

# Introduction to authorisation and how can ECHA support substitution

Sustainable substitution of SVHCs:  
how to move forward?

Brussels, 24 November 2017

Denis Mottet  
Scientific officer  
Risk Management Implementation Unit  
European Chemicals Agency

# Outline

- Overview of the authorisation process
- To prepare or not to prepare an application
- Support
- Strategy to support innovation to safer chemicals through innovation
- Take home messages

# Overview of the authorisation process

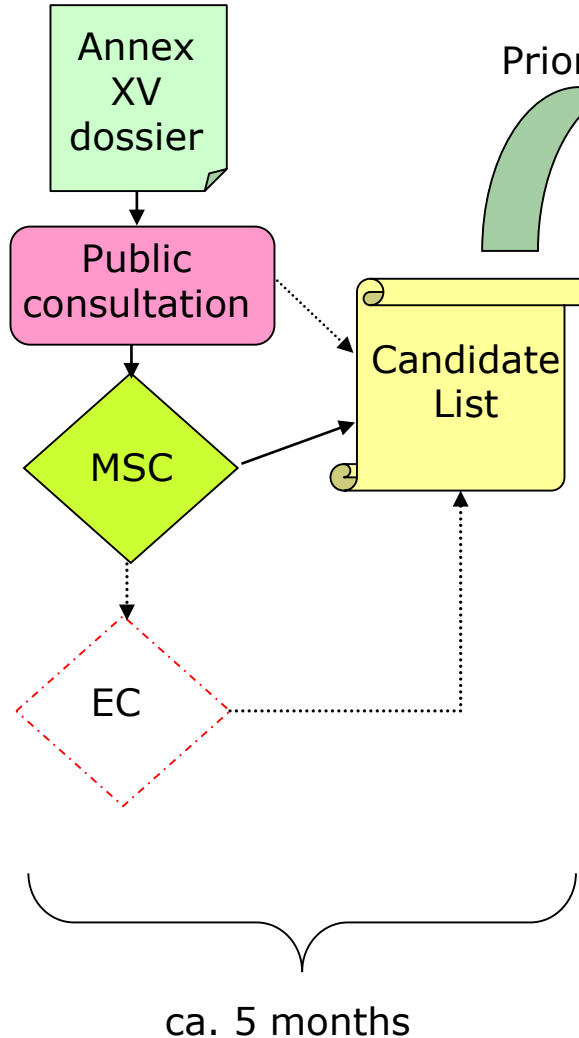


# Authorisation

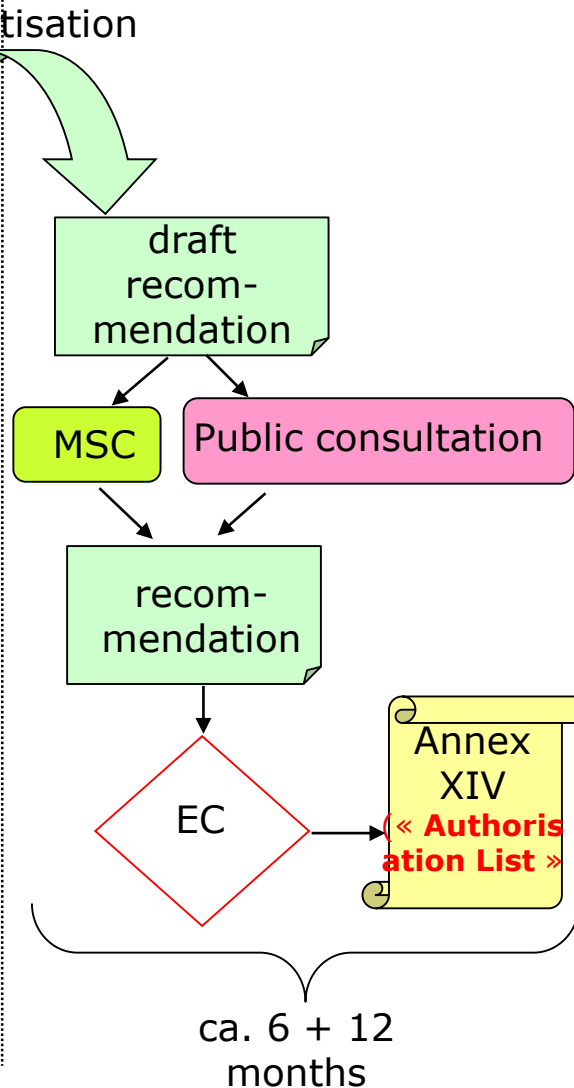
Aim is to ensure that:

- the risks from substances of very high concern are properly controlled and
- that these substances are progressively substituted by alternative substances or technologies
- where these are economically and technically viable whilst
- ensuring the good functioning of the internal market

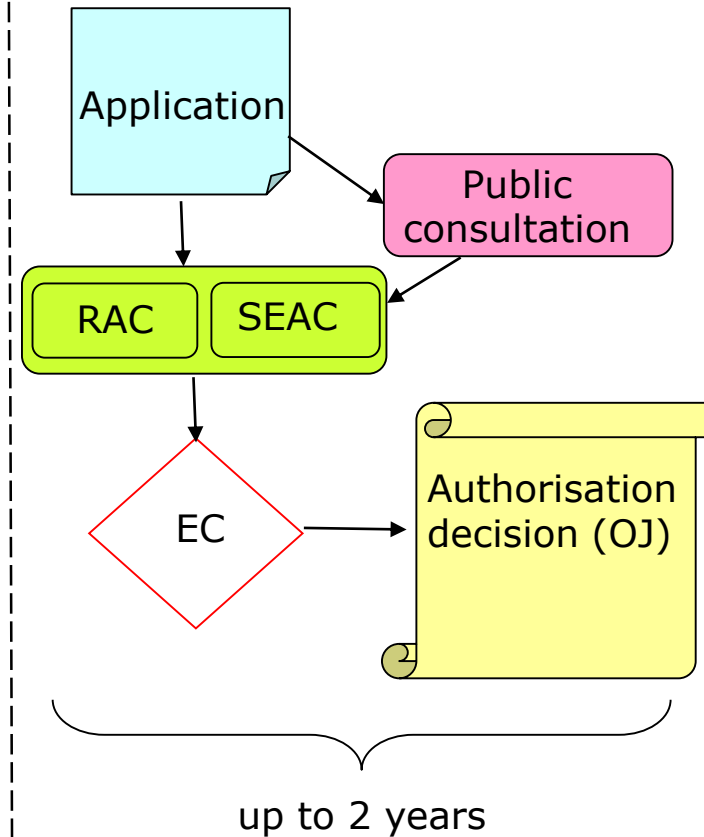
## Step 1.1: Identifying SVHCs



## Step 1.2: Subjecting priority substances to authorisation



## Step 2: Granting (or not) authorisation

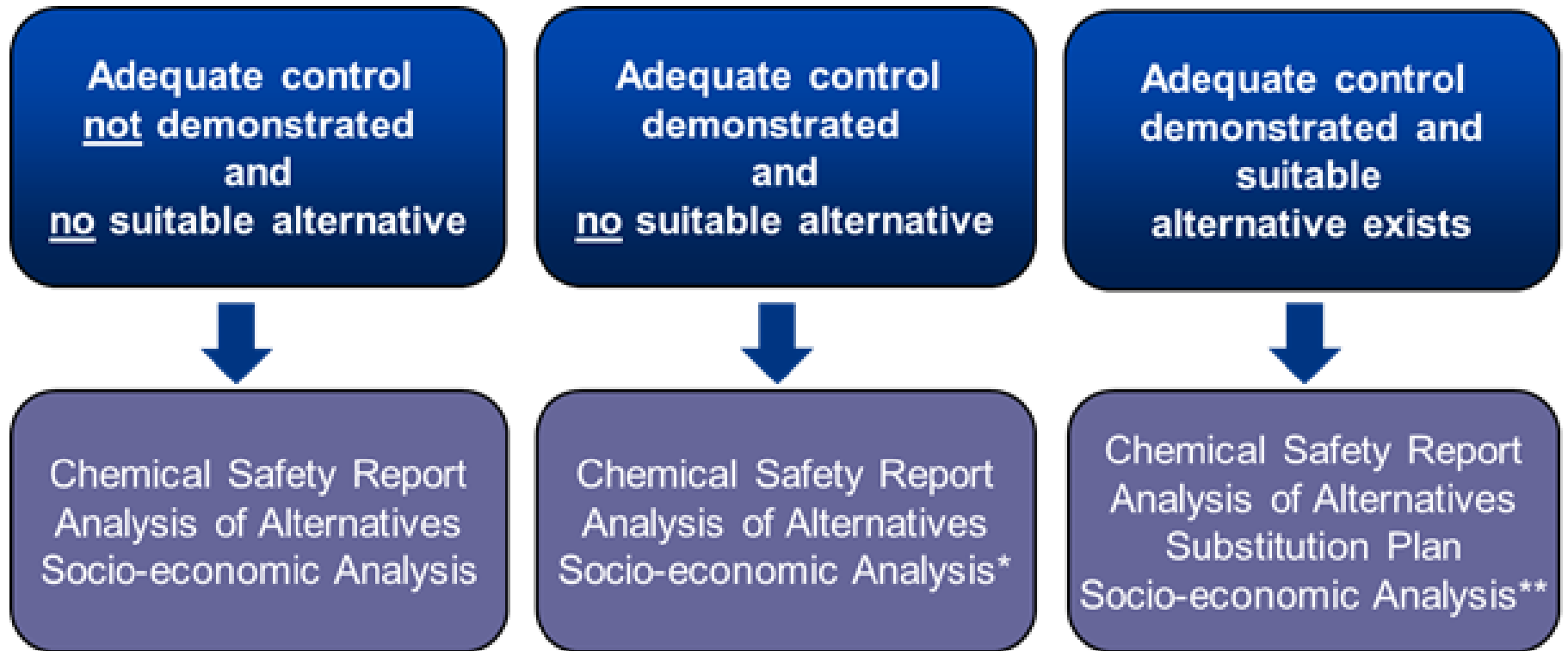


# Authorisation and substitution

- Candidate List of substances of very high concern (SVHC): strong signal for substitution and legal obligations
- Authorisation list (Annex XIV): second signal
- Allows companies to apply for an authorisation for a continued (or new) use of an SVHC
- AfA\*: requires analysis of alternatives
- Public consultation on alternatives + 'dialogue'
- Subject to time-limited review → pressure to substitute

# Content of an application

Risk, alternatives , (socio-economic) components



\* highly recommended

\*\* recommended



REGULATIONS

REACH

CLP

BPR

PIC

PUBLIC CONSULTATIONS

INFORMATION ON CHEMICALS

SUPPORT

ECHA > Information on Chemicals > Candidate List

## Candidate List of substances of very high concern for Authorisation

(published in accordance with Article 59(10) of the REACH Regulation)

**Notes:**

- **Authentic version:** Only the Candidate List published on this website is deemed authentic. Companies may have immediate legal obligations following the inclusion of a substance in the Candidate List on this website including in particular Articles 7, 31 and 33 of the REACH Regulation.
- **Other numerical identifiers:** For those entries with "-" in the EC number and CAS number columns, a non-exhaustive inventory of EC and/or CAS Registry numbers describing substances or groups of substances considered to fall within the scope of the Candidate List entry is included, where practicably possible. This information can be accessed through the "Details" button of the selected entry.

**FURTHER INFORMATION**

- [More information about Candidate list of Substances of Very High Concern for Authorisation](#)
- [Data on Candidate List substances in articles](#)

> [Filter the list](#)

# CL: currently 174 entries

Name	EC no.	CAS no.	Date of inclusion	Intrinsic property(ies) referred to in Article 57	Decision	IUCLID dataset	
<b>Perfluorohexane-1-sulphonic acid and its salts</b> PFHxS	-	-	07/07/2017	vPvB (Article 57 e)	ED/30/2017		
<b>4,4'-isopropylidenediphenol</b> Bisphenol A; BPA	201-245-8	80-05-7	12/01/2017	<ul style="list-style-type: none"> <li>Toxic for reproduction (Article 57 c)</li> <li>Endocrine disrupting properties (Article 57 (f) - human health)</li> </ul>	<ul style="list-style-type: none"> <li>ED/30/2017</li> <li>ED/01/2017</li> </ul>		
<b>4-heptylphenol, branched and linear</b> substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof	-	-	12/01/2017	Endocrine disrupting properties (Article 57 (f) - environment)	ED/01/2017		





REGULATIONS

[REACH](#)

[CLP](#)

[BPR](#)

[PIC](#)

[PUBLIC CONSULTATIONS](#)

[INFORMATION ON CHEMICALS](#)

[SUPPORT](#)

[ECHA](#) > [Information on Chemicals](#) > [Authorisation List](#)

## Authorisation List

List of substances included in Annex XIV of REACH ("Authorisation List").

**Important notice:** transitional measures apply to companies established in Croatia for application for authorisation. For more details see the related "Q&A for Croatian companies pre-registering and registering under REACH" and more specifically the referred PDF document under point "7. What kind of transitional measures are regarding Applications for Authorisation?".

> [Notes to the Authorisation List](#)

### Further information


















- [Recommendation for inclusion in Annex XIV of REACH \("Authorisation List"\)](#)
- [Authorisation process under REACH](#)
- [Applications for Authorisation under REACH](#)
- [Q&A on Authorisation](#)

Last updated 16 June 2017. Database contains 43 unique substances/entries.

> [Filter the list](#)

# Authorisation List: currently 43 entries

Showing 43 results.

Name 	EC no. 	CAS no. 	Entry no. 	Latest application date 	Sunset Date 	
<a href="#">4,4'- Diaminodiphenylmethane (MDA)</a>	202-974-4	101-77-9	02	21/02/2013	21/08/2014	
<a href="#">5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)</a>	201-329-4	81-15-2	01	21/02/2013	21/08/2014	
<a href="#">Benzyl butyl phthalate (BBP)</a>	201-622-7	85-68-7	05	21/08/2013	21/02/2015	
<a href="#">Bis(2-ethylhexyl) phthalate (DEHP)</a>	204-211-0	117-81-7	04	21/08/2013	21/02/2015	
<a href="#">Dibutyl phthalate (DBP)</a>	201-557-4	84-74-2	06	21/08/2013	21/02/2015	
<a href="#">Diisobutyl phthalate (DIBP)</a>	201-553-2	84-69-5	07	21/08/2013	21/02/2015	
<a href="#">Diarsenic pentaoxide</a>	215-116-9	1303-28-2	09	21/11/2013	21/05/2015	
<a href="#">Diarsenic trioxide</a>	215-481-4	1327-53-3	08	21/11/2013	21/05/2015	
<a href="#">Lead chromate</a>	231-846-0	7758-97-6	10	21/11/2013	21/05/2015	
<a href="#">Lead chromate molybdate sulfate red</a>	235-759-9	12656-85-8	12	21/11/2013	21/05/2015	

**To prepare or not to prepare  
an application**



## What are your options?

- Switch substances
- Adapt technologies or processes, develop new ones
- Use additional inputs
- Switch products
- Import products
- Change product specification
- Stop producing, using

## What would the impacts be?

- Technical performance
- Product performance
- Efficiency, resource requirements
- Quality, aesthetics
- Costs, revenues, profits
- Commercial performance, investment, employment
- Competitive position
- Environmental & health risks

**Core business issues:** commercial, technical, strategic, not just about health safety and environmental compliance

# Analysing options and impacts tells you whether you need to apply for authorisation

Analysing:

- the remaining risk of continuing using the substance
- the availability of suitable alternatives
- the related socio-economic aspects of using and not using the substance
- the broader picture (market trends, competitors' behaviour, customers demand, internal CSR policy, etc.)

*Will guide you whether you need to apply for an authorisation or not*

**Support**



## ECHA offers extensive support

- Guidance documents, Q&As, instructions and user manuals, available at: <http://echa.europa.eu/applying-for-authorisation>
- 'How to apply for authorisation' guide published in December 2017: [https://echa.europa.eu/documents/10162/13637/apply\\_for\\_authorisation\\_en.pdf](https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf)
- Publishes information on how RAC and SEAC treat applications (e.g. length of review period, economic feasibility, confidentiality), as well as RAC's Reference DNELs/dose-response relationships: <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>
- Partners' service for applicants: <https://echa.europa.eu/applying-for-authorisation/partners-service-for-applicants>
- Pre-submission information sessions considered very useful
- Specific help to small and medium sized companies: <http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes>
- Authorisation landing page: <https://echa.europa.eu/regulations/reach/authorisation/applications-for-authorisation>

# Strategy to support innovation to safer chemicals through innovation



## Why a strategy?

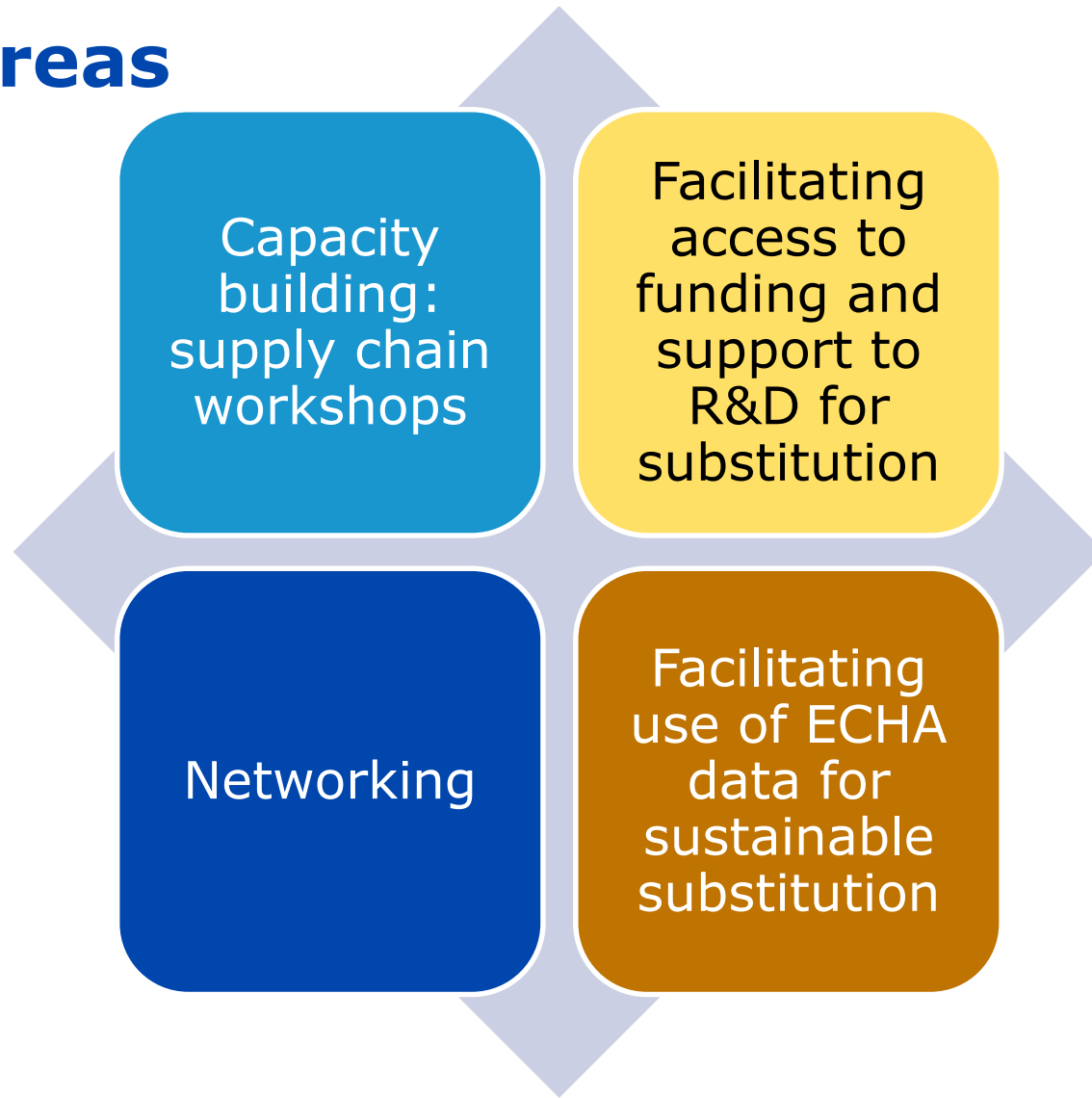
- Aim: to accelerate substitution by supporting and complementing the regulatory stimulus
- Linked with current EU priorities of
  - circular economy,
  - sustainable manufacture and use of chemicals and
  - ECHA's strategic plan for 2019-23
- substitution of SVHCs also one of the aims of REACH authorisation
- Mind-set change: **substitution is part of innovation!**
- Building block for reaching the UN 2020 and 2030 Sustainable Development Goals



# Approach

- Promote best practices and change of mind-set
- Collaboration with all stakeholders is crucial
- Stepwise approach - Four action areas

## Action areas



## Capacity building through supply chain workshops

- Share a specific substitution challenge between substance users and suppliers, providers of alternatives, end-users, retailers, R&D and financial support, etc.
- Learn from others
- Get new ideas
- Identify gaps and training needs

✓ **ECHA as a catalyst**

➔ **MSCAs/IND suggested to take the lead**



# Facilitating access to funding and support to R&D for substitution



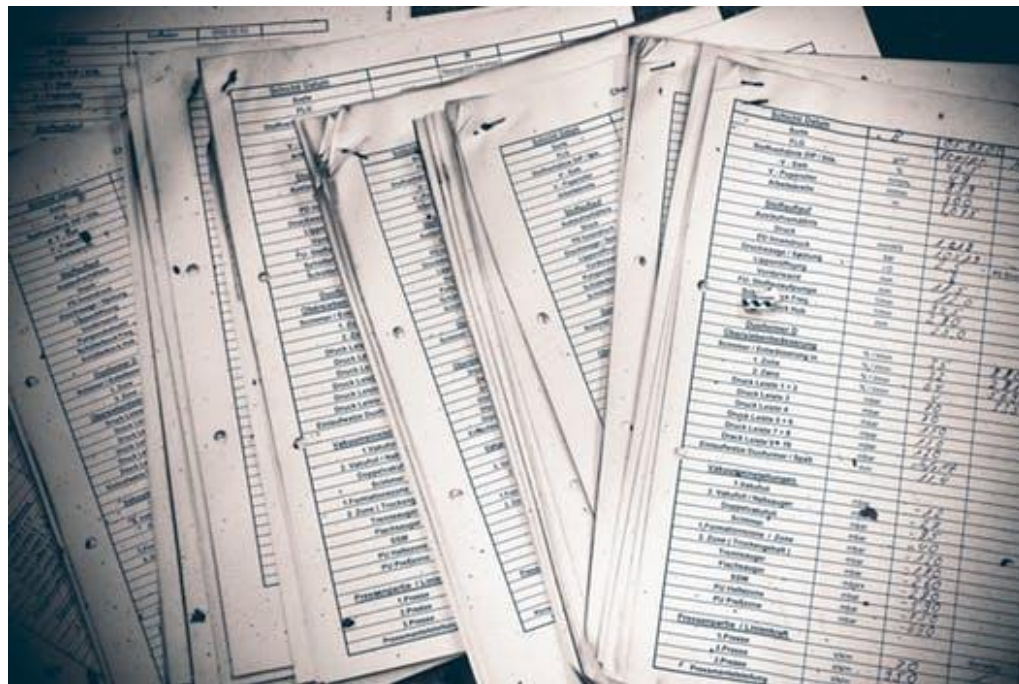
- Fostering technical and financial support
- Easier access
- At EU and national levels

✓ **ECHA's role limited**

# Facilitating use of ECHA data for sustainable substitution

- Make use of ECHA's data (e.g. hazard) for substitution
- Avoid regrettable substitution

✓ **ECHA's role central**





# Networking for analysis of alternatives and substitution



- For what purpose?
    - Share experience
    - Enhance collaboration
  - Multi-stakeholders networks
- ✓ **ECHA's role:  
facilitator/coordinator**

Learning by doing

Finding ways to substitute through better analysis of alternatives

Cannot and should not do substitution work alone

Capacity building:  
supply chain workshops

Networking

Facilitating access to funding and support to R&D for substitution

Facilitating use of ECHA data for sustainable substitution

Discuss with financiers to "open windows"

Use ECHA's data to avoid regrettable substitution

ECHA defining its role...

What  
are  
you  
doing

...to support substitution?



**Willing to organise  
or be part of a  
substance/function  
and sector-specific  
workshop?**



**Talk to your industry  
association and  
Member State  
Competent Authority -  
ECHA can support**



# Examples of substitution supply chain workshops

- Finnish chrome platers workshop – Finland  
January 2017
  - [https://echa.europa.eu/documents/10162/13630/finnish\\_crv\\_i\\_workshop\\_en.pdf/e55d3063-00c2-c69c-004c-48d584257110](https://echa.europa.eu/documents/10162/13630/finnish_crv_i_workshop_en.pdf/e55d3063-00c2-c69c-004c-48d584257110)
- Flame retardants in textile – Belgium 16 January 2018 – info: [substitution@echa.europa.eu](mailto:substitution@echa.europa.eu)
- Antifouling paints in recreational boats – The Netherlands Q4 2018 (to be confirmed)

**You are providing  
support relevant for  
substitution-related  
issues? (finance,  
R&D, technical...)**



**tell ECHA via**  
[substitution@echa.europa.eu](mailto:substitution@echa.europa.eu)  
**Networking, list of support**

## More info

- Latest version of the draft strategy is available here:  
<https://webgate.ec.europa.eu/echa-scircabc/w/browse/7abe525c-0533-4c08-9bb1-b50d935943cb>
- If you are interested in being kept informed about the development of the strategy and its implementation send an email to:  
[substitution@echa.europa.eu](mailto:substitution@echa.europa.eu)

# Support page on substitution

REGULATIONS

REACH

CLP

BPR

PIC

PUBLIC CONSULTATIONS

INFORMATION ON CHEMICALS

SUPPORT

ECHA > Substituting hazardous chemicals

## Substituting hazardous chemicals

Companies are replacing hazardous chemicals with safer chemicals or techniques. This kind of substitution can bring substantial benefits for the company itself, the environment and the health of workers and consumers.

Why should I substitute?



Do I have to substitute?



How do I do it?



Examples from real life



▪ Video: "Painting a safer Europe"



▪ Webinar: Why opt for substitution?



▪ Webinar: Replacing harmful chemicals in the textiles sector



▪ ECHA newsletter on substitution



▪ Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives [PDF]

<https://echa.europa.eu/regulations/substituting-hazardous-chemicals>

# Take home messages



## Take home messages

- Several regulatory actions provide incentives for substitution
- Authorisation is one of them
- Pay attention to early warnings and be proactive
- ECHA wants to support further substitution and developed a strategy to do it
- Substitution cannot be achieved alone – involvement of stakeholders is key: contribute as well!

**Thank You!**

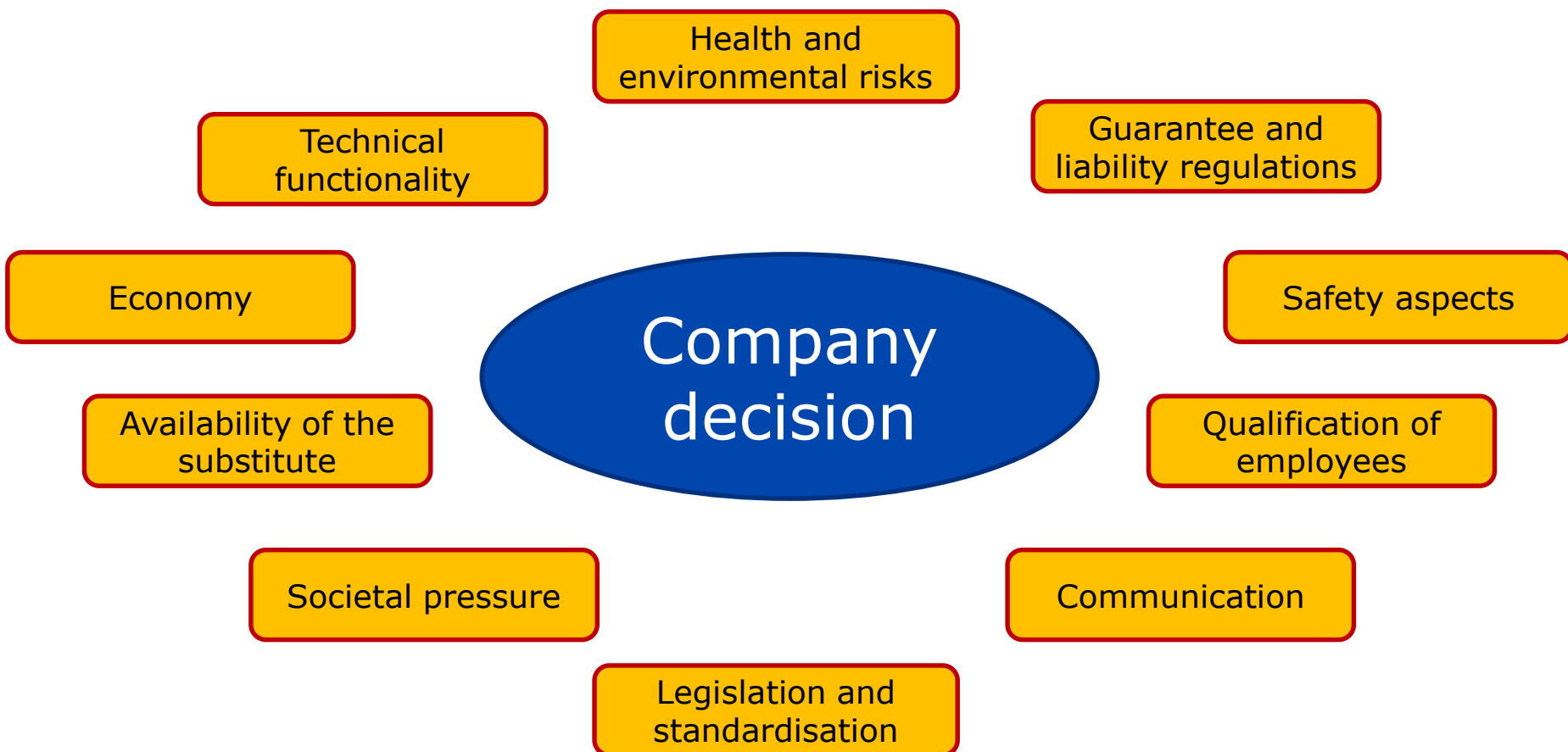
[denis.mottet@echa.europa.eu](mailto:denis.mottet@echa.europa.eu)



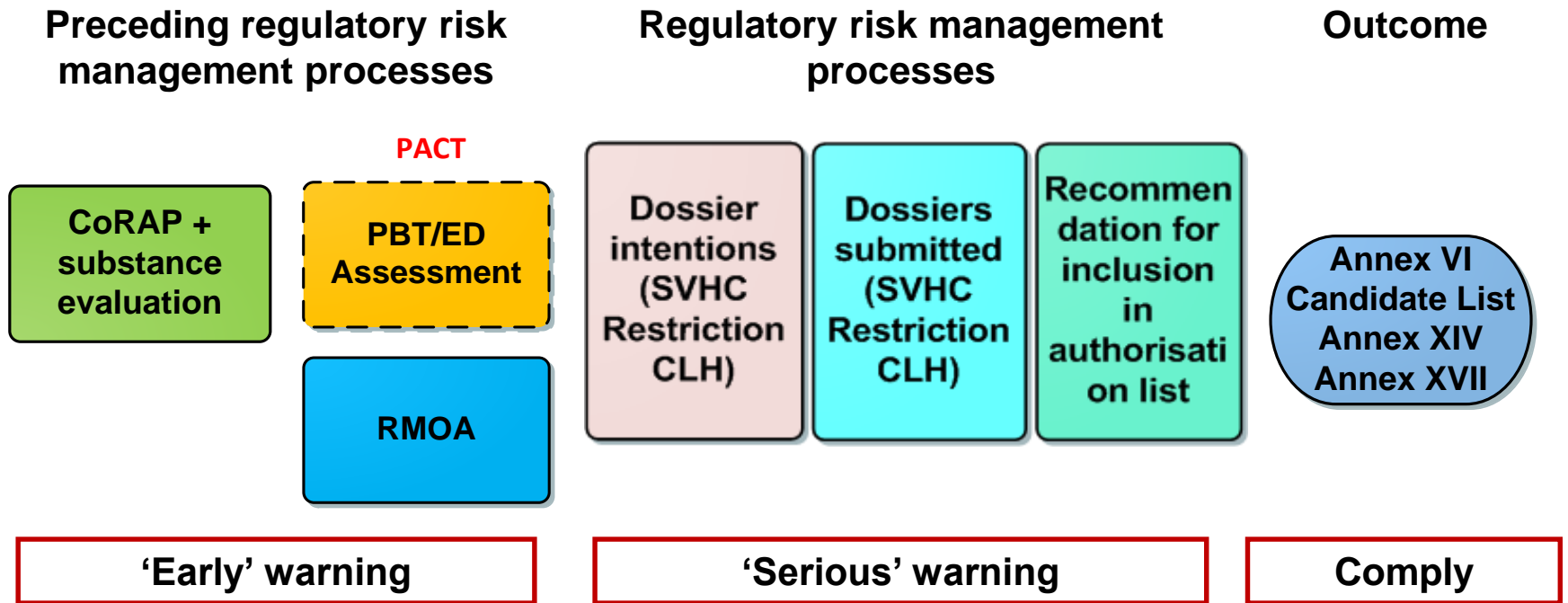
# Complementary slides



# What affects substitution?



# Early warnings - Regulatory Risk Management activities encourage substitution



EU (European Commission with Member States and the Parliament) approves **Annexes**  
ECHA publishes the **Candidate List** 35

## Classification, authorisation & restriction promote using safer chemicals

### Classification to category 1A or 1B

- Consumers cannot use as such or in mixtures
- Industry takes action

### Restriction

- Cannot use...
- Alternatives analysed
  - risks
  - technical and economic feasibility

### Authorisation

- Cannot use unless applied
- Alternatives analysed
  - risks
  - technical and economic feasibility

## Aim of Authorisation

Article 55 of REACH:

Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the **good functioning of the internal market** while assuring that the **risks from substances of very high concern are properly controlled** and that these **substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable**. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

# Analysing options and impacts tells you whether you need to apply for authorisation

1. Environmental and health risks are greater than the costs of alternative options  
*⇒ You have found that authorisation is unlikely to be granted and you chose not to apply for an authorisation and to implement the alternative option*
2. You identified viable alternatives  
*⇒ You have found an option which is cheaper and/or better than authorisation (and saved the application costs)*
3. You found that the costs of alternatives exceed the current risks or that suitable alternatives are not available yet  
*⇒ You have a case for authorisation*  
*⇒ And you have done the core analysis you need for your application*

## Case for authorisation, if benefits > risks

### Benefits

- Avoided cost increases and/or reductions in profit
- Avoided reductions in economic performance, employment, investment
- Avoided environmental impacts: eg CO<sub>2</sub>, air pollution from energy use, transport

### Current risks

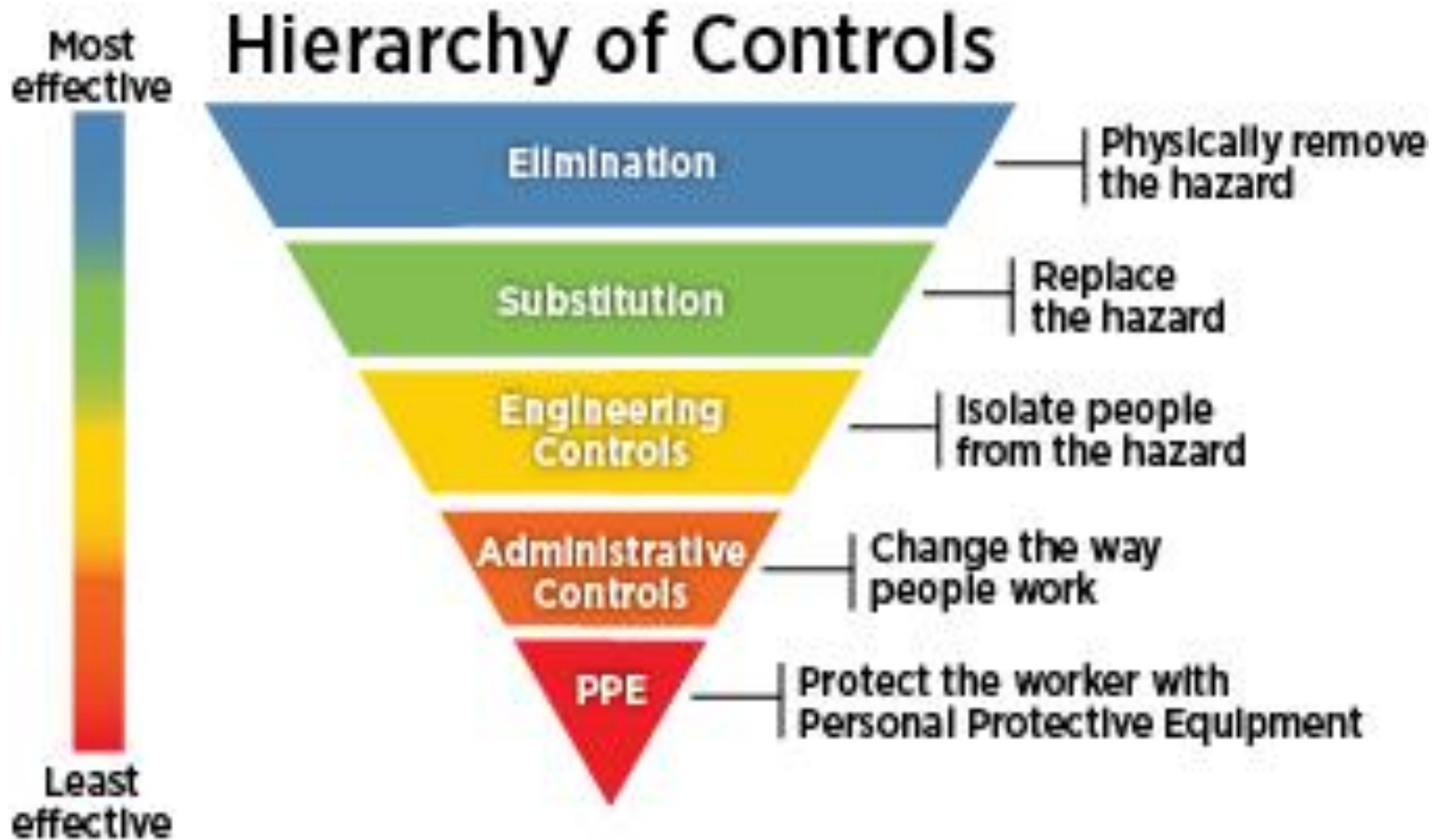
- Environmental and health impacts from using the substance

(Can be zero if risks are adequately controlled)

⇒ Authorisation more likely when costs of the alternatives are higher and/or current risks are more controlled

⇒ **Authorisation more likely when the case is clearer – a stronger case is likely to be a simpler case**

# Always to keep in mind...



Source: NIOSH