EU's approaches to analysing benefits and costs of chemicals risk management

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BCA used in authorisation and restrictions under the REACH Regulation

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

Basic approach

1. Company applies for authorisation or

   Member State or ECHA proposes a restriction

   - Both include BCA

2. European Chemical Agency scrutinises & gives opinions

   - Committee for Socio-economic Analysis in the centre

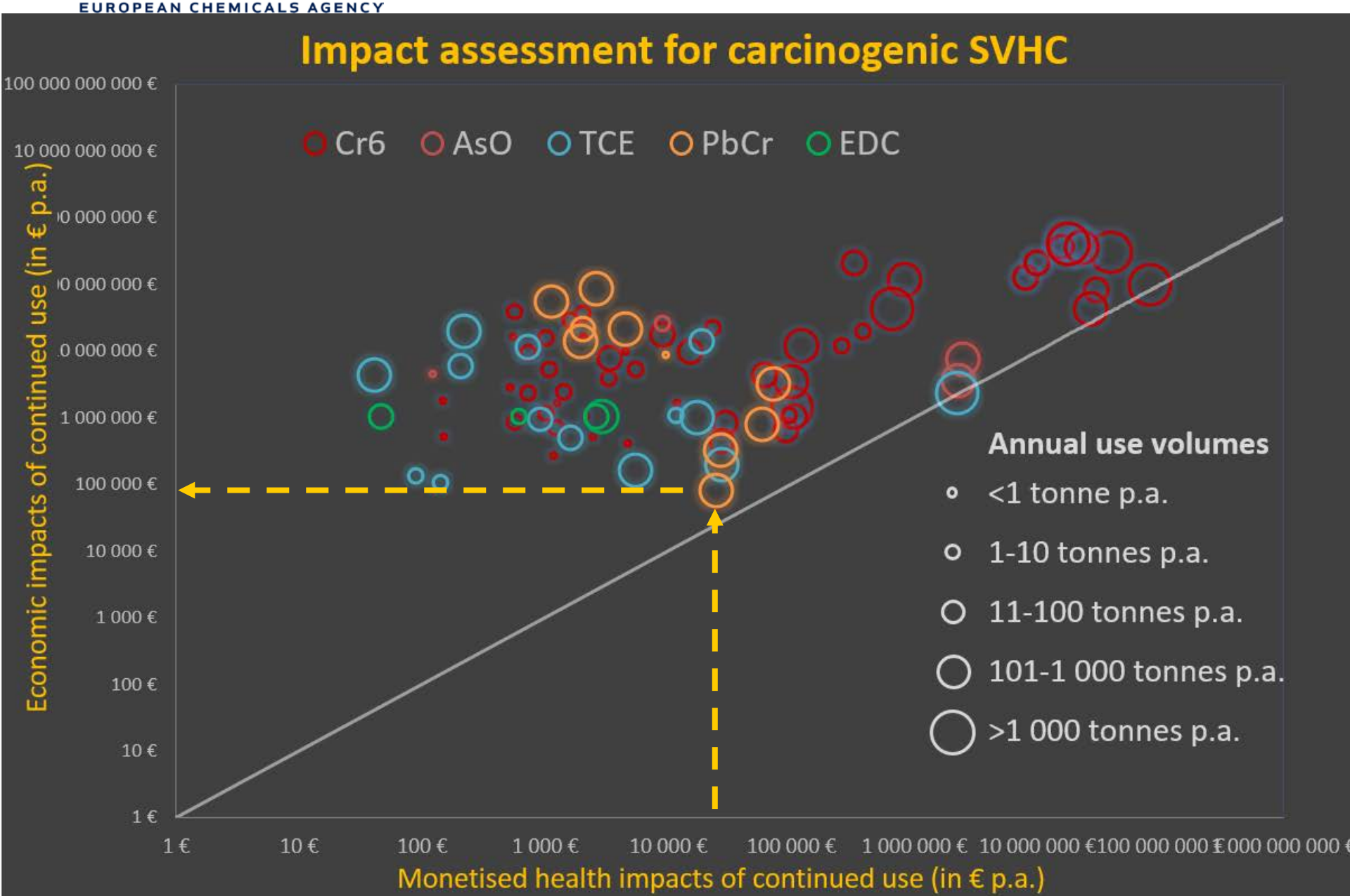
3. European Commission (”Government”) decides

   - with EU Member States (”Senate”)
   - also with European Parliament (for restrictions) (”House”)

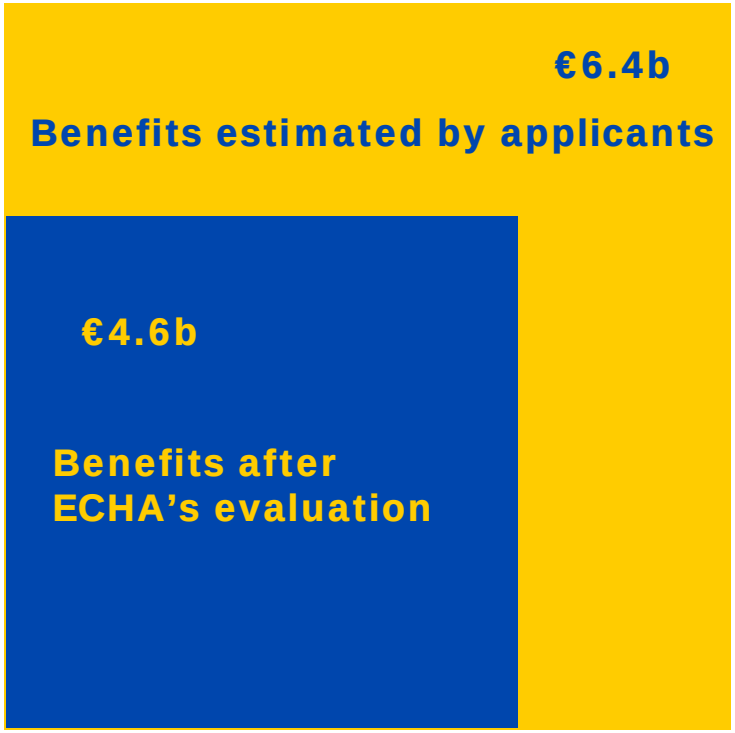
How BCA affects risk management

- At preparation stage
  - Better understanding of impacts
  - Iterations (better application/restriction)
  - BCA synthesises i) analysis of chemical safety and ii) alternatives
- At scrutiny stage, BCA affects opinions
  - Time limited or permanent derogations (for restrictions)
  - Duration of the authorisation (review period) for authorisation
- At decision making phase
  - If all clear, decisions are taken based on the opinions

Benefits vs costs for carcinogens in authorisation cases



Annual welfare impacts of continued use of all applications for authorisation



Monetised damage as estimated by applicants

Monetised damage after ECHA's evaluation

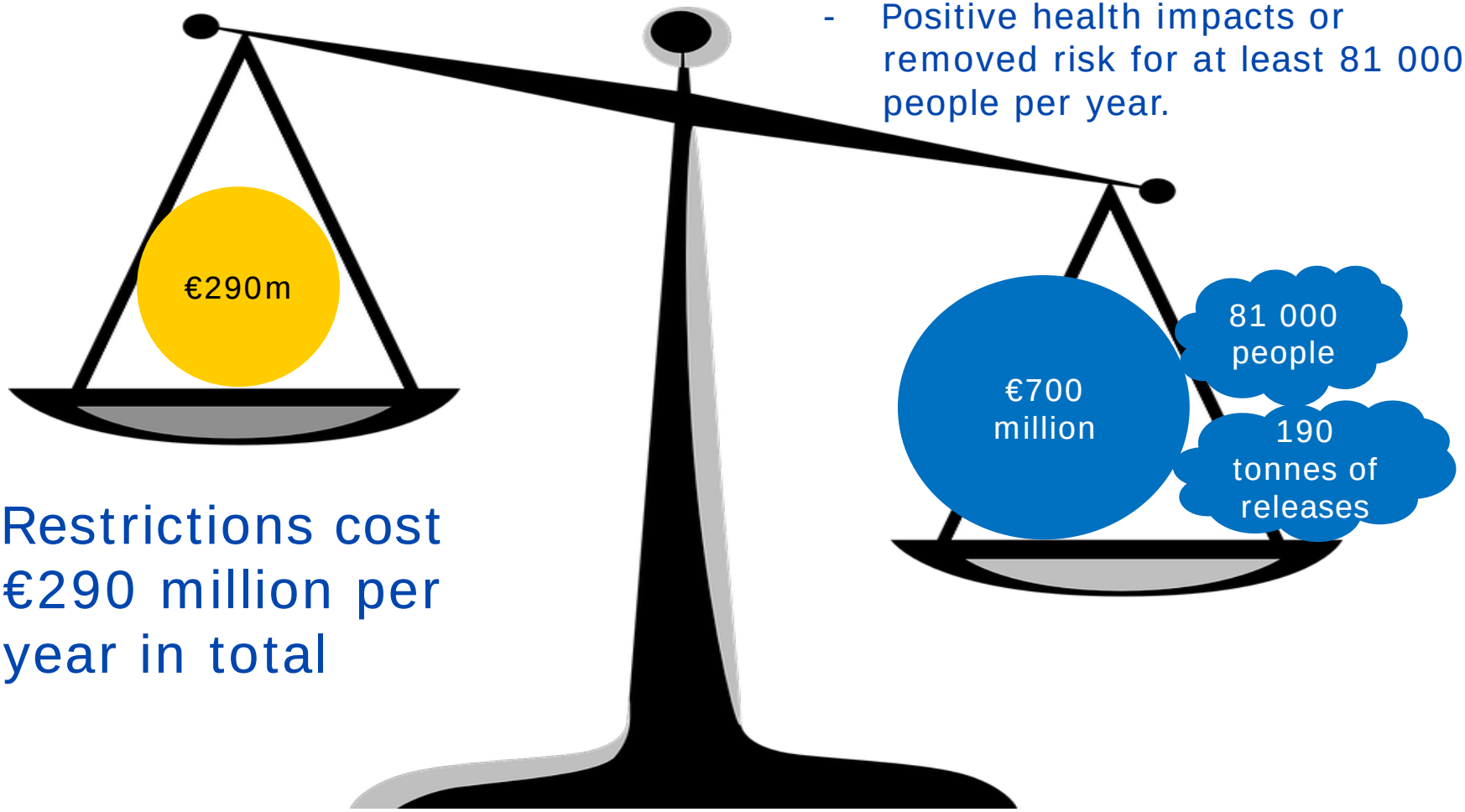
i) Value of Statistical Life used (usually) €3.5m based on ECHA's study and

ii) Almost all used ECHA's reference dose-response functions

Costs vs. benefits of 16 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.



Restrictions cost €290 million per year in total

Restrictions considered lately

- Chromium VI in leather articles
- Lead and its compounds in consumer articles
- Four phthalates (DEHP, BBP, DBP and DIBP)
- DecaBDE as a flame retardant in plastics and textiles
- PFOA and its salts, including substances that may degrade to PFOA
- Siloxanes D4 and D5 in personal care products
- Bisphenol(A) in thermal paper
- Dimethylfumarate (DMFu) in treated articles
- Lead and its compounds in jewellery
- Mercury in measuring devices
- Phenylmercury compounds used e.g. in the production of polyurethane coatings
- 1,4-DCB in toilet blocks and air fresheners
- Nonylphenol (NP) and its ethoxylates (NPE) in textile
- 1-Methyl-2-pyrrolidone (NMP)
- Use of asbestos fibres
- Ammonium salts in cellulose as insulating material
- Methanol in windshield washing fluids
- Cadmium and its compounds in antifouling paints
- Cadmium in artists' paints

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

Try to make it easy and predictable

- Establish dose response functions (for applicants and committees)
- Guidance documents for Socio-economic Analysis
- Transparency: Over 100 BCAs to learn from
- Capacity building for Member States, applicants, ECHA's committees
- Provide WTP values
  - Collaboration through OECD starting
  - Learn from each other: eg. Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP)

Thank you!

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