Benefits and Costs of Authorising the Use of Substances of Very High Concern under REACH

Annual conference of the Society for Benefit-Cost Analysis

16/17 March 2017, Washington D.C.

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Purpose

1. Describe a unique, flexible way to regulate harmful chemicals
2. Understand how firms use BCA to apply for authorisation
3. Show aggregate BCA results
4. Discuss practical challenges when preparing and evaluating BCAs

1.1 Key elements of Registration, Evaluation and Authorisation of Chemicals (REACH)

Regulatory Risk Management	• **Authorisation** • Restriction • Harmonised classification and labelling
Registration	• Substances manufactured and imported into the EU are registered with ECHA • Information for safe use is communicated within the supply chain
Evaluation	• Examination of registrant testing proposals • Compliance check of registration dossiers • Evaluation of substances

1.2 REACH Authorisation: Basics

- European Commission adds **S**ubstances of **V**ery **H**igh **C**oncern (SVHC) to "Authorisation List" (currently 31)
  - ✓ After "sunset date", companies need to have an authorisation (i.e. "permit" or "license")
  - ✓ Flexibility: Firms can apply or not apply
- Purposes: i) Substitute progressively by suitable alternatives, ii) use SVHC as safely as possible, and iii) guarantee good functioning of EU's internal market
- Unique idea: Burden of proof is shifted to industry
  - ✓ Manufacturers or importers of chemicals can apply "upstream"
  - ✓ Users of chemicals can apply "downstream" for their own use

1.3 Authorisation application process

1. Firm → Application → 2. ECHA → Opinions → 3. Commission

i. **C**hemicals **S**afety **R**eport: Exposure

ii. **A**nalysis **o**f **A**lternatives: Substitution potential; what happens if authorisation is not granted

iii. **S**ocio-**e**conomic **A**nal-ysis: Implications of authorising vs not authorising the use

Risk Assessment Committee

Socio-economic Assessment Committee

(with Member States) → Decision

Authorisation

Granted
4-12 years; maybe with conditions

Not granted

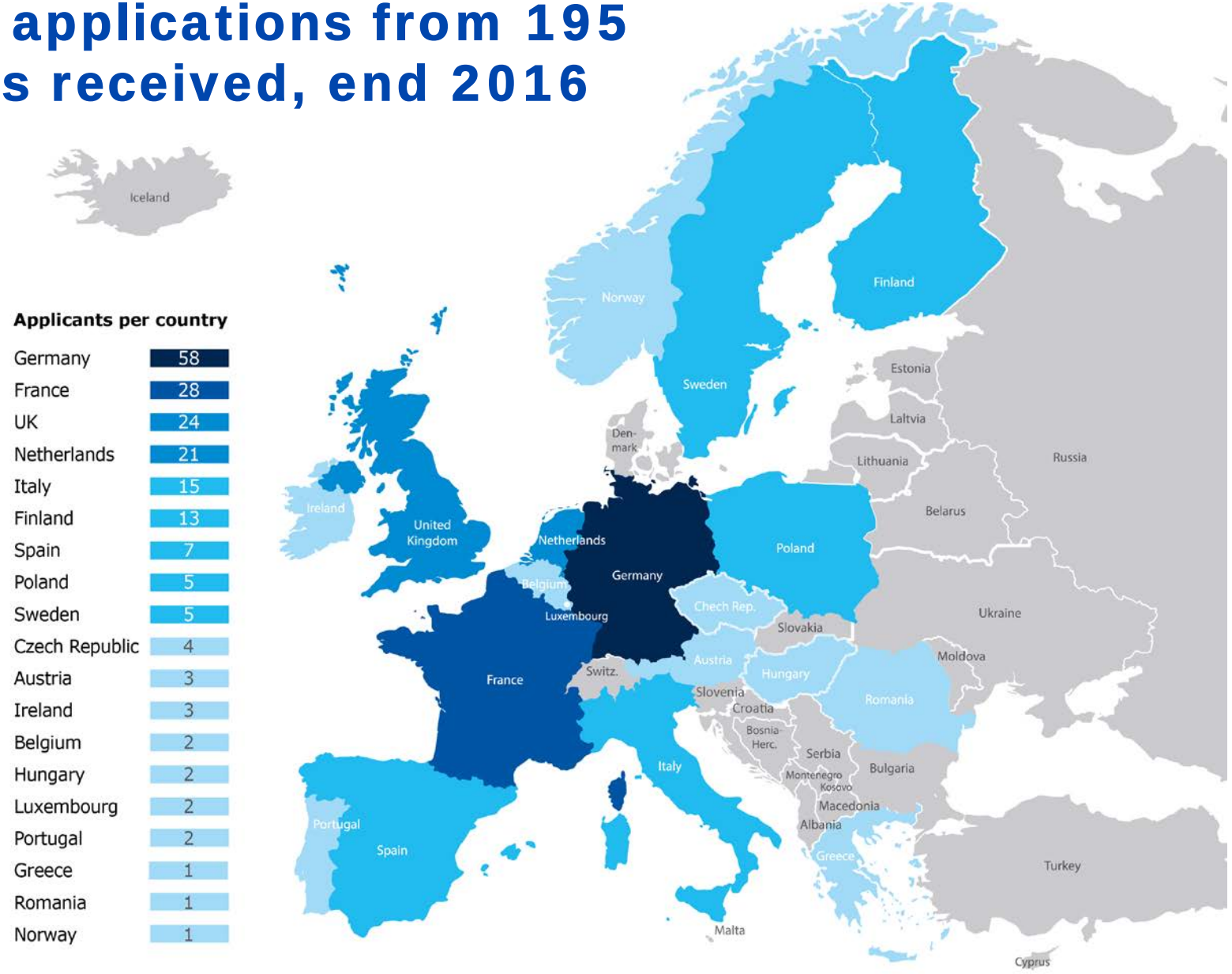
Reapply? → Reapply before expiry if no substitute (Back to 1.)

1.4 Socio-economic Analysis

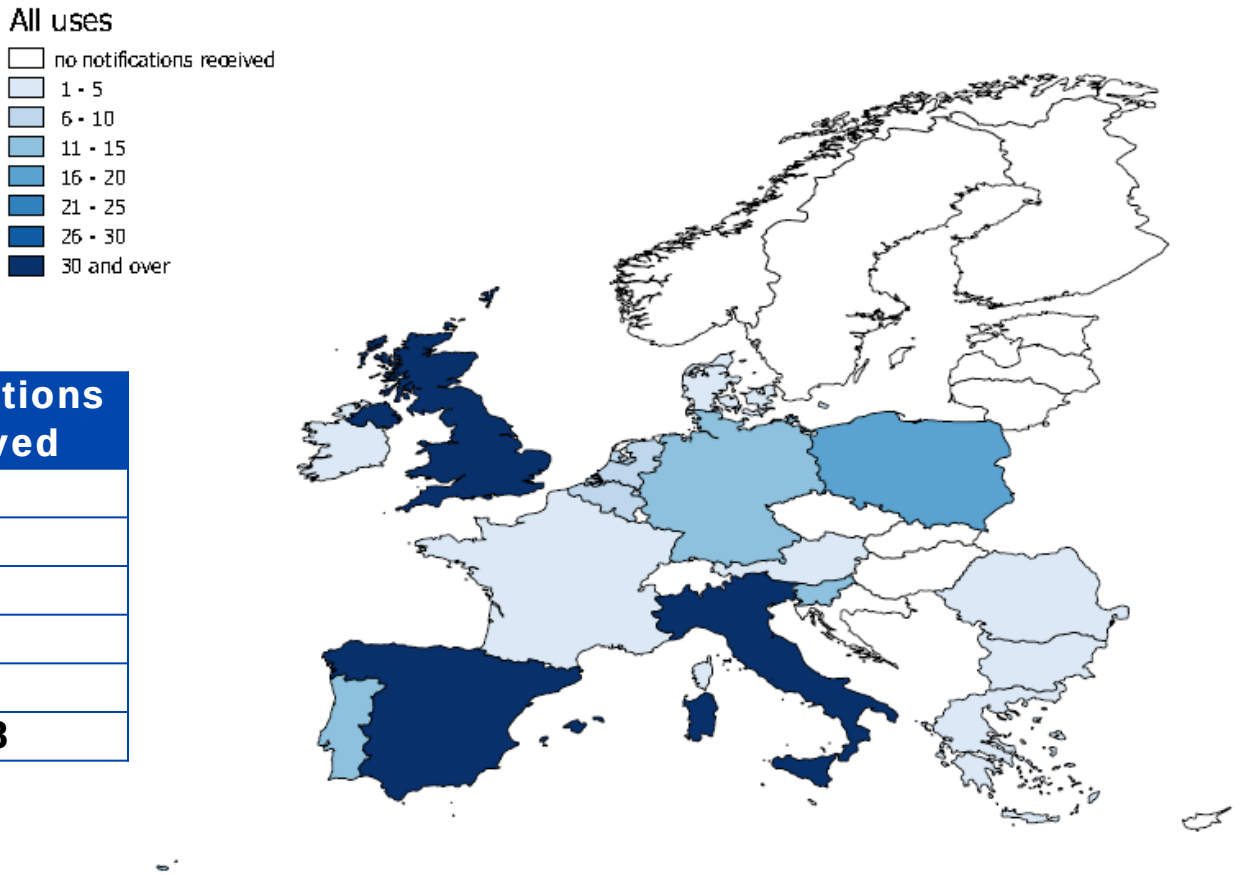
- Uses BCA or cost-effectiveness methodologies
  - Surplus losses to applicant(s) and gains to competitors
  - Externalities imposed on man and the environment
  - Labor market distortions and other welfare costs
- Methodological issues
  - How far should the analysis go (width and depth of scope)
  - Induced unemployment
  - Re-allocation of capital
  - Geographical and temporal boundaries
- Authorisation system a ‘living lab’ of applied BCA

2. Stock-taking from the first applications

111 applications from 195 firms received, end 2016



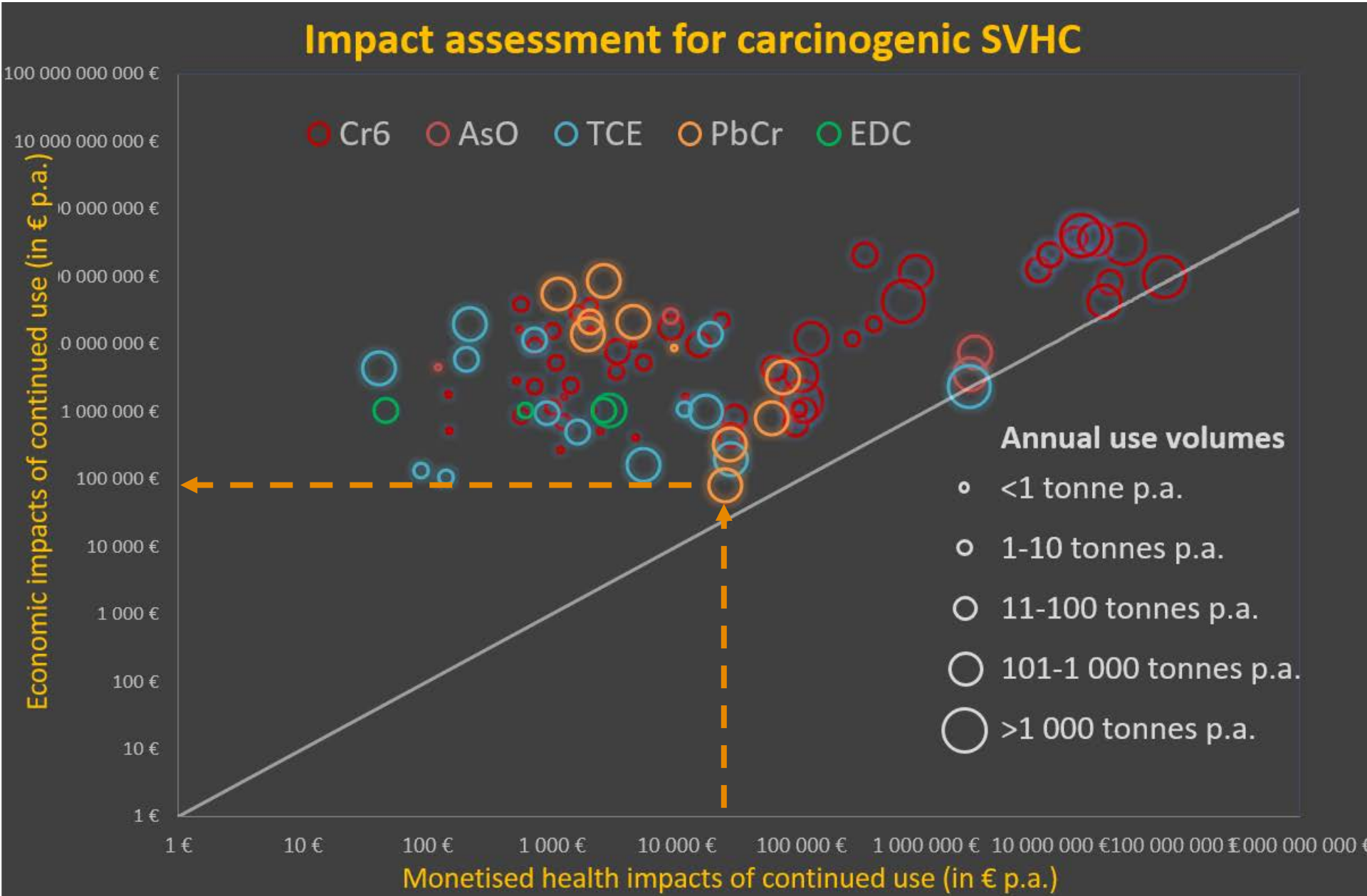
228 firms notified ECHA their use SVHCs, end 2016



	Notifications received
HBCDD	32
DEHP	13
DBP	4
Lead chromate yellow	97
Lead chromate red	82
Total	**228**

- ✓ Notifications will increase to some 3000-4000 when the uses of Tricholoroethylene and Chromium Trioxide are notified

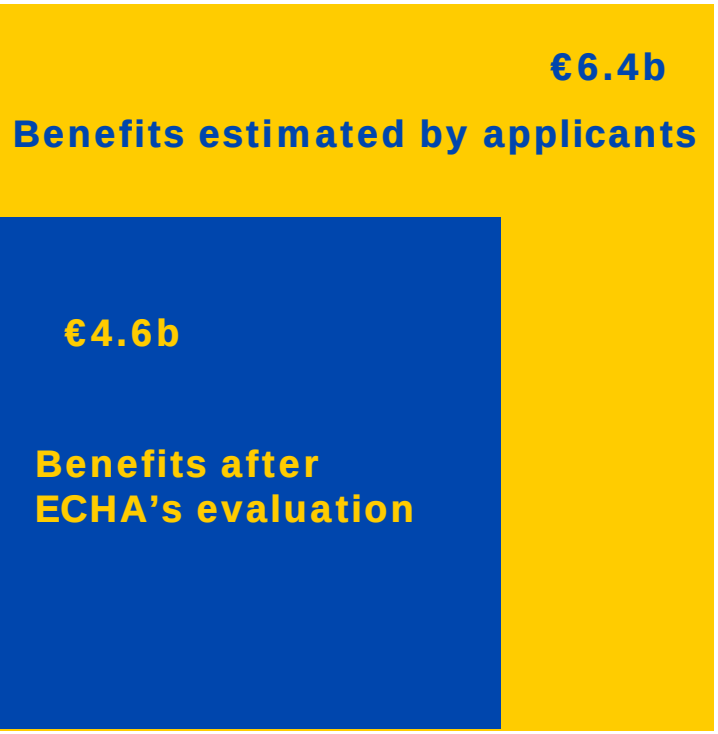
Benefits vs costs for carcinogens



Summary of applications by the end of 2016

- **111** applications received
- **60** scientific opinions sent to the Commission
- Cover up to **366 kt** of **22** different substances
- Estimated the benefits of continued use (i.e. cost to firms and their clients if authorisation was not granted)
- Estimated monetised health damage of continued use, if authorisation was granted
- Environmental damage (Persistent, Bioaccumulative and Toxic substances) not monetised

Annual welfare impacts of continued use of all applications



Monetised damage as estimated by applicants

Monetised damage after ECHA's evaluation

Were applicants

- overestimating their benefits; and
- underestimating the damage

if authorisations were granted?

Usual suspects did not explain: i) Value of Statistical Life used (usually) €3.5m based on ECHA's study and ii) almost all used ECHA's reference dose-response functions

3.1 BCA issues: Applicants (firms)

- This is for real
  - Getting authorisation a “live or die” issue
  - Firms have little or no experience to prepare BCA
- Firms had difficulties to estimate impacts outside their own sphere
  - Overestimated, if they ignored competitors’ potential gains in market share
  - Underestimated, if they ignored the cascading impacts on an industrial value chain
- Firms had difficulties to know
  - Forecasting of market demand, technical progress, etc.
  - What happens if no authorisation? Shutdown, substitution, relocation? How credible is this?
- Firms were ignorant
  - How do their customers actually use SVHCs? Is this safe?
  - Due to authorisation requirement use has become safer

3.2 BCA issues: Authorities

- ECHA's committees anticipated
  - Set reference dose-response functions and key values
- ECHA's committees struggled
  - Weighing risks, and technical and economic feasibility of alternatives – as provided by applicant or competitors
  - knowing what firms and their competitors in and outside the EU would actually do
  - with many methodological issues in practice

- Commission and EU Member States (at decision making stage) have occasionally struggled
  - Not used to seeing explicit trade-offs
  - BCA indirectly "blamed" to make policy decisions

3.3 Some methodological issues

- Missing dose-response function
  - Threshold substances: When “incidences” break-even with costs
  - PBTs: cost-effectiveness (emission reduction per ton of substance), but when to authorise or not?
- Latency
- Difficulty to value some health endpoints
  - Eg. “very low birth weight”, skin sensitisation
  - Starting to work on these through OECD

4. Take home

- Authorisation is a unique, flexible way to regulate dangerous chemicals (has global effects)
- It is for real
- ECHA publishes all applications, including BCA – living lab!
- Average B/C ratio 14:1 – large spread
- Authorisation requirement has made SVHC use safer in the EU
- Methodological challenges: environmental issues (PBT/very Persistent and very Bioaccumulative), endocrine disruptors
- BCA in chemicals is new in the EU: Lot's of fun in applied BCA ahead!

Thank you!

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Information on authorisation applications

https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa

Credits:

Christoph Rheinberger & Jukka Peltola

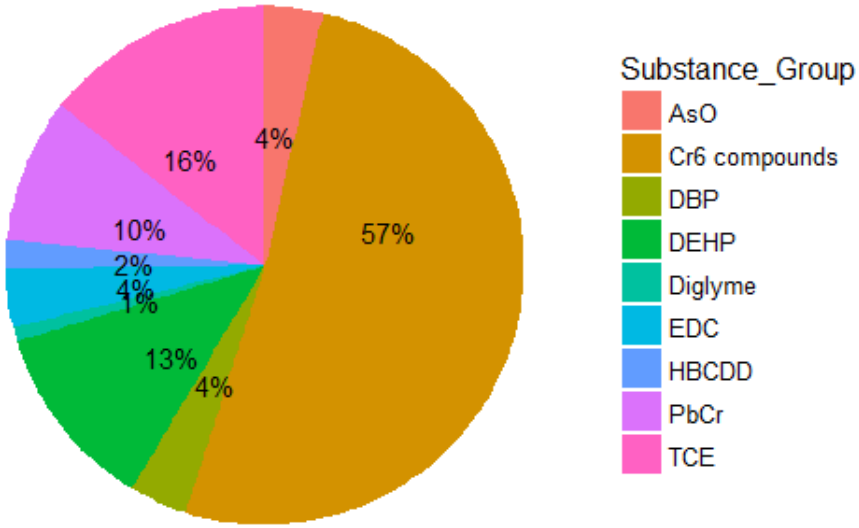
Back up slides

Highlights of the meta-analysis:

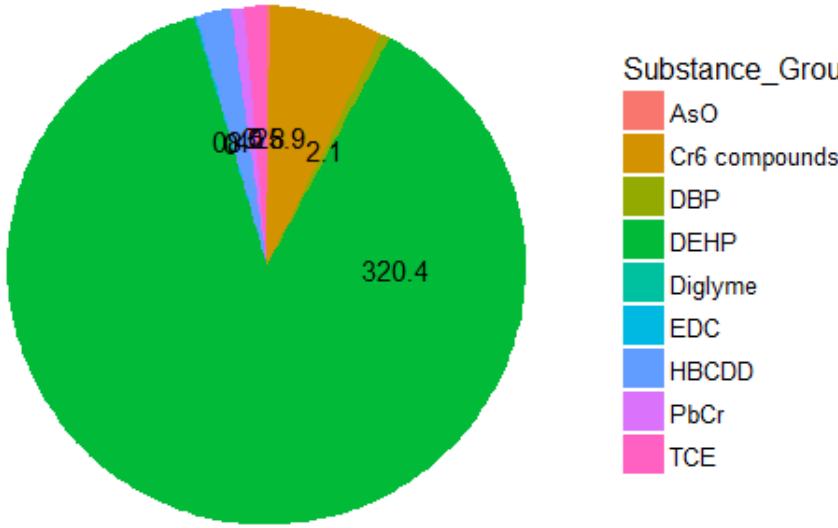
- Authorised uses of SVHCs include bulk chemicals such as Cr6, TCE, DEHP, etc. with large use volumes
- Annual use of **366 kt** of SVHCs have been authorised
- Under worst-case assumptions up to **75** excess cancer cases per year associated with the authorised uses
- But economic benefits of continued use are in the order of billions of Euros per year
- Net benefits of continued uses **€4.2-6.2 bn** per year; benefit-cost ratio about **14:1**

Substances applied for by

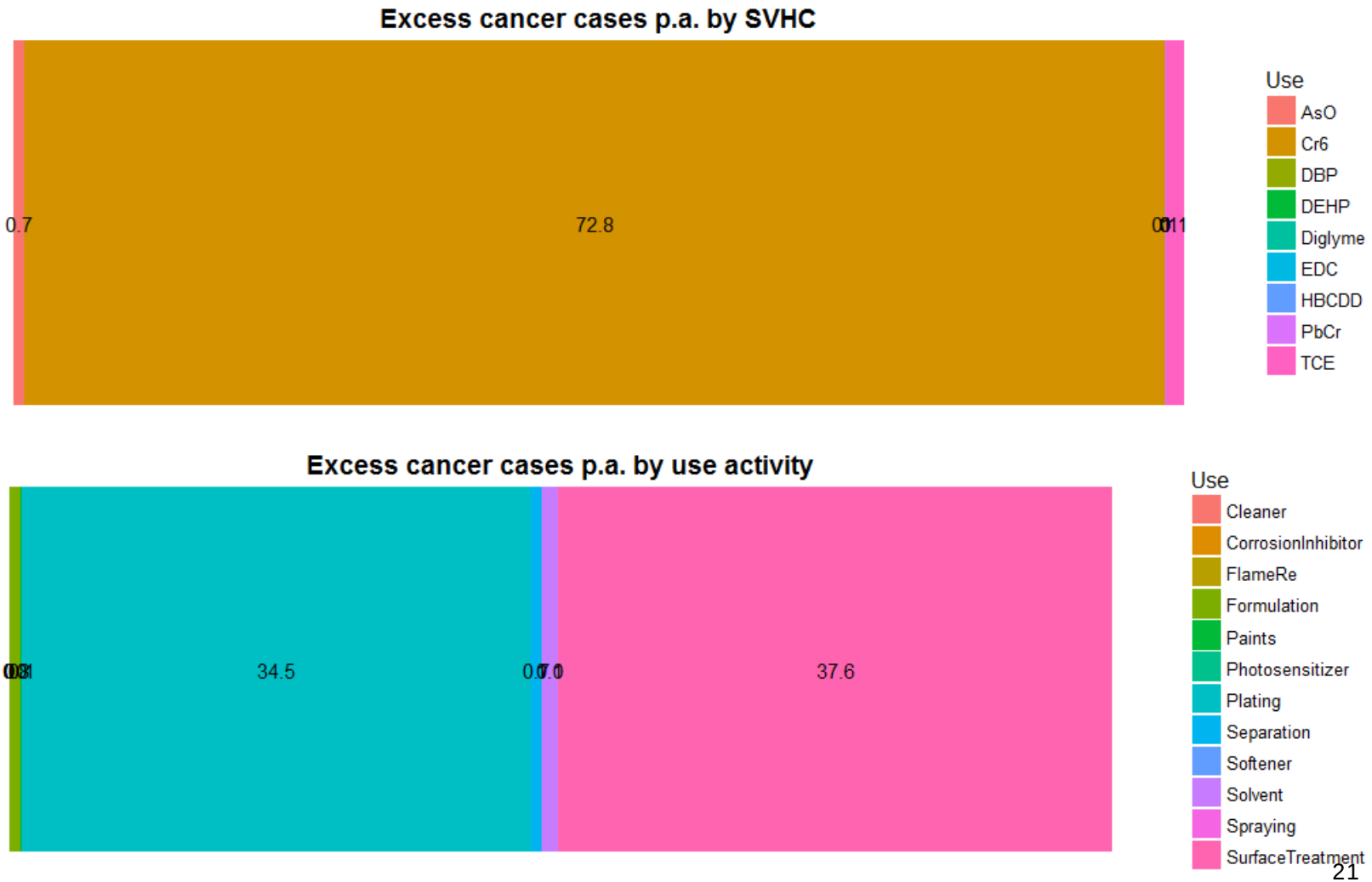
Applications Received



Use Volumes (in kT per year)

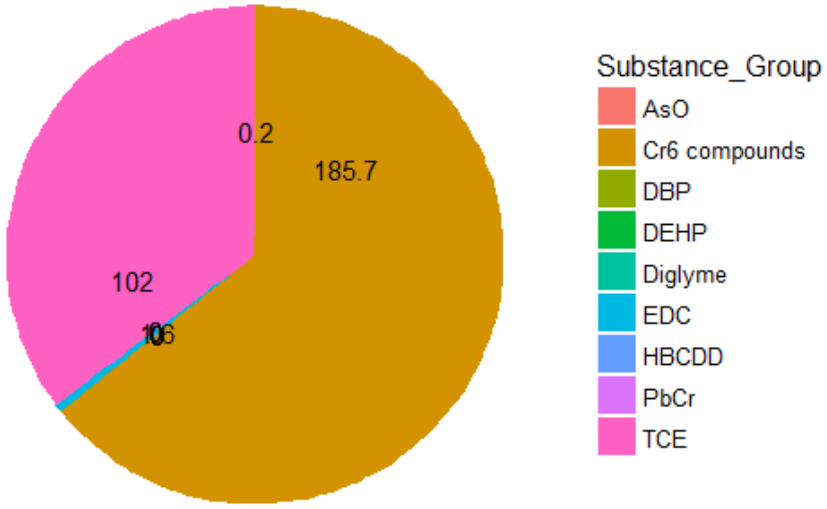


Excess cancer risk by SVHC / Use

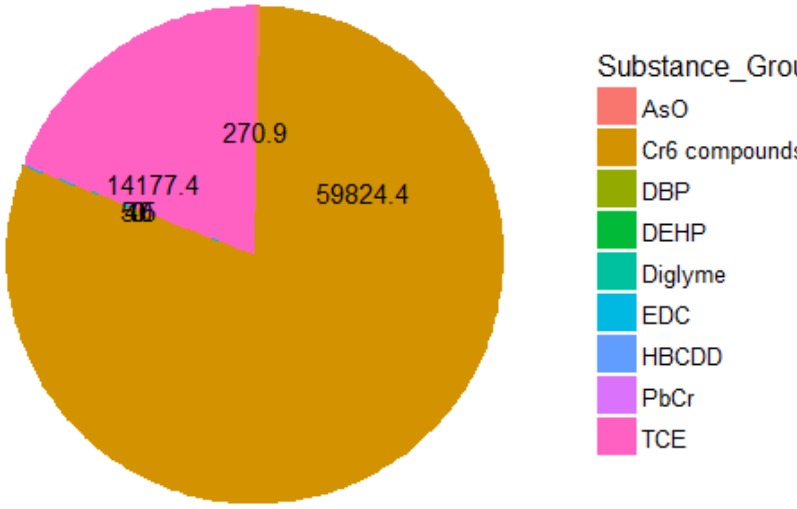


Number of people exposed

Workers Exposed (in 1,000)



Local Population Exposed (in 1,000)



Excess cancer risk on the aggregate

- Adopting a **reasonable worst-case approach**, the total number of excess cancer cases p.a. was assessed at **44** in applications and at **75** in opinions.
- This suggests an underestimation of **40%** by applicants when benchmarked against ECHA scientific committees.
- Total number of workers exposed: **290k**
- Total number of local population exposed: **74m**
- Crude normalization using all exposed people as numeraire results in annual individual excess cancer risk of **~10^{-6}** associated with the continued use of SVCH

Review periods