steel capacity of 28 million tonnes
- Serving customer all across the globe
- Turnover in 2014-15 approximately \$ 25 billion

1.2 Our comprehensive product portfolio

Supporting customers with steel products that make a difference

				
A partner for many automotive customers for Body in White, Chassis and Suspension, Seating and Interior and Powertrain	Steel products that go into just about every part of a wind turbine, from the foundations structure to the gearings and bearings in the nacelle	One of Europe's leading suppliers of high quality innovative packaging steels	Offering a wide range of components and systems for building envelope, structural and fit-out applications	Supplier of high strength steels for the manufacture of steel semi-trailers that are both high quality and lightweight

1.3 Tata Steel committed to adopt best environmental practices in all operations



We seek to improve environmental performance through

- Sustainable usage of raw materials
- Water conservation and treatment
- Energy conservation and waste utilisation
- Emissions reduction

3. Three different situations

1. Critical chrome coated articles used in manufacture

2. Development alternative with unique performance requirements

3. Conversion progressing, some applications critical

2. Authorisation of Chromium trioxide

Chromium trioxide

Main classification – Carcinogenic 1A and Mutagenic 1B



Dates and consequences

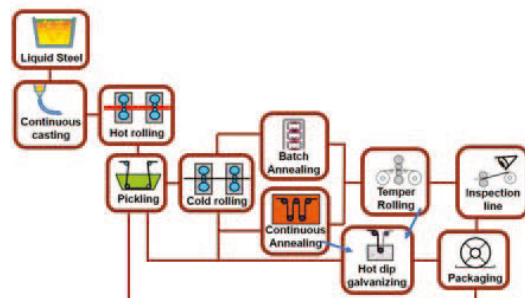
- Chromium trioxide **Prioritised** (April 2013)
 - 21st March 2016
Deadline for Application
 - 21st September 2017
Sunset Date
- **Sunset Date**
Use of substance illegal, unless European Commission has specifically granted Authorisation

Application for Authorisation

- **Chemical Safety Report**
Physical, chemical and toxicological data
- **Analysis of Alternatives**
Proof that no suitable alternative is available
- **Socio Economic Analysis**
Comparison of health and economic impact

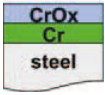
3.1 Critical chrome coated article

Work rolls are critical for Cold and Temper Mill



- Loss of production and quality dominant economic impact
- Socio Economic Analysis easily becomes overly technical
- 'Active support' to Application for Authorisation only option

3.2 Development of article with unique performance



ECCS

- Chromium trioxide mainly used for manufacture of Electrolytic Chromium Coated Steel (ECCS)
- ECCS economical alternative for tinplate with unique property profile
- European project to investigate alternatives for chromates in ECCS manufacture unsuccessful

Status

- New alternative identified in research, now needs to be scaled up and proven
- Authorisation required

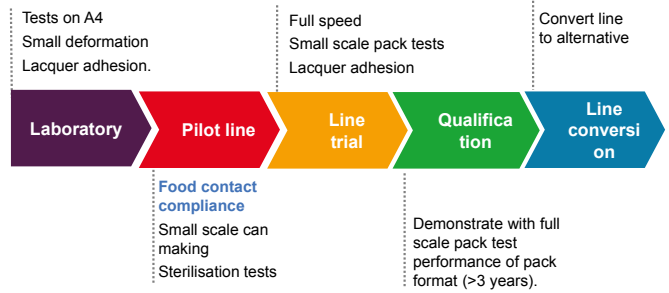
Protect unique application of ECCS

- combines robustness of steel with versatility of plastic
- provides even more efficient material solution for can



3.2 Complex supply chain

Final canned food product needs to be food safe after can making and food processing, in retail and at home



robust quantification of market loss quite a challenge

3.3 Conversion progressing

- Other down stream operations

Color coated

- Plan to replace in review period
- Some critical applications require more time for qualification
- Only for reduction of risks of conversion Authorisation (review period) required

Tubes

- For Tubes limited use of treatments with chromates
- Alternative tested and developed with supplier
- Close to sunset date final conversion planned
- Only for reduction of risk of conversion Authorisation (review period) required

4. Three authorisation scenarios

1. Critical chrome coated article used in manufacture – active support

- No alternative yet available
- Supplied chrome plated articles critical part of manufacture process
- No driving seat possible, only viable option is **active support**
- Collection of economic data easily becomes overly technical

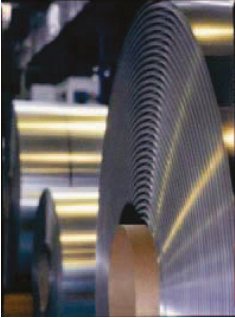
2. Alternative in development – cooperative driving seat

- Joint approach both strength and threat, not only for Socio Economic Analysis
- Impact of poor performance dominant factor in Socio Economic Analysis
- Key are food contact legislation and **coordinated market conversion**

3. Conversion progressing – monitor regulatory developments

- Most of market converted, some critical applications challenging
- To reduce risk of conversion **monitor regulatory developments**

5. Final general remarks



- Tata Steel committed to replace chromates as soon as possible
- Tata Steel spent considerable efforts on Research and Development for replacement of Chromates
- Tata Steel demonstrated to replace where possible and only continue where required
- Significant part of review period of Authorisation is required for market conversion

TATA STEEL



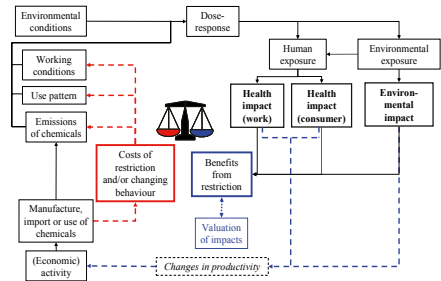
The Cost of EU Regulation of Siloxanes (D4/D5) in Personal Care Products & Dichlorobenzene Toilet Blocks

Stavros Georgiou
Health and Safety Executive, UK

OECD workshop on socioeconomic impact assessment of chemicals management
European Chemicals Agency
6-8 July 2016, Helsinki Finland



Economic Analysis of Chemicals Regulation



- To provide support to decision-making as to whether it is a good idea for society as whole to:
 - impose a restriction (compared to continued use or using other risk management options)
- Focus on difference in impacts (Δ) between the two scenarios, e.g.
 - What happens if a restriction on use is introduced (alternatives, relocation etc.)
 - In which ways and how much the positive and negative impacts change

Costs Assessment of EU Regulation: D4/D5 and DCB

Case Study 1

Chemicals:

- Cyclotetrasiloxane (D4)
- Cyclopentasiloxane (D5)

Use:

- improve the quality of personal care products: shampoo, Conditioners, etc

Environmental Concern:

- PBT/vPvB:
- Washes off and builds up in sediment and water bodies
- Potential to enter bird and mammal food chain

Case Study 2

Chemicals:

- 1,4 Dichlorobenzene

Use:

- air fresheners and toilet blocks used to deodorise public and domestic toilets.

Health Concern:

- Category 2 Carcinogen

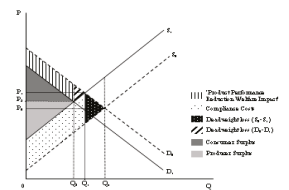
Case Study I: Impact of restriction (concentration limit) on market for wash-off PCPs containing D4/D5

Producers (Supply):

- reformulate product
 - remove product from mkt!
- Firms choose option that maximises their net benefits (profit)

Consumers (Demand):

- Δ Price → Δ selection of products
- Δ Quality → Δ WTP for product



Partial Equilibrium Analysis

D4/D5: Cost Estimation (1)

Total Costs of Restriction

- = 1. Raw material substitution costs
 + 2. Reformulation costs
 + [3. Product performance (quality) welfare loss]

1. Raw material substitution costs - additional costs from purchasing D4/D5 substitutes

- Based on difference in unit cost (adjusted by use ratio of substitute) x amount of D4/D5 eliminated
- Industry consultation suggests <50% Price ↑
- No Direct 'like-for-like' substitute
- Assume 100% Price ↑ to account for uncertainty

D4/D5: Cost Estimation (2)

2. Reformulation costs – one time investment to reformulate products to replace D4/D5

- Gross Reformulation Costs = Reformulation cost per product¹ x total number of products reformulated²
- Subtract 'baseline' reformulation costs³ (in absence of restriction) → Net Reformulation costs
- Convert to annualised basis⁴

¹ Based on studies from literature and industry consultation (€50K~500K) **assumes no knowledge transfer**

² Based on % of All PCP products on Mkt that contain D4/D5 (use tonnage share to estimate) **likely gross overestimate**

³ Products routinely reformulated → accelerate costs incurred in absence of restriction + some coordination of routine reformulation efforts. **Simplified model of reformulation cycle (illustrative of order of magnitude)**

⁴ Since reformulation is 'knowledge' investment (useful life of formula: t).

D4/D5: Cost Estimation (3)

3. Product performance (quality) welfare loss

- Reformulated Products not of equal quality → Δ demand and hence in CS+PS
- Welfare loss = ΔCS + ΔPS
 \approx WTP for quality attributes of D4/D5
- Estimation of WTP based on (CE) stated preference survey – Tradeoffs between product performance, env accumulation and price (**study validity issues?**)

Results

- Costs: Compliance (substitution) costs = Raw material substitution costs + Reformulation costs

Compliance period (years)	Compliance Costs per annum			Cost-effectiveness (€/kg)	Total cost of compliance per kg of wash-off PCP sold (€/kg)	% Retail Sales Price increase (%)
	Raw material substitution Costs (€)	Reformulation Costs ¹ (€)	Total cost of compliance (€)			
2	3,420,000	19,664,952 - 58,044,340	23,084,953 - 61,464,340	115.66 - 307.94	0.0636 - 0.1692	0.34 - 0.91
5	3,420,000	4,188,567 - 38,307,702	7,608,567 - 41,727,702	38.12 - 209.06	0.0209 - 0.1149	0.11 - 0.62

- Costs: Product quality consumer & producer surplus losses ~ €45 million (pa)?

Case Study 2: Impact of restriction (Ban) on 1,4 DCB toilet blocks and air fresheners

Cost Methodology: 2 approaches

- Financial costs of switching from 1,4 DCB to alternative (direct substitution cost)
 - Based on Δ market price and equal quantities (tonnage) sold
- Consumer surplus change of switching from 1,4 DCB to alternative
 - Based on Δ market price and Δ in quantities (tonnage) sold assuming $\epsilon_p = -1$ and linear demand

Information on alternatives to DCB

- Alternatives dominate the market
- Alternative products may contain several substances
- Technical feasibility
 - In most of the applications alternatives can provide the same service
 - Alternatives might not provide the same service when strong odour masking is necessary
- Economic feasibility
 - Alternatives are cheaper in most of the applications
 - Alternatives are more expensive for (high traffic) urinals

Costs of 1,4 DCB Restriction

- For domestic use, it is assumed that alternatives are functionally equivalent to 1,4-DCB
 - Switching to (cheaper) alternatives will result in **savings**
- For professional use, it is assumed that there are no suitable alternatives
 - The restriction will result in **costs**

Restriction Option	Change in consumer surplus (€m)	Substitution costs (€m)
Domestic use only	2.7	2.0
Professional use only	-4.0	-0.6
Domestic and professional use	-1.2	1.4

Note: positive values indicate savings; negative values indicate costs

Cost Assessment: Lessons learned (I)

- It was possible to estimate the 'order of magnitude' of cost impacts for both D4/D5 and 1,4 DCB restrictions
 - Compliance costs and (some) Welfare costs assessed
- In both cases assessment was not straightforward:
 - Data challenges/missing information;
 - Modelling of producer and consumer behavioural changes
 - Realism of assumptions made – scenarios/sensitivity/worst case?
- Understanding and sound estimation of magnitude of cost impacts provides important context for benefit cost comparison in chemicals regulation
 - Benefits assessment v.difficult (esp for Environmental impacts)!
 - Costs may be small or negative (cf 1,4 DCB)!
 - Use (and limits) of Cost-effectiveness/break-even/affordability assessments to assess 'proportionality' of restriction



Cost Assessment Lessons learned (2)

- Importance of collaboration with industry/trade associations
 - Crucial when considering 'targeted' restrictions
 - Not a panacea – time consuming and requires trust on both sides
 - Good info on some cost elements/ not for others (problems of confidentiality/competition law to overcome)
 - Problem of aggregated data
 - Collaborate early in process and involve throughout
 - incentives to exaggerate costs remain ?
- Use of Consultants
 - Not a Panacea – can be administratively burdensome and expensive
 - Often good at data collection in short time (removed from regulator; existing industry contacts)



Recommendations

- Start with theory e.g. D & S (comparative statics diagram)
- Ensure assessment is proportionate to magnitude of impacts – focus on most important sectors/cost elements in practice and use appropriate methodology
- Work with those who are affected and who have the data (industry/trade associations) - Build trust by bringing in at beginning of process and consulting/transparency throughout the process
- Use simplified models of behaviour/reactions and use assumptions, but recognise limitations and build into analysis
- Ensure transparency of all assumptions and highlight uncertainties (make use of worst case/scenarios/sensitivity)



Thank you!



Components of Regulatory Cost

- Compliance costs
 - eg. pollution control equipment; input & process changes; permit applications
- Government regulatory costs
 - eg. monitoring, admin & enforcement
- Social Welfare losses
 - Loss in Surpluses due to change in price and quantity of goods
 - Transitional costs
 - Reallocation of resources e.g. capital obsolescence due to plant closure; production disruptions
- Indirect costs
 - Changes in market structure; Product quality; innovation; productivity



Cost Estimation Methods

→ Compliance costs

- the cost of all policy compliance actions (e.g. abatement; process change).
- may be sufficient when “behavioral response, transitional costs and indirect costs are small”

→ Partial equilibrium/ behavioral response

- Captures behavioral responses, but confined to effects on directly regulated firms or households

→ General equilibrium/ Secondary effects

- Where effects on large number of markets; the net burden once all good and factor markets have equilibrated;
-

Towards benchmarks for the proportionality assessment of PBT/vPvB restrictions and authorizations

OECD workshop on socioeconomic assessment of chemicals management
Helsinki, 8 July 2016
Frans Oosterhuis

*assistance and suggestions from Roy Brouwer, Thea Sletten, Karen Thiele, Kalle Kivela, Stavros Georgiou,
Julia Verhoeven, Martien Janssen, Richard Luit and Cees Lutikhuisen gratefully acknowledged*

Outline

- Background
- Objective and approach
- Scope and information sources
- Results and analysis
- Role of cost estimates in decision making
- Conclusions
- Suggestions for further work

Background

- PBTs and vPvBs (for short: PBTs)
- Cost-benefit analysis usually not feasible
- Cost-effectiveness can be used instead, but needs benchmarks
- Proportionality: a 'reasonable' level of cost per kg PBT reduction

Objective and approach

- To estimate society's 'willingness to pay' for PBT risk reduction
 - using evidence on past expenditures to see if they can provide building blocks for proportionality benchmarking
- Collection and analysis of cost and effectiveness data
 - initial focus on 7 (groups of) substances
- Assessing the relevance of this evidence for benchmark development
- Formulating suggestions for further work

Scope and information sources (1)

8 (groups of) PBT substances:

D4/D5	Restrictions proposed in EU (wash-off personal care products)
DecaBDE	Flame retardant; restrictions proposed in EU (already banned in EEE)
HBCDD	Flame retardant; to be phased out under Stockholm Convention
HCB	Production, trade and use banned; still legacies / contamination
HCH	Production, trade and use banned; still legacies / contamination
PCBs	Production, trade and use banned; still legacies / contamination
PFOA	Restrictions proposed in EU
PFOS	Banned with some exemptions; still legacies / contamination

Scope and information sources (2)

- 36 studies, mainly EU-based and mainly post-2000
 - Academic literature
 - Consultancy reports
 - Policy documents (incl. restriction and authorisation dossiers)

Results and analysis (1)

Summary statistics (cost estimates in €/kg)

Substance	Min	Median	Mean	Max	N
D4/5	-4	28	76	399	9
HCH/HCB	1	5	117	760	10
HBCDD	-194	25	1290	10,114	14
PFOA	28	1508	1581	3,281	4
deca-BDE	1	327	29,688	251,281	14
PCBs	1	3,675	46,354	413,200	10
PFOS	6	7,703	1,213,837	21,412,950	23

Results and analysis (2)

Different cost types along the chain / life cycle

	Development / design	Service life / use	Waste	Environment
Process / measure to control or remove the PBT	Substitution (substance or product); process change	Emission reduction Clean up / decontamination	Safe disposal	Remediation from environmental compartment
Example 1 (HBCDD)	Producing new EPS with an alternative FR or replacement of EPS by an alternative insulation material	Removing installed EPS insulation panels that contain HBCDD from buildings	Incineration of materials with HBCDD	Sanitation of construction waste dumps
Example 2 (PCBs)	Using alternatives to PCBs in new transformers / capacitors	Removing PCBs from existing stock of transformers / capacitors	Incineration of PCB waste and soil/sludge with PCBs	Removing PCBs from contaminated sites
Example 3 (PFOS)	Introducing a PFOS-free process in electroplating	Replacing PFOS in fire fighting installations; minimizing emissions in applications that are still allowed	Thermal treatment or controlled landfilling of PFOS waste and soil/sludge with PFOS	Removing PFOS from soil, groundwater and surface water (e.g. polluted by fire fighting foam)
Associated direct costs	Additional development and production cost Cost of quality / performance loss	Clean up and replacement cost Cost of emission control	Cost of collection and separation Cost of the various waste treatment routes	Remediation cost
Possible indirect costs	Loss of competitiveness (turnover, employment) due to cost increases	Unavailability of equipment or infrastructure during decontamination operations	Foregone recycling opportunities	Unavailability of land or water until remediation is completed
Cost effectiveness	Costs can be expressed per kg avoided/reduced use or per kg avoided/reduced emission			

Results and analysis (3)

- Cost per kg emission reduction often higher than per kg use reduction
- Example: substitution of PFOS in photo imaging
 - emission reduction: EUR 22 mln per kg
 - use reduction: EUR 2200 per kg
- Cost of substitution often lower than other costs
 - but substitution may be imperfect => 'hidden' costs

Results and analysis (4)

- What is included / excluded in cost estimates:
 - **Substitution:**
 - > drop-in
 - > additional investments
 - > substitute not necessarily equivalent
 - quality / performance
 - environment / health
 - > sunk costs / capital destruction
 - **Remediation / clean-up:**
 - > separating / isolating / removing the PBT
 - > final treatment / disposal
 - > foregone recycling
 - > indirect costs and wider economic impacts

Results and analysis (5)

- Substance and situation specific features
 - Concentration / dispersion
 - Groundwater vs soil pollution
 - 'Closed' and 'open' applications
 - 'Point' and 'non-point' sources
 - Specific geographic conditions

Role of cost estimates in decision making

- Explicit statements on 'disproportionately high' costs are scarce
- Indications can sometimes be derived from actual decisions
- Preliminary, tentative conclusion:
 - Below ± EUR 1000 per kg costs seem to be generally acceptable
 - Above ± EUR 50,000 per kg costs tend to become prohibitive (clean-up decisions postponed; exemptions granted)
 - Broad 'mixed zone' in which other considerations determine the outcome



Conclusions

- Evidence gathered = small step towards possible benchmarking
- Important to distinguish between different types of decision making situations and different types of costs
- Only comparable cost effectiveness figures should be compared:
 - similar cost types included in and excluded from the estimates
 - similar results (e.g. amount of PBTs emitted to or removed from the environment)
- Differences between PBTs (disregarded here) may be relevant

Suggestions for further work

- Expand the evidence base (add to the current database)
- Focus on the role of cost effectiveness considerations in decision making
- Develop a set of benchmarks taking into account the relevant type of measure and cost types

Thank you!

You can find the final report at:

https://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

You can contact me at:

frans.oosterhuis@vu.nl



Content

What are the **cost drivers**?

The **generic costs** of an application for authorisation: how does it evolve?

The impact of the **organizational level**

Integrating SEA and AoA helps defining focus and decreasing costs

Level of **refinement** needed

Repetitive AfAs needed for a single use

Outstanding challenges that impact the cost of an application

Conclusions and recommendations

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EM

The cost of authorisation to EU industry

What are **the cost drivers**?

- Data collection (time, effort, ...)
- Consultancy (for SEA and AoA)
- Number and type of uses covered
- Organizational level (management model, joint or single, need for a trustee...)
- Technical approach (integration AoA & SEA) and level of focus
- Need for refinement
- Authorisation fees

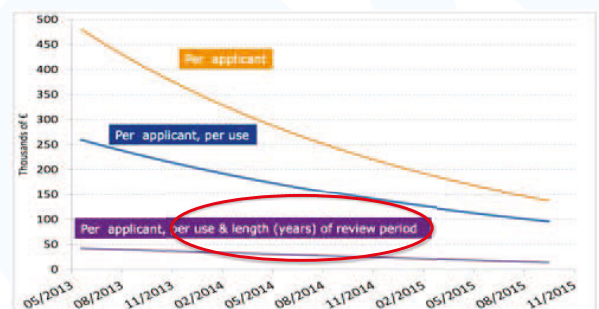


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EM

The cost of Authorisation In general

ECHA inventory: integrated costs for authorisation (for AfA submission)



4

EM

The cost of Authorisation

Trend seems declining.....



Is this realistic or not?

Probably NOT:

- Non-representativeness of the first substances
- Relatively simple uses
- No need for refinement

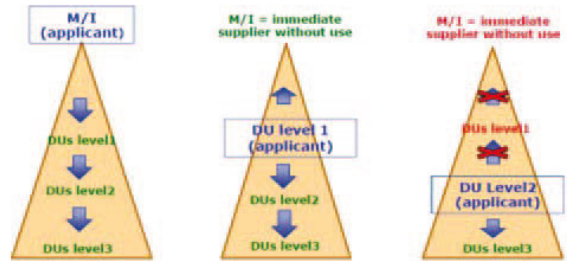
Certainly helped reducing costs:

- More focused SEAs and AoAs
- More experienced consultancy



Factors that impact the costs of Authorisation

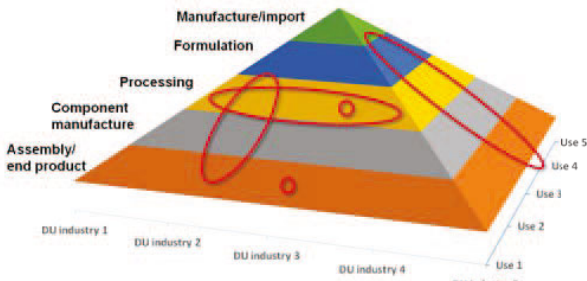
Organizational level : sharing the cost over the supply chain



Factors that impact the costs of Authorisation:
Organizational level

Organizational level : sharing the cost over the supply chain

- Supply chain cost or cost for a user depends on the organizational level
- Managerial costs varied between: < 5000 € to > 1 mio €



Factors that impact the costs of Authorisation:
Organizational level

Review Period for comparable cases*:

- Upstream functional plating cases : 4 or 7 years
- Downstream functional plating cases: 7 or 12 years

Review period defined on the basis of:

- Relevancy and robustness of AoA data
- Clarity and level of remaining exposure
- Relevancy and robustness of the SEA data

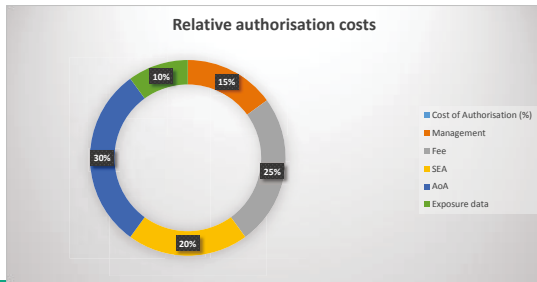


*based on todays experience.

Cost of Authorisation for the EU Industry

Relative Authorisation costs for a couple of cases in the metal sector:

- SEA and AoA cover half of the costs
- Management costs and fee around 40 %
- Remainder for the collection of exposure evidence



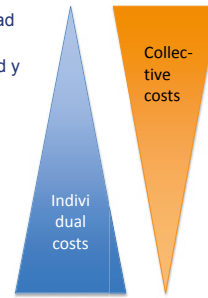
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Factors that impact the costs of Authorisation: Organizational level

UPSTREAM application:

- Good cost sharing
- Knowledge/workload sharing
- Higher cost/granted y



- Better cost/granted y
 - No sharing of knowledge or workload
 - High individual costs
- DOWNSTREAM** application:

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Factors that impact the costs of Authorisation: Level of integration of the SEA-AoA assessment: example of metal catalyst used in steam reforming

Steam reforming is the main industrial process for producing hydrogen. It is applied at very large scale for hydrogenation processes in refineries and chemical industry

Estimated 1400 plants worldwide

Currently **all commercial steam reforming** catalysts are metal X-based.

Identified **alternatives**:

- Ruthenium (Ru) based catalysts
- Platinum group metals (PGM) catalysts: platinum, palladium, iridium, rhodium



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Scoping Case on AoA: steam reforming

Technical performance

- PGM are more active, more poison resistant and have a longer lifetime

Metal	Cost performance	Other performance	Raw material	Catalyst product
Metal X				
Ruthenium			Oxid. Solid (H272)	Skin Irr. H315
Platinum			Skin Corr. 1A (H314)	Eye Irr. H319
Palladium			Eye Dam. 1 (H318)	
Rhodium			Met. Corr. 1 (H290)	

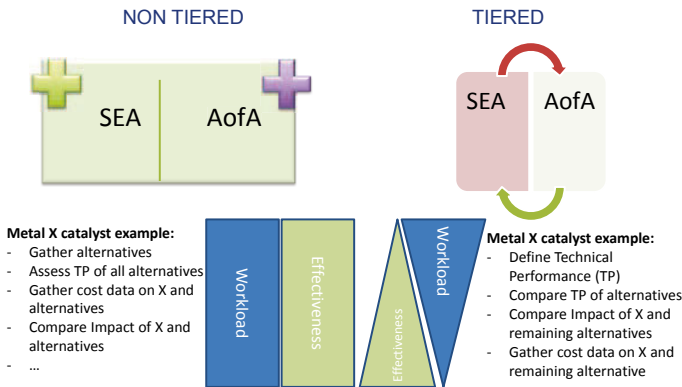
Cost performance and impact assessment

- Others than Ruthenium are not considered feasible alternatives.

Other performance

- Based on availability...no reasonable substitute seems available

Conduct SEA-AoA in a Tiered way



Factors that impact the costs of Authorisation: Level of refinement needed

SEA assessments made on Excess Cancer Risk

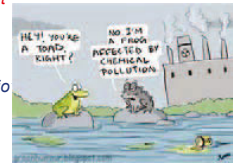
- Applicants therefore focus usually on **Workplace exposure**:

- levels
- n° exposed workers
- Exposure time

- Often they do not focus on **other factors that define the cost to society** given assumed being low: *example Man via the Environment*

- See example

- Suggestion: conduct a **sensitivity analysis** of scenario and parameters that impact the excess cancer risk and refine the assessment with real measurements when needed.



PS a program for MvE refinement may cost up to > 250 k€ when based on monitoring evidence !!!

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Factors that impact the costs of Authorisation: Level of refinement needed

Example of Man via the Environment assessment in a recent AfA case on Chromium trioxide use for Functional Chrome Plating

Estimated additional statistical fatal cancer cases, based on 40/70 years of exposures, RP applied for, 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA (µg/m³)	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)		
					40 y	12 y	1 y
Workers – Combination of WCS	<1	0.25	0.001	4392	4.39	1.32	0.10
	1-3	0.75	0.003	2062	6.19	1.86	0.16
	4-6	1.5	0.006	2289	13.73	4.12	0.34
	6-8	2	0.008	7608	60.86	18.26	1.52
	Not regularly exposed	0.25	0.001	6577	6.58	1.97	0.16
Workers total				22928	91.75	27.53	2.29
	Exposure 24h (µg/m³)				70 y	12 y	1 y
Man via environment - Local	2.85 × 10 ⁶		8.27 × 10 ⁵	10,000 x 1,590 sites = 15,900,000	1314.93	225.42	18.78
Man via environment - Regional				Not relevant			
Total					1406.68	252.94	21.08

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Factors that impact the costs of Authorisation: Number of repetitive AfAs for the same use

Authorisations are applied on a **“substance basis”**

However, some “uses” are **“multi-substance based”** and may even have a low control level on what substances they receive.

This could lead to **“multiple authorisation needs”** for a single use resulting in increased costs level

Example: mixing as a use in the refining sector (End of Life recycling)



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Factors that impact the costs of Authorisation:
Number of repetitive AfAs for the same use

Example: mixing as a use in metal recycling of End of Use



Recent study by Mike Holland EMRC:

Multiple authorisations for mixing as a use
 up to 20 different substance/use combinations
 due to the variable nature of the input materials

Total costs estimated in the order of
 €0.5 to 2 mio € / company

Factors that impact the costs of Authorisation:
challenges in the cost/benefit quantification

Uncertainty, bias or inadequate data decreases the review period and hence increase the costs for submission.

They are probably still somewhat related to the "novelty" the SEA scheme and include in particular:

- *Defining the Non-Use scenario:*
 - The most cost-effective scenario is not always chosen
- *Cost estimates through "job/employment-losses"*
 - Rather than "profit loss" or temporally employment loss
- *Lack of "discounting"*
 - Making the assessments "too worst case"
- ...

Novelty.



Conclusions

and how to improve the relevancy of the SEA while decreasing the cost?

Conclusions

Authorisation scheme is still new but trends on costs of EU industry becomes clearer with experience.

The overall **cost/applicant is declining** (up to the 100 k € range) but the representativity of the documented cases/costs is unsure

Costs for industry should not be expressed as total cost but at **cost / year granted** ! (to encourage the quality of the applications.

Level of organization, quality and robustness of the exposure data/SEA/AOA determine the **costs and Review Period**

The level of refinement is another cost driver but **cost savings** (while increasing the relevancy/focus can be made by aligning of integrating SEA and AoA

Clarifying **outstanding challenges on methods and scenarios** (how to account for Job-losses, and the Man via the Environment, ...) can reduce the costs while increasing the relevancy of the SEA assessments.

Applicants should conduct an **integrated screening AoA/SEA followed by a sensitivity analysis** to define the focus of the assessment and need for refinement.