

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

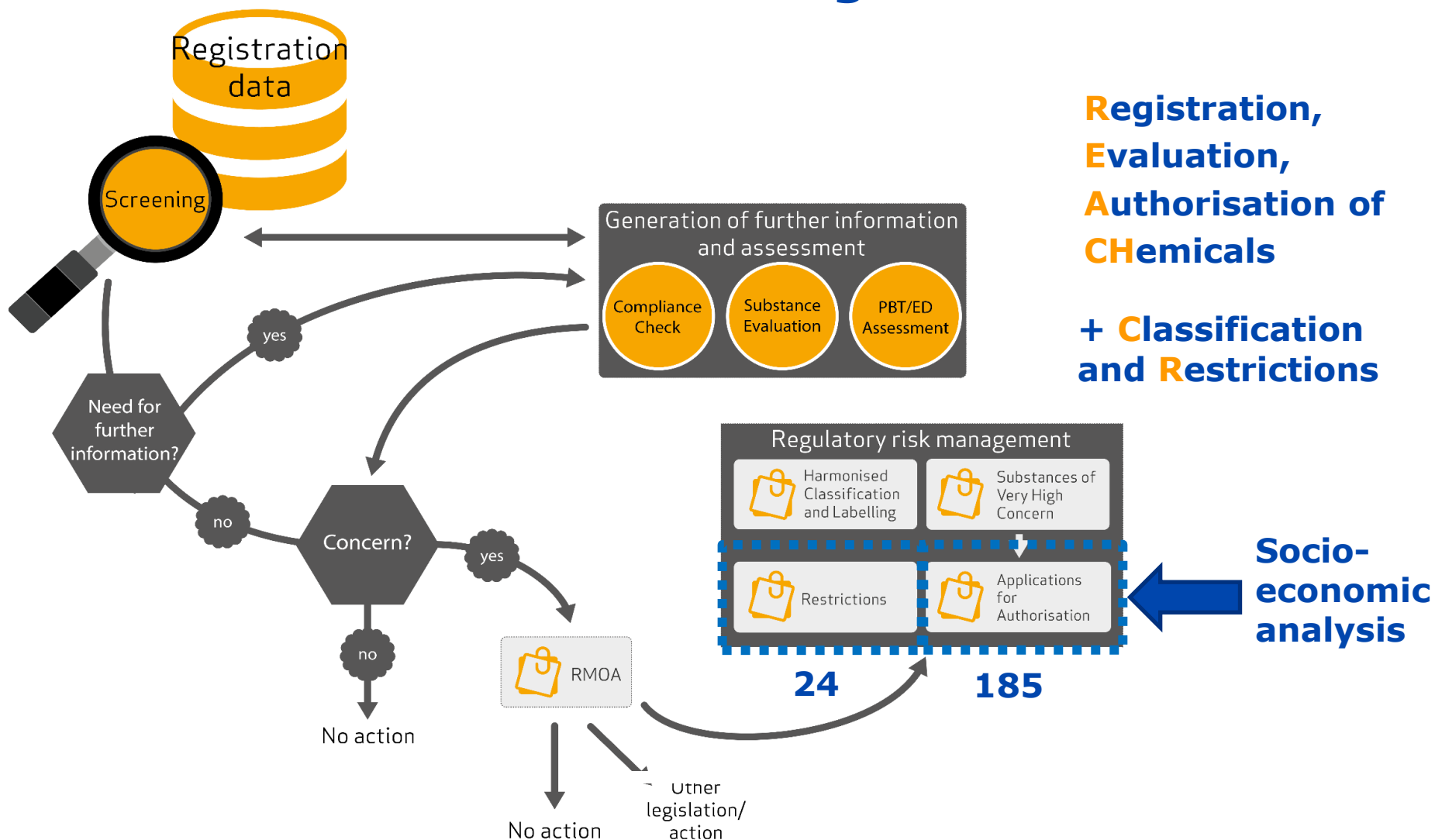
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Outline

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



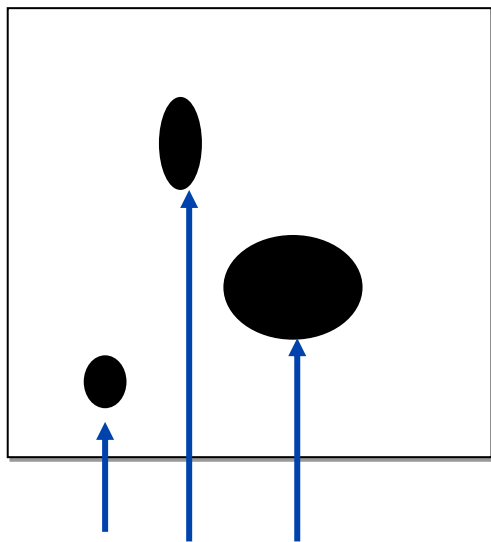
**Registration,
Evaluation,
Authorisation of
Chemicals**

**+ Classification
and Restrictions**

**Socio-economic
analysis**

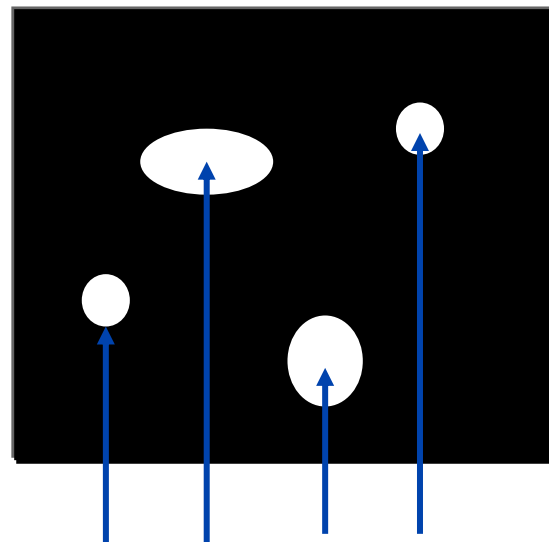
Relationship between Restrictions and Authorisations

Restrictions
(Annex XVII)



Restriction of placing on the market or of uses

Authorisation of substances of very high concern (Annex XIV)



Authorisation of uses

SEA in restrictions and authorisations

➤ Restrictions (Title VIII)

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



May prepare SEA



Shall take into account socio-economic impact



WTO consultation

➤ 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)



May prepare SEA



**Suitable alternatives?
Benefits > Risks?**

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

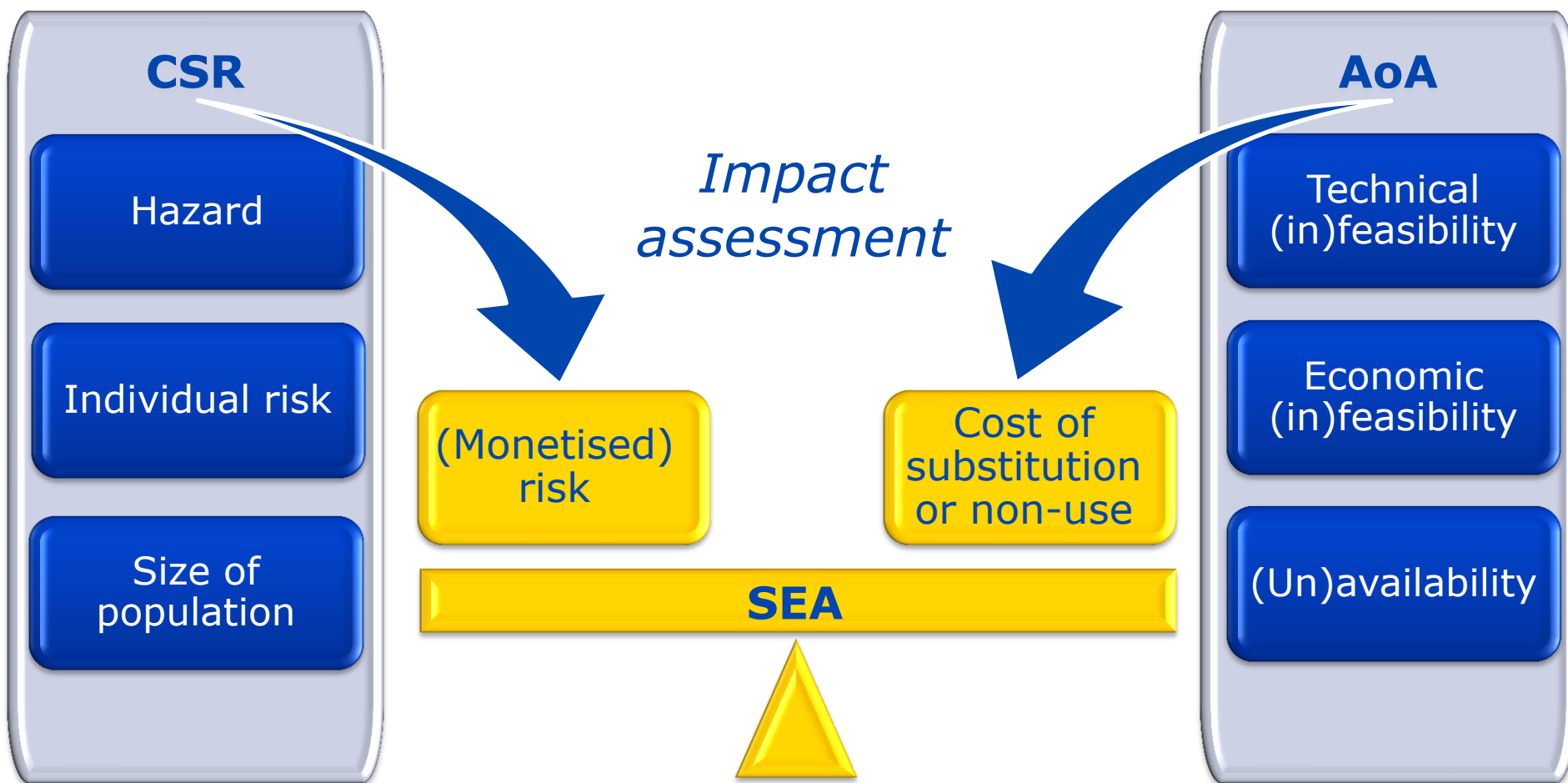
- Changes in production costs
 - Investment and operating costs
- Change in the characteristics of the good
- Treatment of residual value of capital
- Ensuring that only additional costs are included

- 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 [...]."*

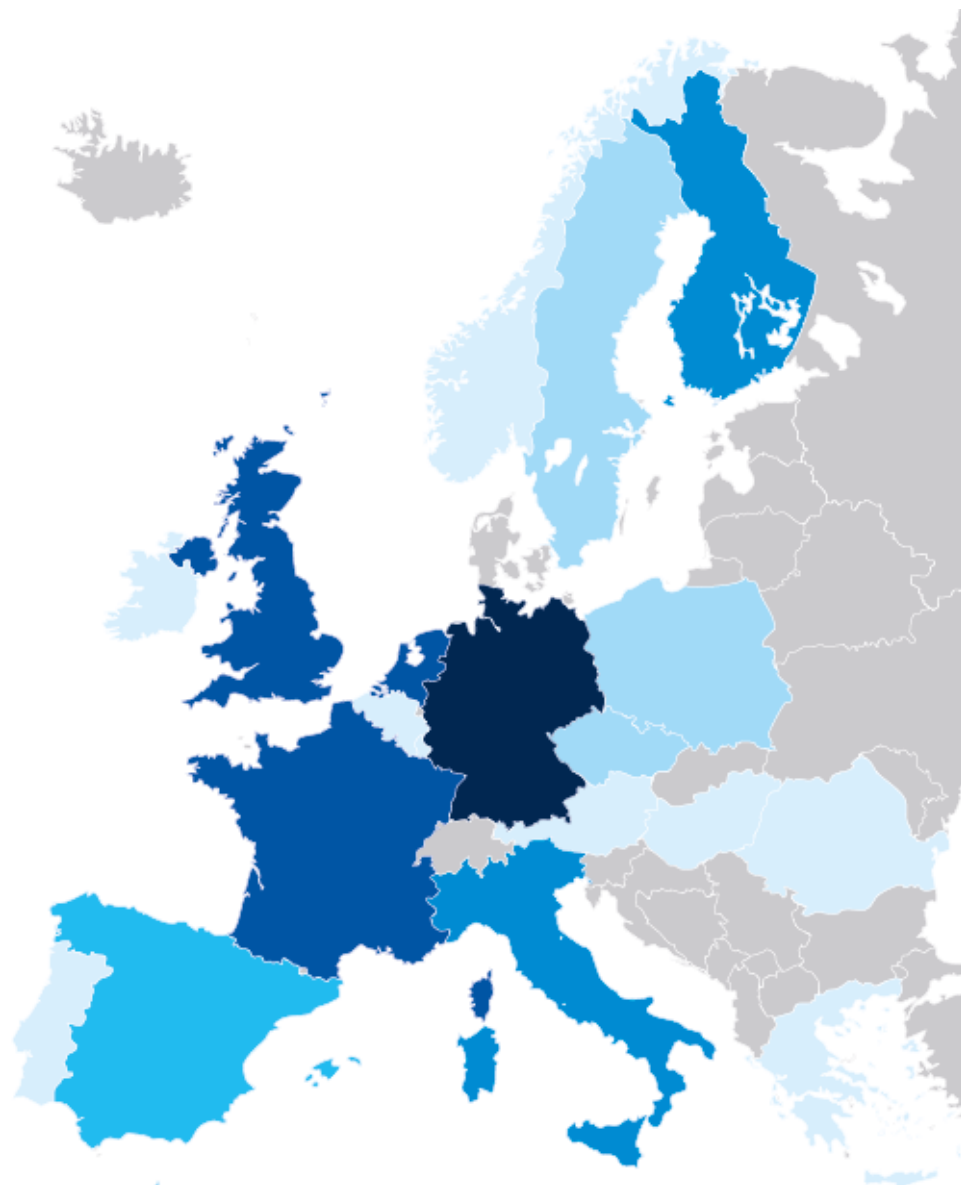
REACH Article 64(4)(b)

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	24	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 interating 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)

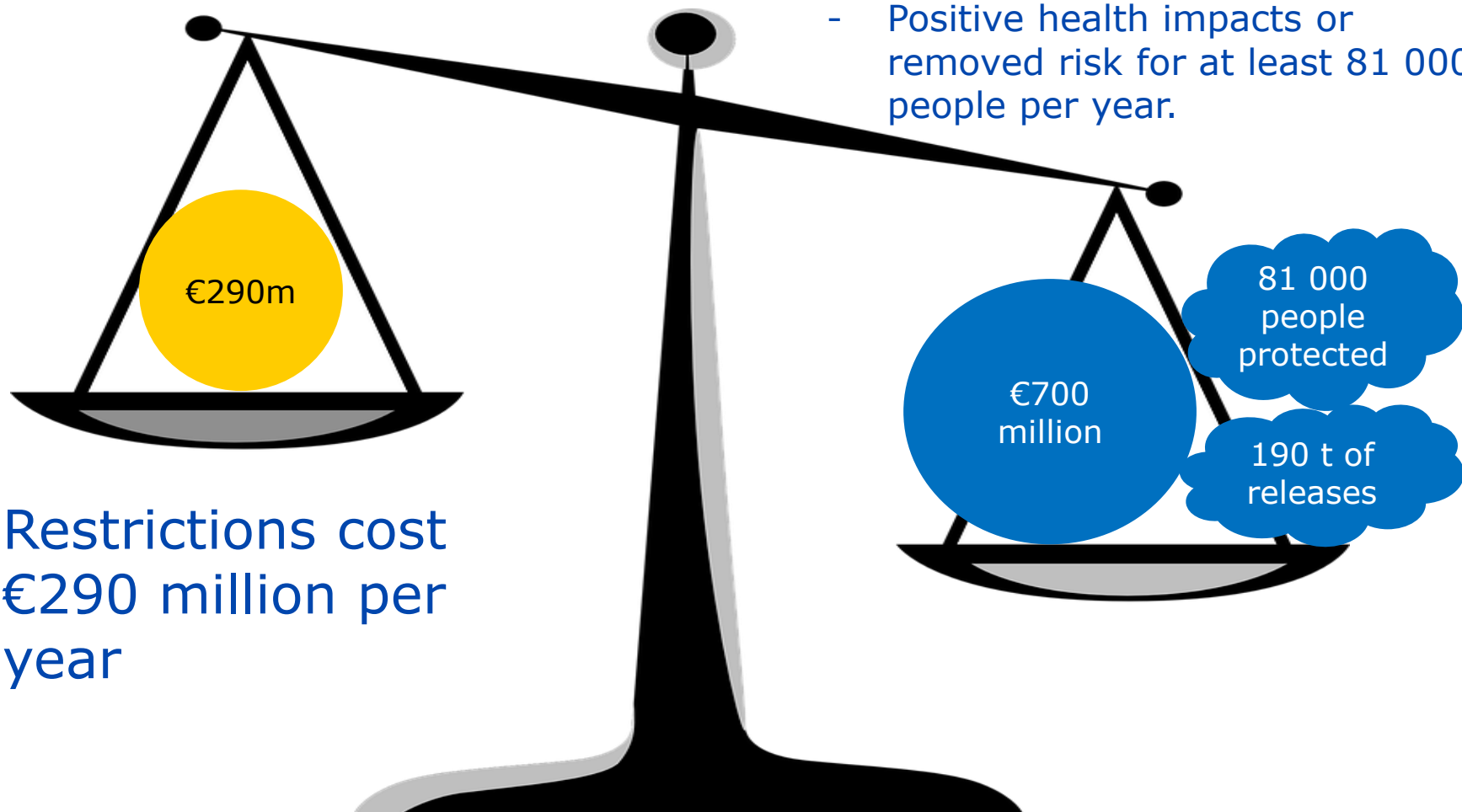
2016

- 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



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.)

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

Thank you!

Credits:

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

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