Implementation of REACH and CLP: Overview, Status and post 2018 possible actions

European Seminar
Chemical Risk Assessment – REACH and CLP

Aveiro, Portugal,
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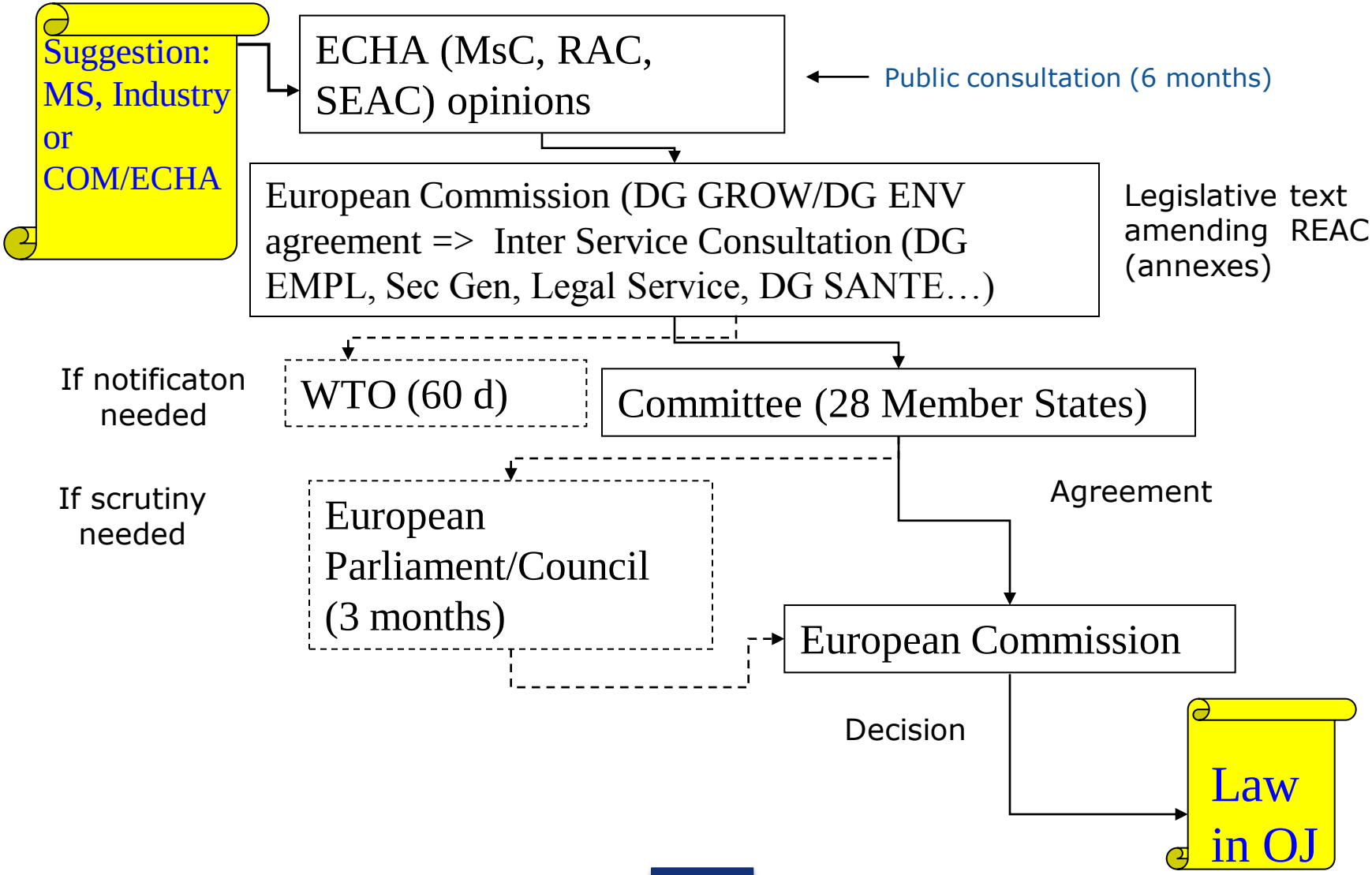
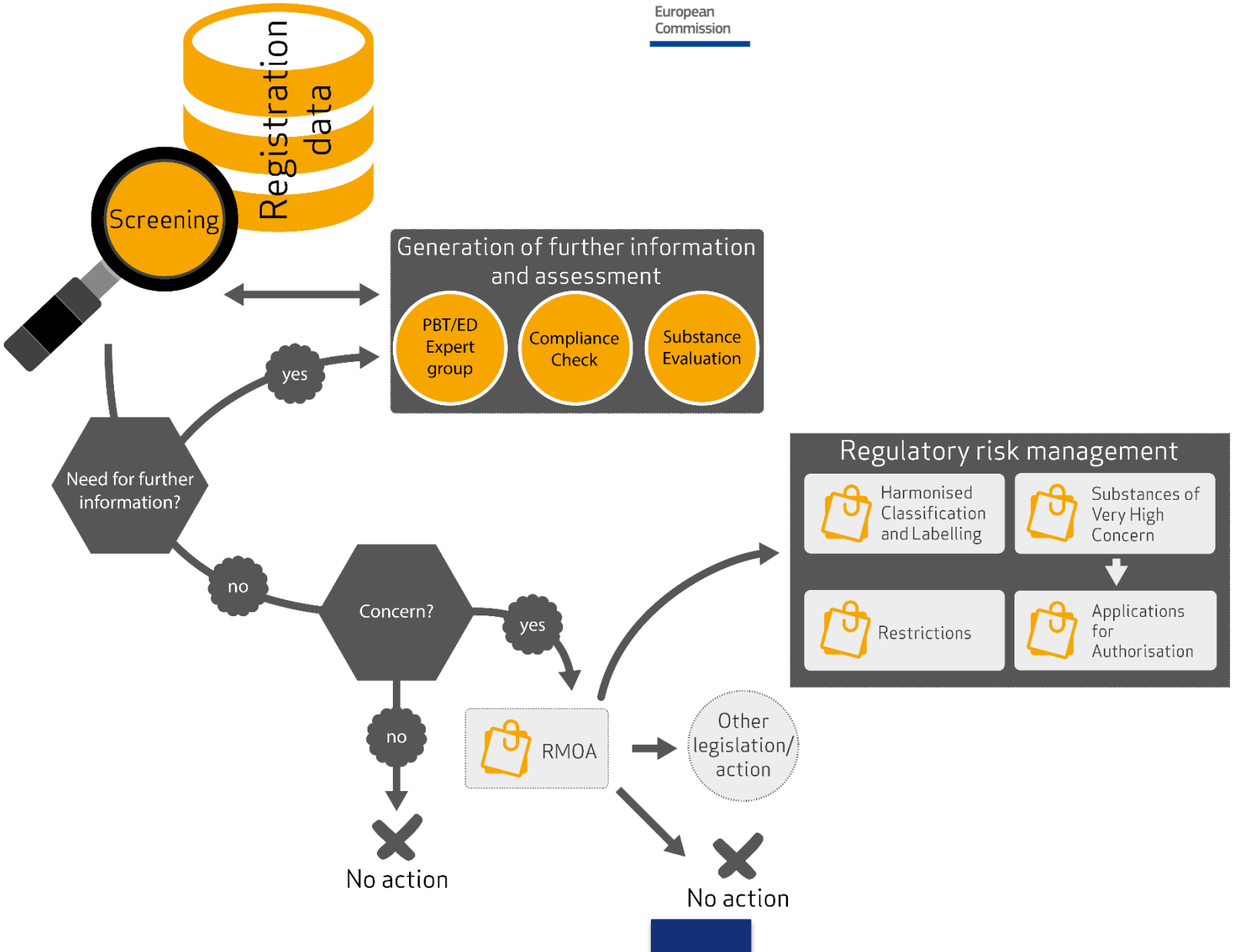

Suggestion: MS, Industry or COM/ECHA
ECHA (MsC, RAC, SEAC) opinions
Public consultation (6 months)
European Commission (DG GROW/DG ENV agreement => Inter Service Consultation (DG EMPL, Sec Gen, Legal Service, DG SANTE…)
Legislative text amending REACH/CLP (annexes)
If notificaton needed
WTO (60 d)
Committee (28 Member States)
If scrutiny needed
European Parliament/Council (3 months)
Agreement
European Commission
Decision
Law in OJ


Registration data
Screening
Generation of further information and assessment
PBT/ED Expert group
Compliance Check
Substance Evaluation
yes
Need for further information?
no
Concern?
yes
no
No action
RMOA
Other legislation/ action
No action
Regulatory risk management
Harmonised Classification and Labelling
Substances of Very High Concern
Restrictions
Applications for Authorisation

What has REACH achieved so far?

70 Restricted (group of) Substances

174 Substances of Very High Concern

460 Risk management proposals

1 500 Dossiers for HPV checked for compliance

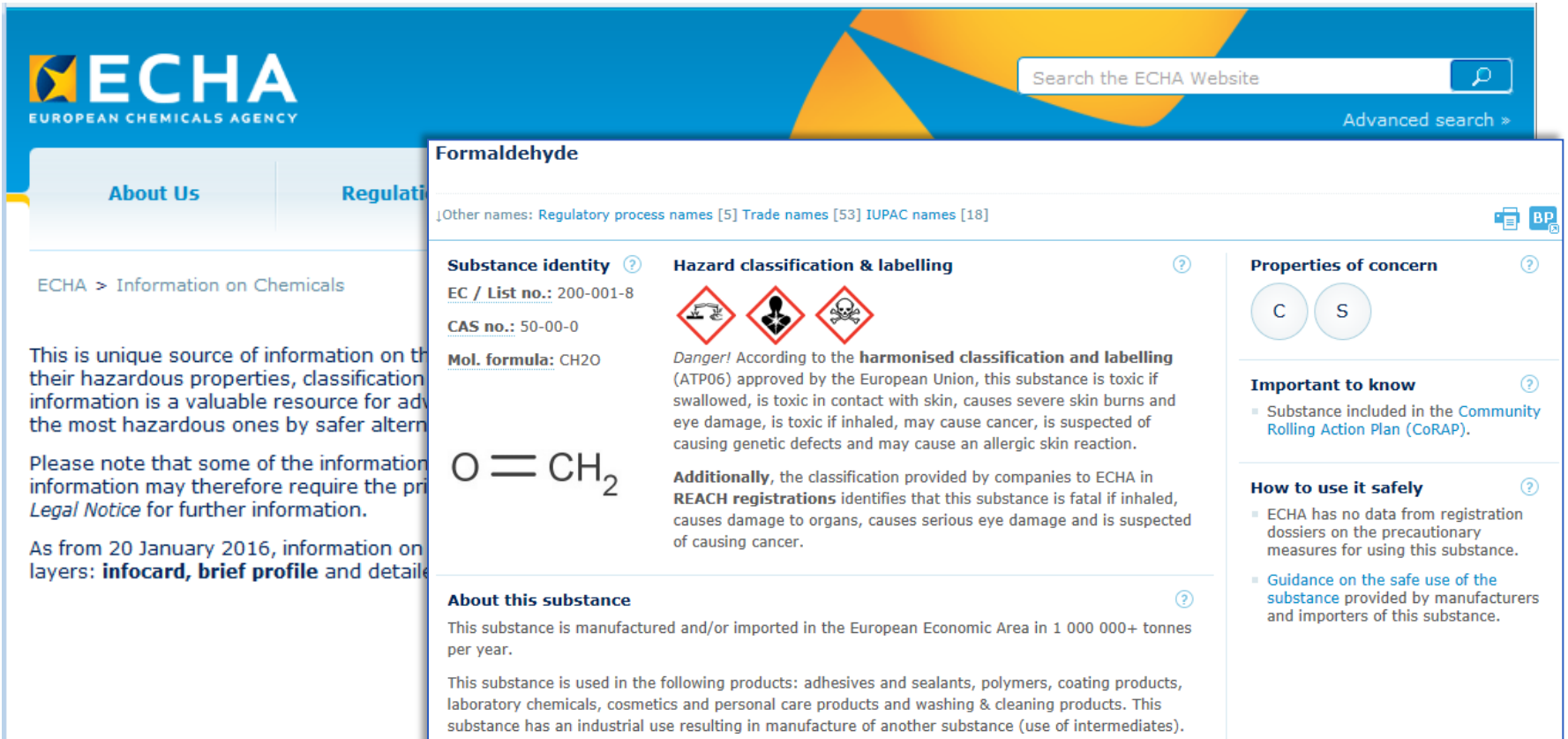
17 000 Substances registered under REACH

	2010	2013	2018
Substances	~ 3 400	~ 3 000	up to 25 000
Dossiers	~ 20 000	~ 9 000	up to 60 000

>2 million Study summaries on properties and effects of chemicals

What has REACH achieved so far? (2)

- *probably the* best chemicals database worldwide, on physico-chemical and toxicological properties, uses and classification & labelling

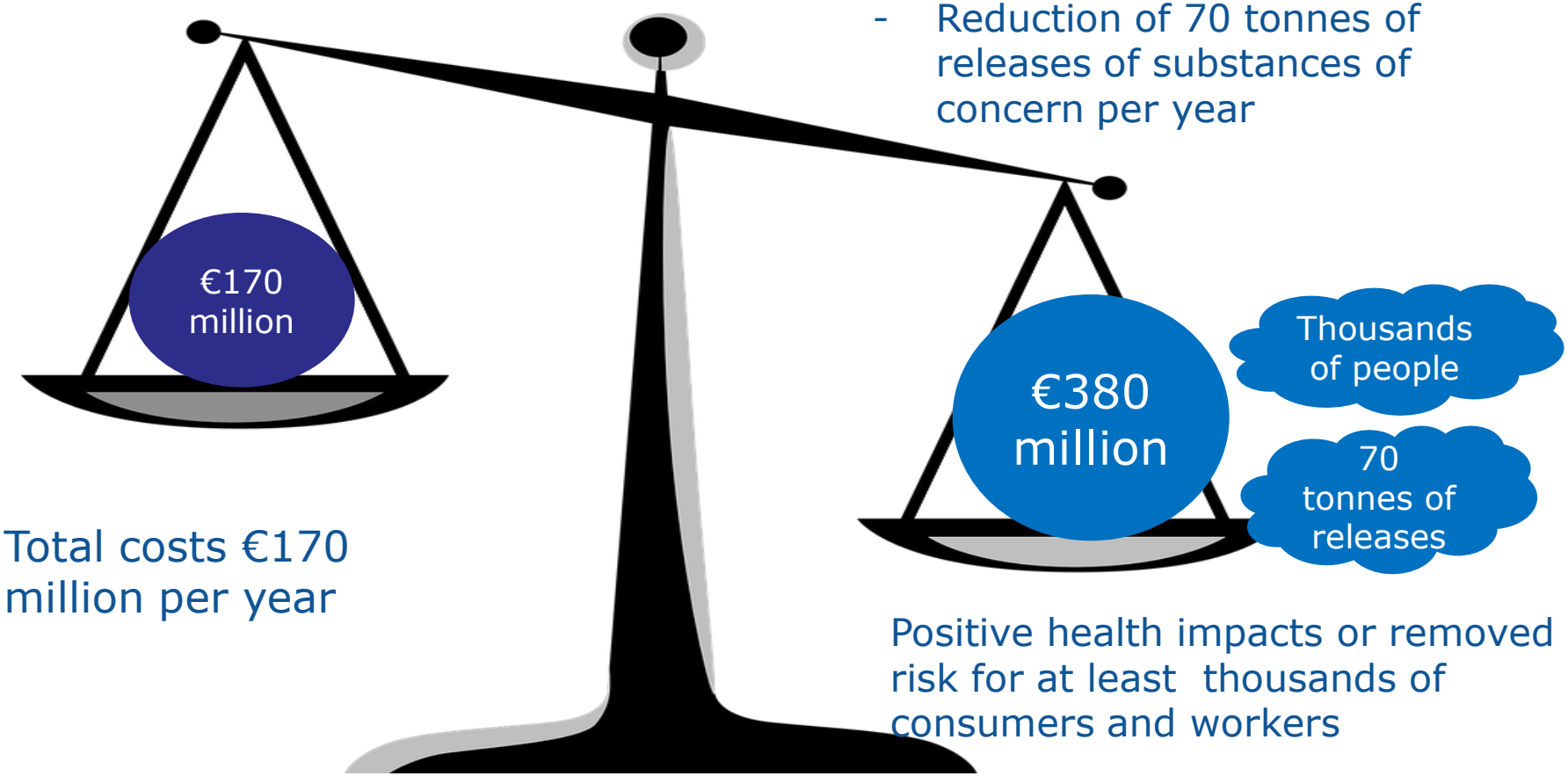


What has REACH achieved so far? (3)

- Improved **information flow** along the supply chain *(via extended safety data sheets)* from manufacturer to downstream user to the (end) consumer
- This leads to better **workers protection** through better safety data sheets and knowledge about exposure and hazard
- REACH authorisation is the driving force for **substitution** of hazardous substances at the workplace

Benefits of restrictions done between 2012 and 2017 includes

- Health impacts equivalent to over **€380 million** per year
- Reduction of 70 tonnes of releases of substances of concern per year



Total costs €170 million per year

Positive health impacts or removed risk for at least thousands of consumers and workers

Risk management under REACH

Authorisation *(… of substances of very high concern - SVHCs)*

- 174 identified SVHC
- **31** SVHC prioritised to be subject to authorisation
- **91** applications for authorisation for **23** substances,
  for *155* uses of these substances
  (*59* uses so far authorised, under strict conditions)

What has REACH achieved so far? (4)

- **Innovation**: In particular **SMEs** develop **safe alternatives** to substances which have to be authorised before use or are restricted in their use *(also non-chemical solutions, such as new process design, product design …)*
- Improved **consumer protection** by restrictions for hazardous substances in textiles, paints and other household products that we use on a daily basis
- Improvements in **waste management**, in particular for the *(up-coming)* **circular economy**: Recycling of plastics without toxic flame retardants and heavy metals

…BUT

REACH evaluation 2017- evidence base

- Legal obligation for the Commission to review the functioning of REACH every 5 years (Articles 117 (4) and 138)
- Information sources:

i. Member States reports: June 2015

ii. ECHA reports: June 2016 (functioning of REACH), 2014 and 2017 (alternatives to animal testing)

iii. 16 thematic studies carried out between 2014 and 2017

iv. Stakeholders views

v. Experience gained through concrete cases

REACH evaluation 2017

- Positive feedback of the Regulatory Scrutiny Board of the Commission on the 29 September
- Submission for (interservice) consultation to the other Commission services and adoption
- A Commission communication will also be delivered in parallel with the Staff Working Document of the REACH evaluation => Q1 2018

The time aspect: Too slow

Harmonised classification and labelling (CLH)
Approximately 3 years*

Identification of Substances of Very High Concern (SVHC)
6 months**

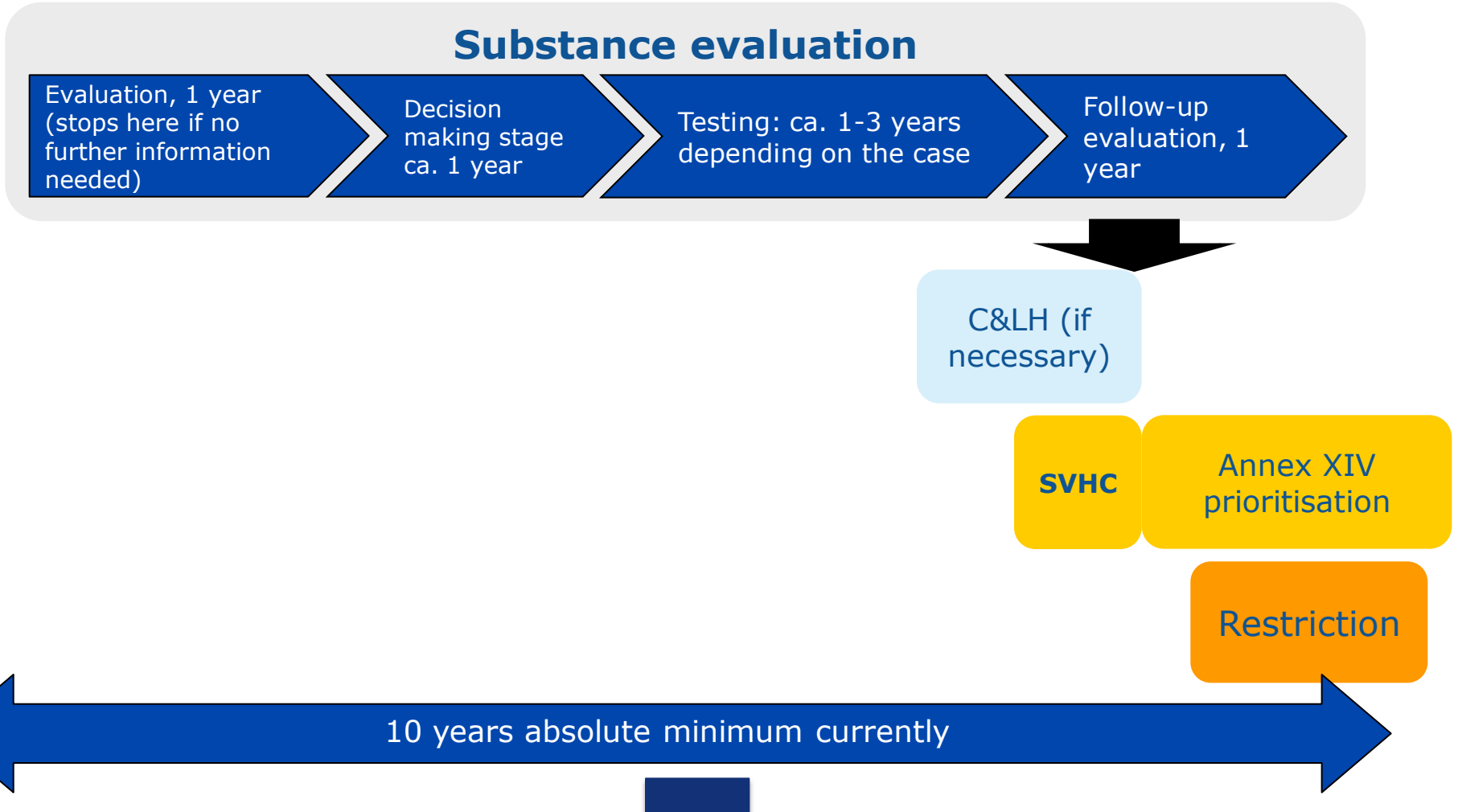
Recommendation and addition to Annex XIV: 3 years
Application for authorisation: 2 years
Decision for (no) authorisation: 2 years
***

Restriction
Approximately 3 years*

The minimum process time in ECHA and the EU Commission decision process : **to be added :**

- **the transitional period for entry into force**.
- **the preparation of the dossiers for these processes.**

Already very long, but if on top we need substance evaluation……



Some possible outcomes of REACH evaluation

- Registration: update of registration dossier Compliance, post-SIEF, registration of polymers, information requirements for low tonnage substance, 2018 is not the end
- Evaluation: Too slow, proposal from some to MS to mandate EU agencies to contract testing directly
- Restriction: strengthen public consultation, simplify the restriction dossiers, more MS to be involved, scope of 68(2), 69(2), use of precautionary principle
- Authorisation: further simplifications,
- SVHCs identification: more C&LH proposals
- Interaction with other legislations: *e.g.*: OSH
- Enforcements: huge difference between MS

REACH evaluation 2017: COSTS

- Half the registrations are for substances produced outside the EU.
- Registration costs: €2.3 to €2.6 billion Euros over the 10 years so far.
- Cost estimates for the registration of new substances
  - **USA: € 6,500**
  - **Korea : € 50,000**
  - **EU: € 86,000**
  - **Canada : € 116,000**
  - **Japan € 120,000**
  - **China € 125,000**

- Total cost for dossier evaluation €200 million (additional data mainly gaps in original dossier)
- Between: 2007-2016, ECHA's budget : EUR 757 million and the fees collected by ECHA amounted to EUR 581 million
- Total costs of restrictions € 170 million per year.
- Cost for authorisation: study just finalised
- REACH appears to have strengthened the internal market but there is no clear (positive or negative) net impact on competitiveness and innovation as those depend on other more important factors that influence the market.

REACH evaluation 2017: BENEFITS

- Benefits of REACH will still take time to materialise but
  - benefits for human health over a 30-year estimated as € 50 billion
  - avoided environment damage over a 25-year as € 50 billion
  - The 10 years update of REACH Baseline Study: decline of the risks caused by chemicals & improvement of the quality of substance-specific data available for risk assessment
  - Another study: registration requirements for low tonnage substances provide about € 10 benefits for every € 1 of cost
  - Restrictions: health and environmental benefits > €380 million per year and a reduction of about 70 tonnes of releases of substances of concern

Results of the study on the impacts of authorisation

Industrial stakeholders advocacy activities:

- Authorisation requirement is only a burden (cost, administration, regulatory uncertainty)
- There is no added value and it will lead to delocalisation of industries outside of the EU
- Substances are used only in industrial sites, closed system, exposure and emissions reduced to the minimum already
- There are no alternatives for the current uses, they are critical uses
- Substitution already happened in the past, because of
  - CMR classification
  - OSH legislation

Key findings of the study

Stakeholder survey: 57% of respondents (n = 46) reported major impacts in the market after SVHC identification

- **Reduction in availability of supply for their use**
- **Increase in SVHC price**
- **Conditions being imposed on safe handling and use**
- **Increase in R&D on alternatives but this diverts funds for new investment and new market opportunities**
- **Trigger for substitution where technically feasible**

Alternatives: no clear indications of changes in the market

Key findings of the study

Substitution

43% of respondents to the online industry survey said they had substituted a use of a SVHC

Survey respondents (n=83) identified:

- **Over 60 examples of substitution of SVHCs**
- **Over 70 examples of investment in substitution related activities**

In some cases, substitution had very high costs

- **Applying for authorisation would have been less expensive, at least in the short term**
- **Importance of regulatory uncertainty (especially for investment plans and long term contracts with customers)**
- **Stigma of using a SVHC**

Key findings of the study

When is substitution happening?

- **30%: at Candidate Listing**
- **23%: at the recommendation**
- **25%: at the inclusion in Annex XIV**

Drivers for substitution

- **REACH authorisation: 59%**
- **REACH, but not specifically authorisation: 18%**

Conclusions

- Our initial question "Is authorisation only a burden with no added value?" can now be answered:

=> no, we see that it achieves its objectives in terms of substitution and improvements in the way SVHCs are used

- Are the benefits higher than the costs?

=> It is not possible to answer from the results of the study.

Classification and labelling Inventory

- The **C&L Inventory** is the central database containing classification and labelling information about notified substances available on the EU market
- Harmonised classification (more than 4500 substances or group of substances) **and** industry notifications *(self classifications)*

- Based on 6 million notifications for today **130 761** substances, growing every day

BUT NO harmonisation in self-classification: need to act but how!

Chemicals Fitness Check - Policy Context

REFIT Programme

- **Fitness check on chemicals legislation** *(excluding REACH)*
- **REACH REFIT Evaluation**
- **Cumulative benefit & cost assessments**

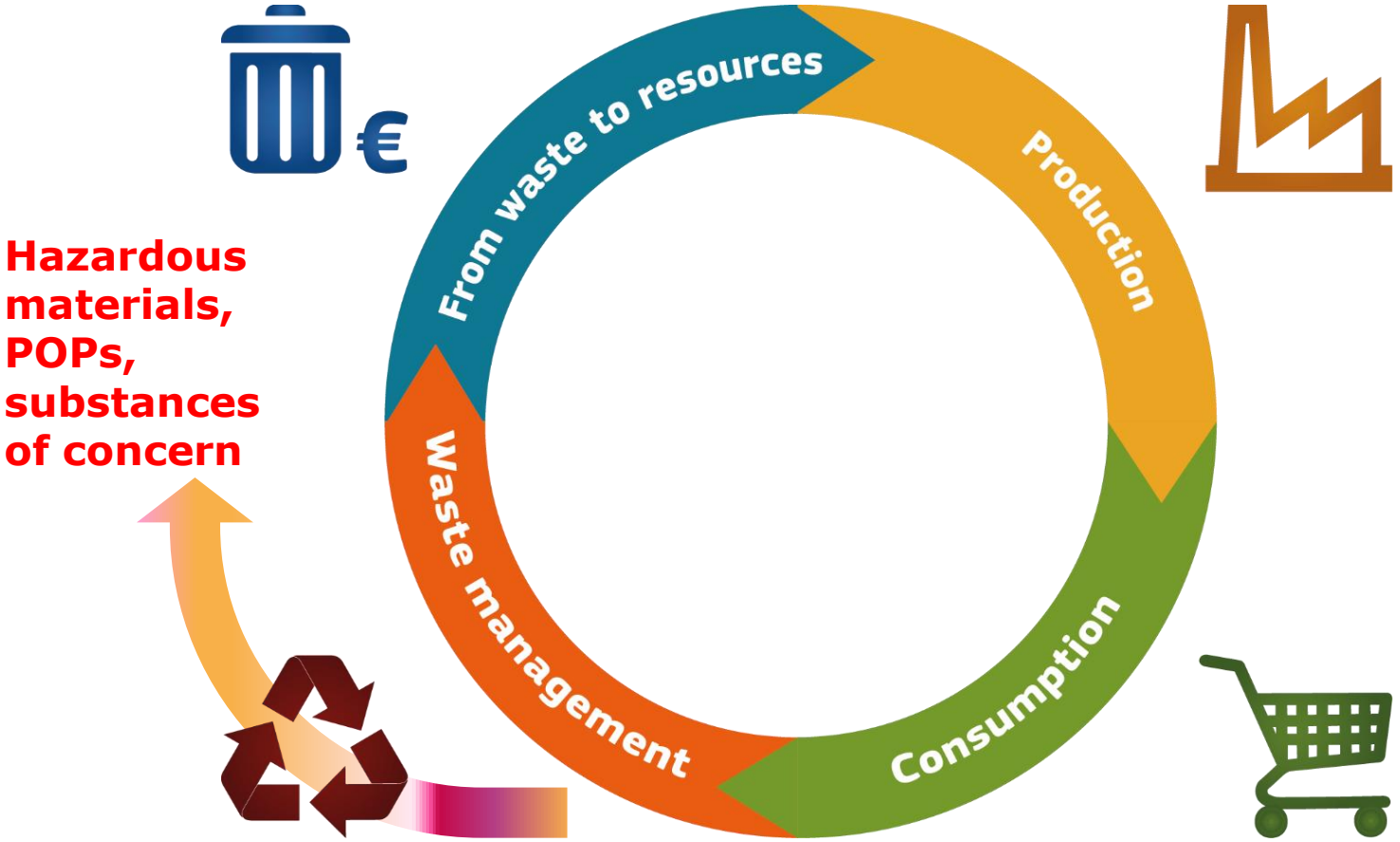
Circular economy

- **Plastics strategy**
- **Chemicals-product-waste interface**

7th EAP

- **Non-toxic environment strategy** *(roadmap pending)*

REACH and the circular economy



Chemicals and waste

Governed by the following principles

- **REACH does not apply to waste**
- **Classification of waste as hazardous is largely based on rules set in the CLP Regulation**
- **REACH could set limits to the use of certain substances if they meet the end of waste (EoW) criteria**

REACH and waste

- **Waste is not subject to registration, evaluation, authorisation or restrictions**
- **Those REACH procedures apply only to materials (substances/mixtures) that have ceased to be waste**
- **Articles containing recycled material/substances/mixtures do fall under the scope of REACH (registration, authorisation, restrictions)**
- **Interface between REACH and waste legislation containing restrictions on the use of certain substances (in particular RoHS and ELVs directives)**

REACH's contribution to recycling

- **Materials that cease to be waste must be registered: unless benefiting from the exemption in Art 2(7)(d) of REACH**
- **Information on exposure to substances at the waste stage must be given as part of REACH registration**
- **Substances in materials that cease to be waste may need to apply for authorisation**
- **Substances may be subject to EU restriction which prohibit the use of those substances in both virgin materials and materials that cease to be waste.**

→ **Objective: Level playing field between primary and secondary raw materials**

Chemicals and circular economy

Chemicals priorities for a circular economy

- **Promotion of non-toxic material cycles**
- **Tracking of substances of concern in products.**

Objectives

- **To facilitate good quality recycling in the Union**
- **To improve the uptake of secondary raw materials**
- **To address the presence of substances of concern**
- **To limit unnecessary burden for recyclers**
- **To facilitate traceability and risk management of chemicals.**

Chemical, product, waste interface

Commitment in the Circular Economy Action Plan

→ **to analyse the interface and develop policy options**

The options that will be developed, based on the analysis:

- **May result in specific legislative actions;**
- **May also inform other relevant actions announced in the Circular Economy Action Plan, including the development of quality standards for secondary raw materials and the strategy on plastics in the circular economy;**
- **Will feed into the future EU strategy for a non-toxic environment.**

Issues identified by the Commission

- **Insufficient information about substances of concern in products and waste**
- **Dealing with the presence of substances of concern in recycled materials**
- **Uncertainties about how materials can cease to be waste**
- **Difficulties in the application of EU waste classification methodologies and impacts on the recyclability of materials**

Next steps

- **Roadmap published on 27/01/17**
- **Targeted Stakeholder Consultation until 07/07/17**
- **Policy Options to be developed by the Commission in 2017: Communication to bee published**
- **Future legislative actions evaluated through an impact assessment in 2018**
- **REACH REFIT evaluation and fitness check on chemicals legislation will provide further elements to be considered**
- **Non-toxic environment strategy**

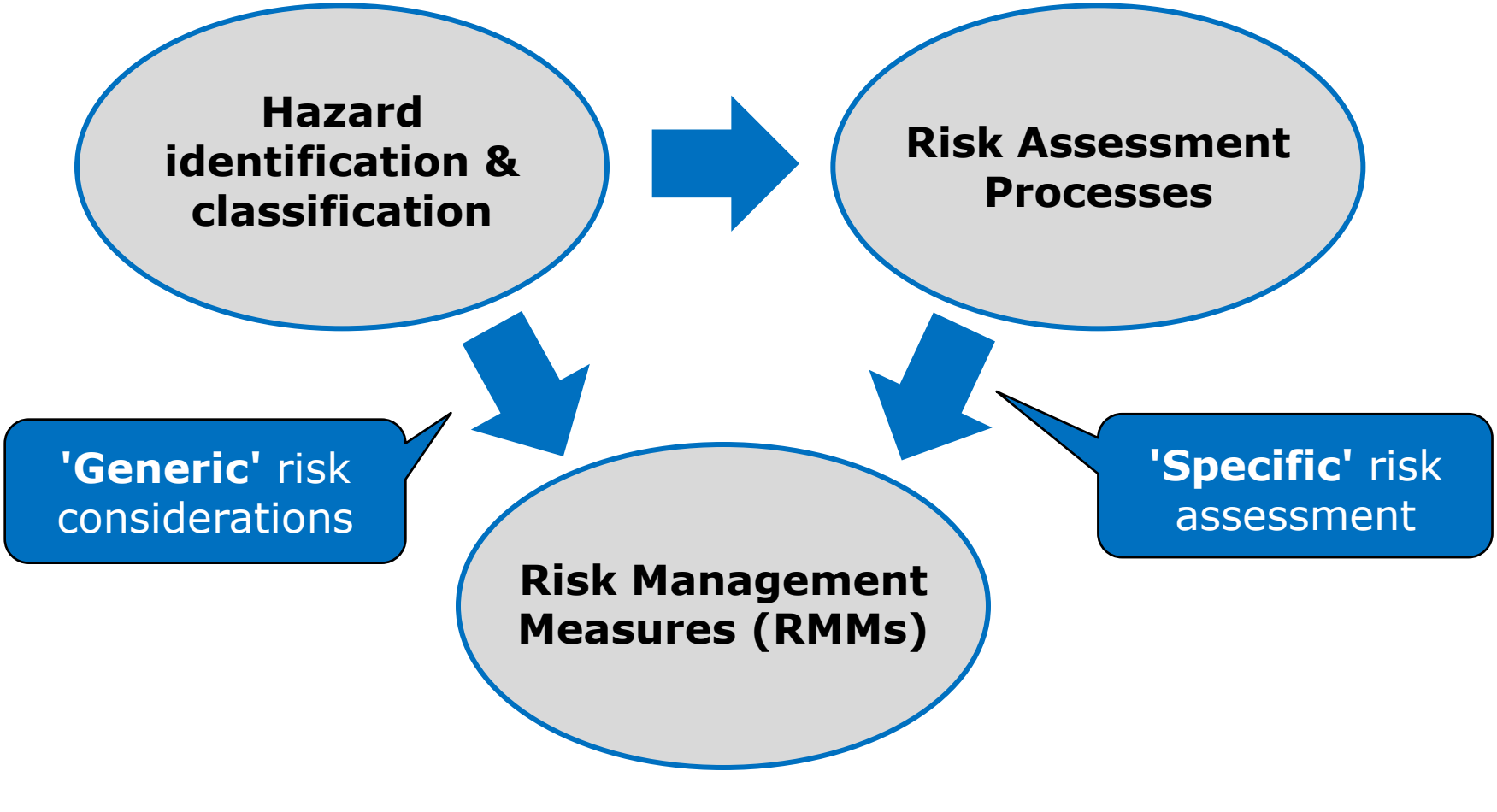
Background

REFIT Communication of 2013:

Fitness Check on the most relevant **chemicals legislation** (other than REACH) as well as related aspects of legislation applied to downstream industries

- Covering > 40 pieces of chemicals and chemicals-related legislation (excluding REACH) with three general objectives: health/environment, single market, competitiveness/innovation
- Roadmap published in May 2016
- Focus on the risk management process of chemicals
- Improve delivery, remove red tape and lower costs
- – Staff Working document, Communication (TBD), spring/summer 2018

Risk management approaches



Risk management approaches

Based on specific risk assessment

- Assessing both the hazards and the potential specific exposure scenarios of humans and the environment to the substance or mixture in question at the same time

Based on generic risk considerations

- Automatically triggered based on the outcome of a hazard identification / classification
- Possible exposure scenarios considered generically at the level of the legislation in question
- Used in EU legislation in particular for hazard classes of greatest concern and a high likelihood of exposure

DG Environment study on the non-toxic environment strategy of the 7th EAP

Finalised in August 2017, published at:

http://ec.europa.eu/environment/chemicals/non-toxic/index_en.htm

- **Main report (overall aspects and conclusions)**

Seven sub-studies

a. Substitution, including **grouping of chemicals** and measures to support substitution

b. Chemicals in products and **non-toxic material cycles**

c. The improved **protection of children and vulnerable groups** from harmful exposure to chemicals

d. Sub-strategy for **very persistent chemicals**

e. Policy Means, **Innovation** and Competitiveness

f. A **Green Chemicals** Program

g. The creation of a joint **early warning system for approaching chemical threats** to health and the environment

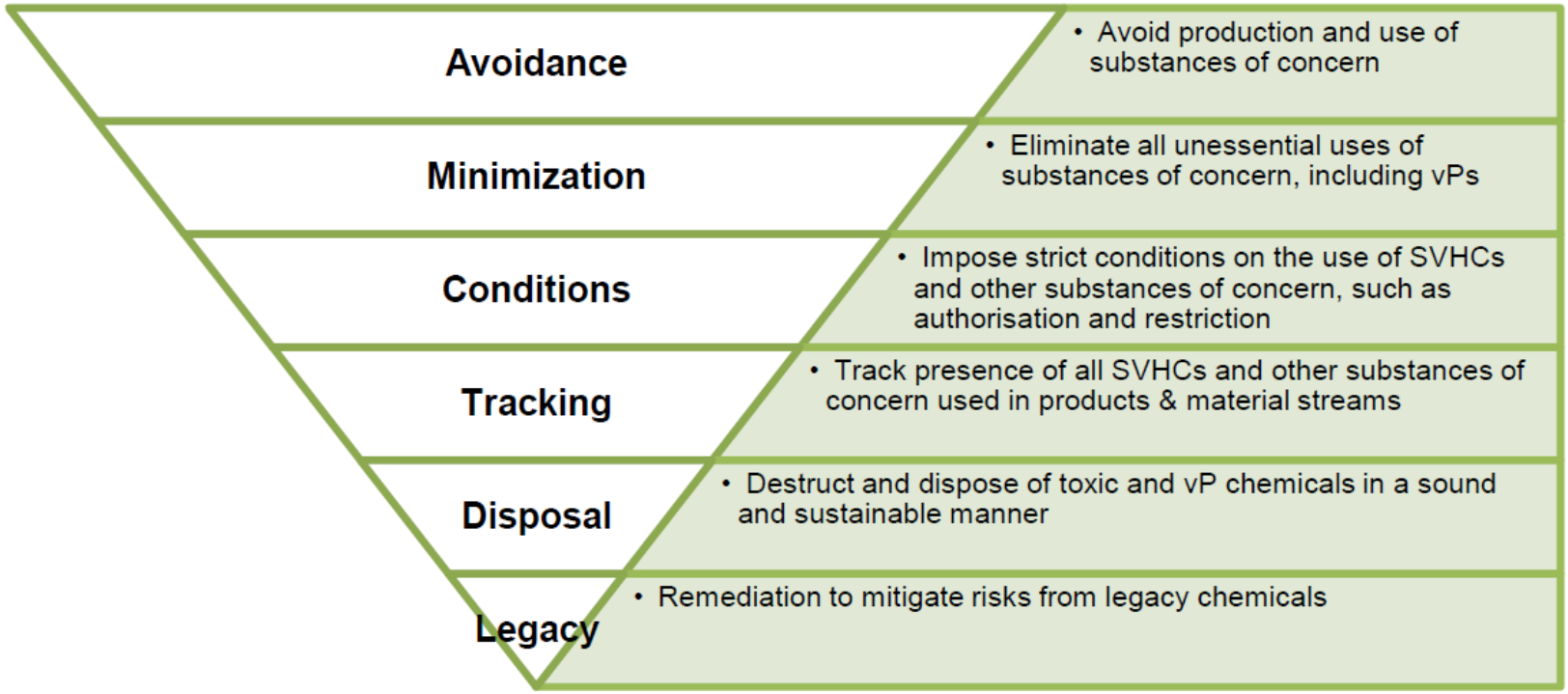
The non-toxic environment study: findings overall gaps/weaknesses in current policy

- Current chemicals **legal framework has delivered** – a lot of **work remains**…
- **Slow progress** in **SVHC identification** and in **substitution**
- **Lack of knowledge/information/attention** on **chemicals in articles, in material flows (circular economy)**
- **Insufficient protection** of **children** and **vulnerable groups**
- **Insufficient means** to address **persistent chemicals**
- **Lack of monitoring** of **chemicals in environment/human** body, e.g. drinking water
- Better incentives to **develop new non/less toxic chemicals** and non-chemical solutions
- Need for more focused compilation of data – an **EU early warning system**

The non-toxic environment study: Some themes in the way forward

1. Long term development of **chemicals knowledge bases** (properties, uses, presence, exposure)
2. Develop **EU early warning system** for chemical threats
3. Move **from chemical-by-chemical to grouping** approaches
4. Promote **innovation of non/low toxic chemicals** and **non-chemical solutions**
5. Promote a **non-toxic circular economy**: chemicals and materials better adapted to recyclability
6. **Support substitution**: provide knowledge, tools and platforms
7. Address **very persistent chemicals** (rules, tests, knowledge)
8. Establish a **use hierarchy for hazardous chemicals** (avoidance, minimisation, control, disposal/destruction)
9. Establish **system(s) for tacking** of **chemicals in products**
10. Approach/framework for **protection of children and vulnerable groups**

Suggested chemicals use hierarchy



Thank you

for your attention

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