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

Regulering van PBT/vPvB stoffen

REACH Restrictie, Autorisatie en Socio-Economische Analyse

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PBT workshop 2019
21 maart 2019

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

Introduction REACH
SEA in REACH
Case study

PBT workshop 2019
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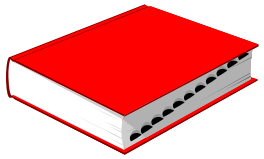
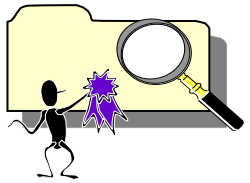
Introduction into REACH

European chemicals Regulation since 2007:



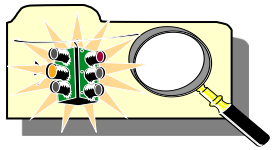
Registration:

industry needs to show and document safe use



Evaluation:

authorities (European Chemicals Agency and EU Member States) evaluate safe use

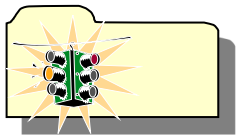


Authorisation:

substitution of substances of very high concern

restriction:

limit the use of substances posing unacceptable risks



of **CH**emical substances

PBT in REACH

- Proposals Substance of Very High Concern (SVHC, article 57d/e)
  - Annex XV SVHC dossier (by ECHA or MS)

  ⇒ Candidate list (https://echa.europa.eu/candidate-list-table)

  - Prioritising for Autorisation

    ⇒ Possible listing on Autorisation List (Annex XIV) https://echa.europa.eu/nl/authorisation-list)

- Proposal of Restriction possible
  - Annex XV Restriction dossier (by ECHA or MS)

  ⇒ Restrictielijst (Annex XVII) https://echa.europa.eu/substances-restricted-under-reach

- Other possibilities outside REACH (POP, …)

SVHC – Candidate list

- REACH defines hazard criteria for SVHC (Article 57)
  - (a) Carcinogenic
  - (b) Mutagenic
  - (c) Reprotoxic
  - (d) **Persistent, bioaccumulative and toxic** substances
  - (e) **Very persistent and very bioaccumulative** substances
  - (f) Substances of equivalent level of concern

- Criteria for PBT and vPvB set out in Annex XIII

SVHC – Priorisation for Annex XIV (Autorisation)

- Article 58 (3)
  - (a) **PBT en vPvB stoffen**
  - (b) Wide dispersive use
  - (c) High volumes

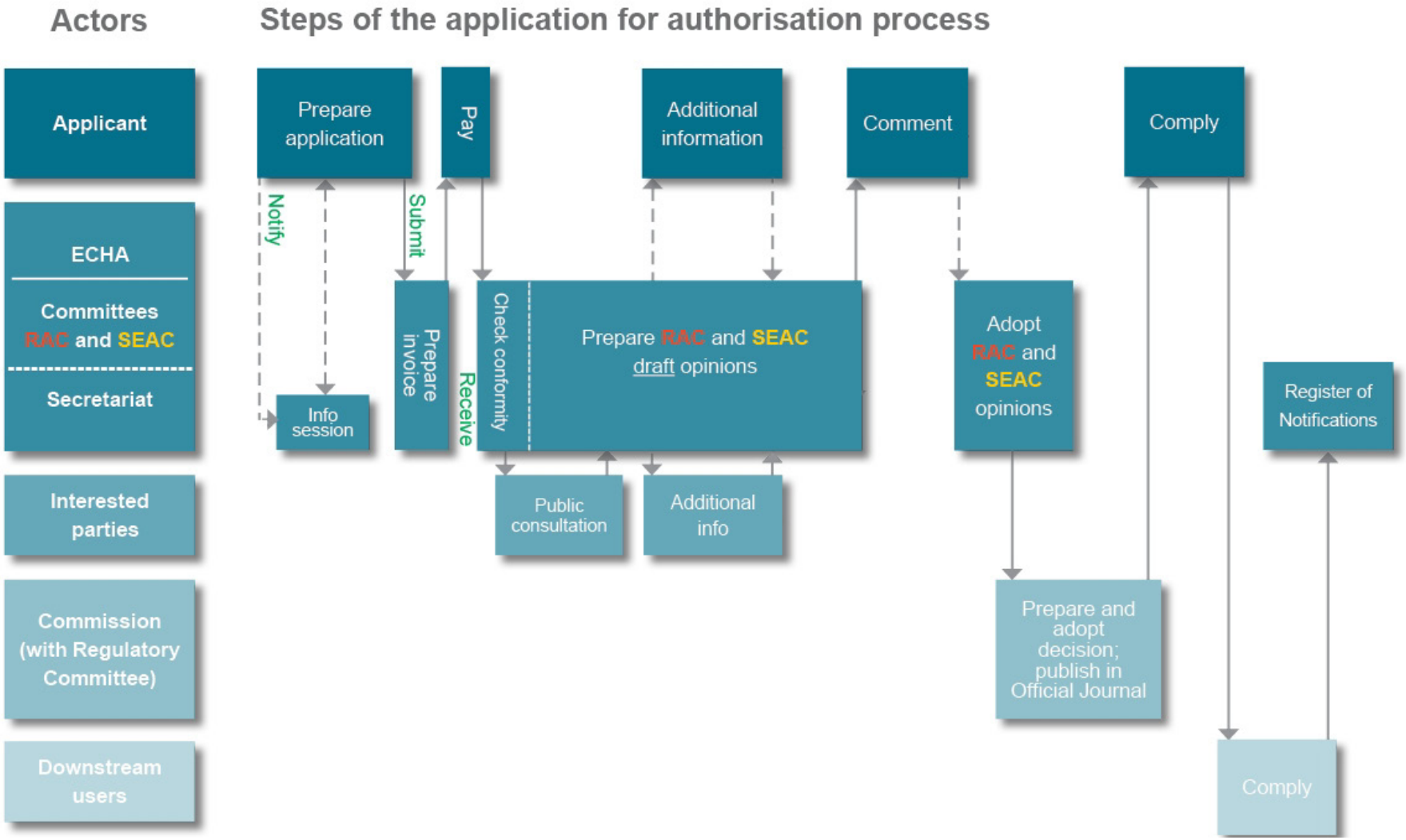
PBT in REACH - Authorisation

- For authorisation of PBT and vPvB substances the so-called SEA route is always followed

Elements to consider in an authorisation decision:

- **Socio-economic benefits outweigh the risk**
- **No suitable alternative substances or technologies**

Authorisation process



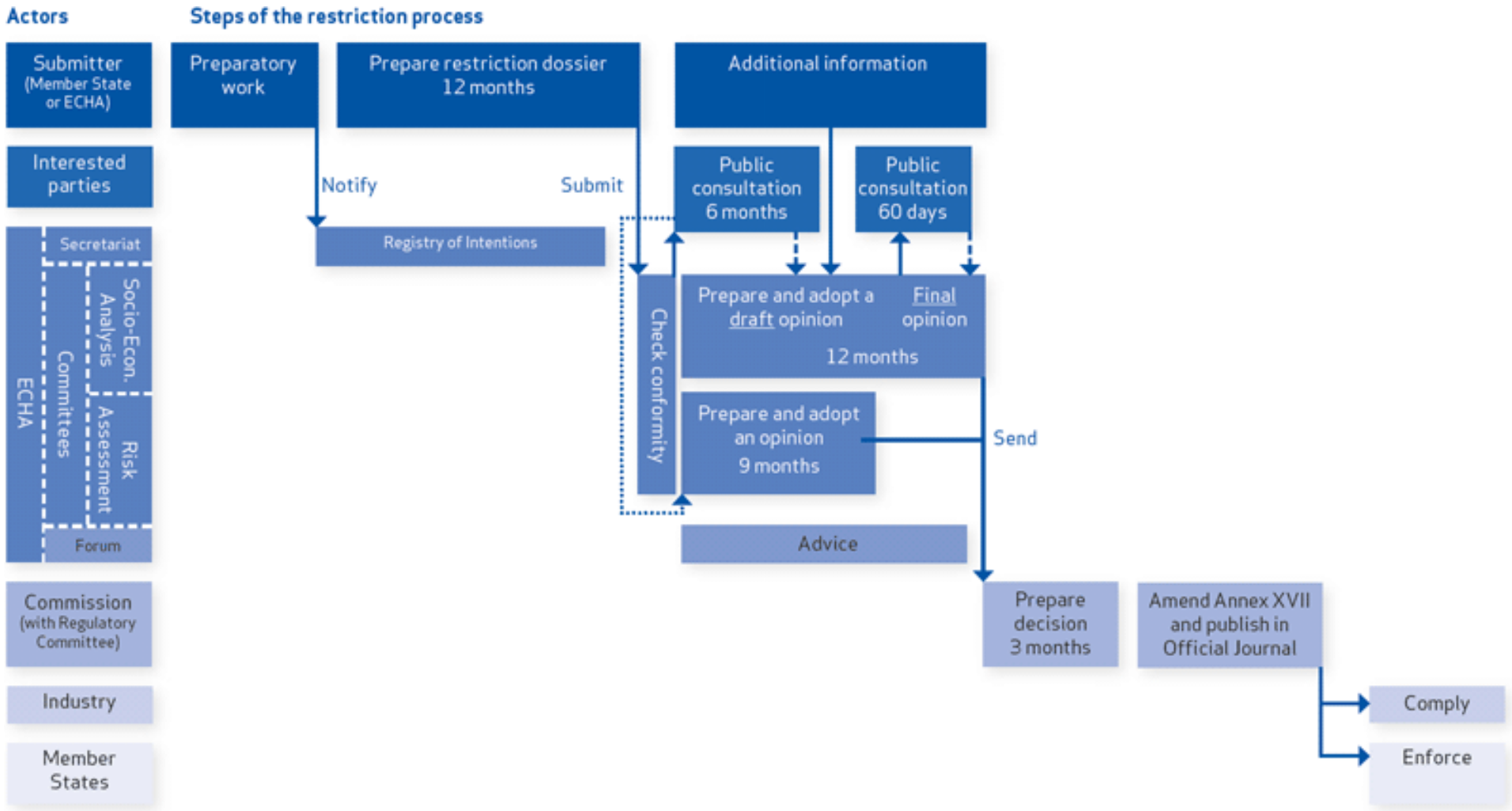
Source: https://echa.europa.eu/nl/regulations/reach/authorisation/applications-for-authorisation/authorisation-process

PBT in REACH - Restriction

Elements to proof/consider in a restriction proposal:

- **Unacceptable risk** due to **manufacture, use or placing on the market**
- Need to addressed the risk on a Community-wide basis
- Take into account the **socio- economic impact** of restriction
- **Availability of alternatives**

Restriction process



Source: https://echa.europa.eu/nl/regulations/reach/restrictions/restriction-procedure/restrictions-process

Which PBT/vPvB substances are regulated?

- Candidate list: 197 substances, of which 52 PBT and/or vPvB
- 9 restrictions on PBT substances and 3 substances subject to authorisation
- Some substances regulated outside REACH: e.g. PCBs, PFOS, HCH

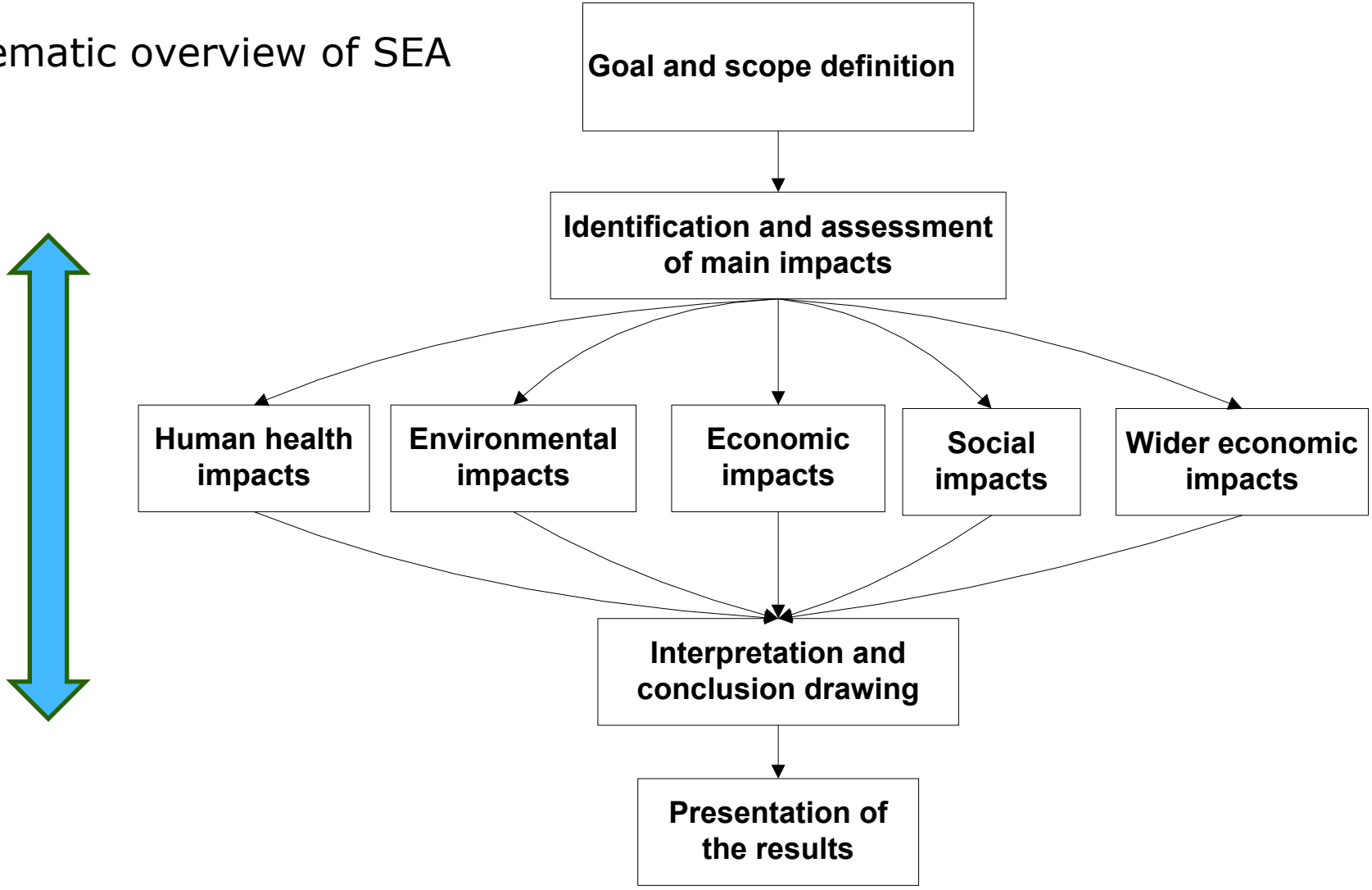
Candidate list	Type of REACH regulation	Examples of substances
1	Both authorisation and restriction	Anthracene oil
9	Only restriction	D4/D5, DecaBDE, Fluoranthene, TBTO, PFOA, B(a)P
3	Only authorisation	Coal tar pitch, HBCDD, Musk xylene
39	Only candidate list	PFHxS, Pyrene, Phenantrene, Dechlorane-plus

What is a socio-economic analysis?

"SEA is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented" (ECHA)

More information: https://echa.europa.eu/nl/support/socio-economic-analysis-in-reach/

Schematic overview of SEA



SEA within REACH

- Multidisciplinary assessment > need for broad range of expertise
- Impacts can be described qualitatively/quantitatively
- Monetarization simplifies comparison of positive and negative impacts
- SEA guidance for restriction and authorisation: no standard approach

Approaches
Benefit cost analysis
Break-even analysis
Cost effectiveness analysis + benchmark
Multi criteria analysis
Compliance cost analysis
Qualitative description of impacts incl. illustrative calculations

ECHA SEA guidance authorisation: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf
ECHA SEA guidance restriction: https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf

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How is SEA for PBTs carried out?

- Quantification of risks and impacts of PBT/vPvB for man and environment is (currently) not possible
- Therefore, comparison of the costs and benefits is not possible

- Proposed by SEAC (2014) **Cost effectiveness analysis**:
  - Aim: minimisation of emissions PBT/vPvB substances
  - What does it cost society to reduce the use/emission of PBT/vPvB substances (euro/kg)
  - Which measure is most cost effective?
  - Which costs does society consider acceptable to reduce use/emission of PBT/vPvB substances?

Source: https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

Benchmark development

- Project commissioned by Ministry I&M, and carried out by Free University (IVM, 2015)
- Main question: how much has been paid in the past to reduce the use/emissions PBT substances?
- Implicit assumption: past expenditures provide information on the willingness to pay to reduce the use/emissions of PBT substances
- Used for first contours of a benchmark
- Substances studied: D4/D5, HBCDD, HCB, HCH/lindane, PCBs, PFOS
- Costs for various types of measures included: substitution, replacement and disposal, remediation/clean-up

IVM 2015: https://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

First impression of possible benchmark

- Below around 1000 euro/kg seems generally acceptable
- Above around 35 000 euro/kg is possible a hurdle for carrying out measures (clean-up activity postponed, exemptions introduced)

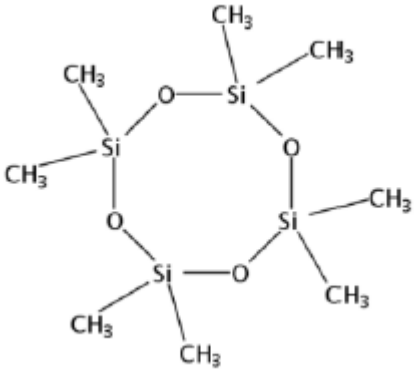
- Large grey zone
- And: data in the analysis limited, no hard conclusions or benchmark yet
- Further exploration of information base preferable/necessary

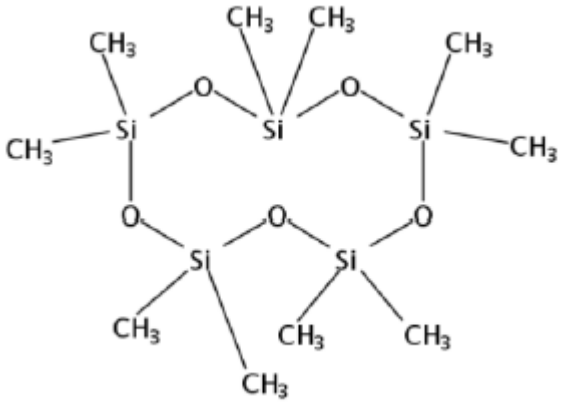
Note: the red and green areas do not relate to actual cases and are for illustrative purposes only.

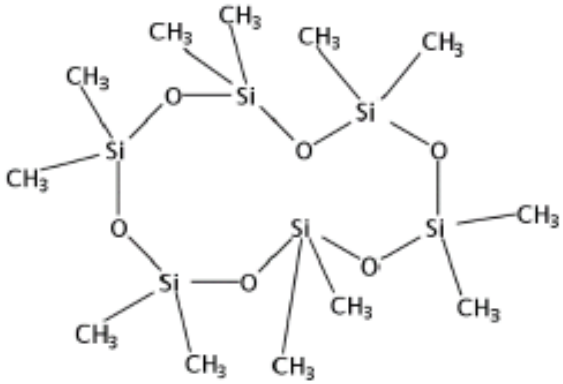
Source: IVM 2015

Case study: D4, D5 and D6 – Restriction proposal

- Restriction proposal submitted by ECHA (January 2019)
- Wash-off application of D4 and D5 in cosmetics already restricted
- Scope of the restriction proposal based on largest emission sources:
  - D4, D5 and D6 leave-on cosmetics
  - D6 wash-off cosmetics
- E.g. uses at industrial sites derogated (e.g. silicone polymer production), medical applications, art cleaning



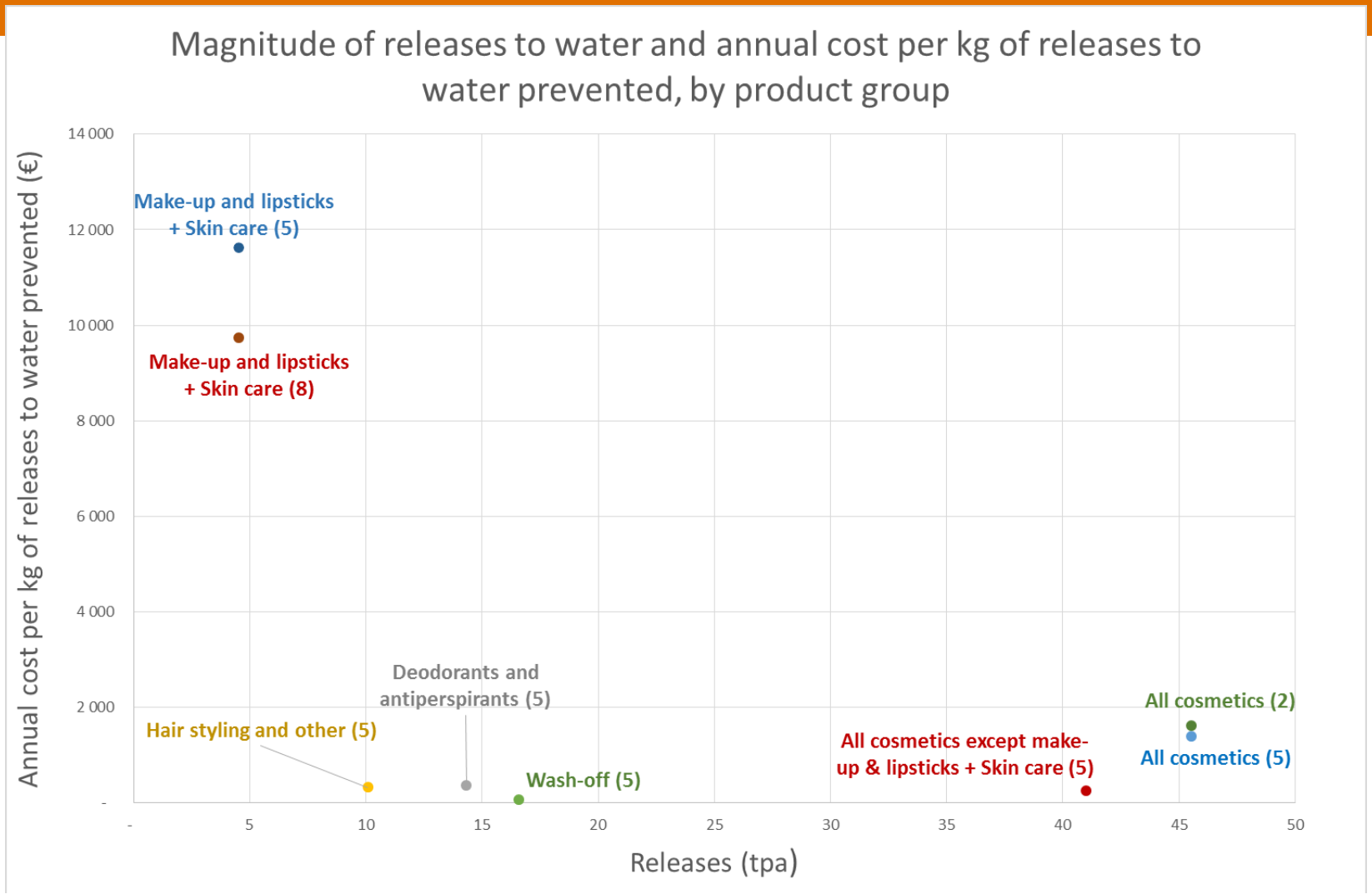




Case study: D4, D5 and D6 – Restriction proposal

Information provided in the SEA

- Alternatives: formulations (on the market) that do not contain siloxanes
- Costs estimated
  - Costs per reformulation
  - Number of (early) reformulations expected due the restriction
  - For various types of cosmetics containing siloxanes (after shave, deodorant, creams and lotions, foundation, body wash, make up remover, etc.)
  - Or: no reformulation but shift to alternative consumer products already on the market
- Emission and stock estimations to water and air as proxy for risk



Source and additional information: ECHA 2019, https://echa.europa.eu/documents/10162/26cc3562-d0a0-1e09-b1eb-72f6bdf9309a

Case study: D4, D5 and D6 – Restriction proposal

- Average cost effectiveness estimates:
  - 4 €/kg prevented releases to air and water
  - 1400 €/kg prevented releases to water
  - 85 €/kg to avoid an environmental stock

Table 16: Cost effectiveness of recent REACH restrictions

Restriction under REACH	€/kg pa central value
Lead in shot in wetlands	9
Lead in PVC (under opinion making)	308
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

Source: ECHA

Public consultation will start soon: https://echa.europa.eu/nl/restrictions-under-consideration


thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
спасибо
dank je
merci
obrigado
bedankt
dziękuję
sukriya
kop khun krap
go raibh maith agat
mochchakkeram
tapadh leat
arigatô
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감사합니다
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sagolun
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Questions for discussion

- What is the best risk management route for PBT/vPvB substances (within REACH: SVHC candidate listing, authorisation, restriction)?
- Is the relevance of the use of SEA in the context of PBT/vPvB substances recognized?
- Is it appropriate to treat various PBT and vPvB substances equally within cost effectiveness analysis?
- Are benchmarks based on (previous) cost estimates meaningful for (regulatory) decision making?