

# Why should you apply for an authorisation?

Seminar on Applications for Authorisation

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- To prepare or not to prepare an application
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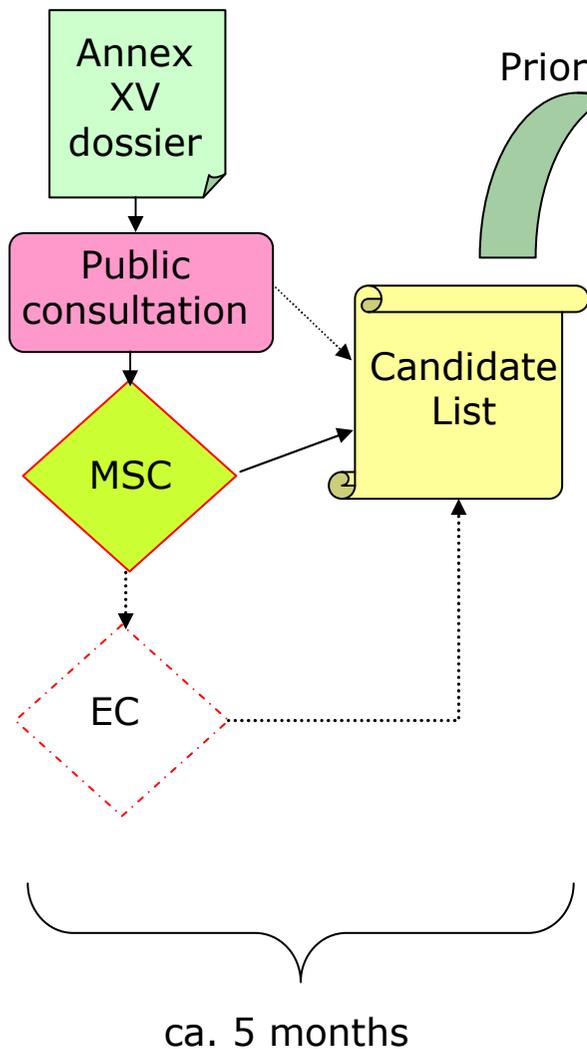
# Overview of the process



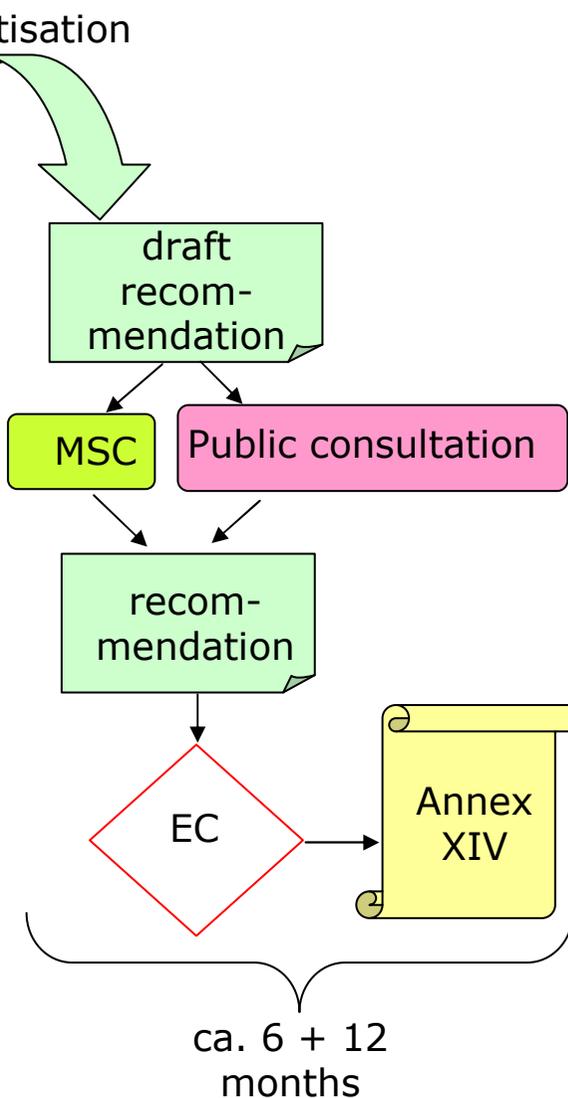
# ECHA Authorisation: Overall procedure

EUROPEAN CHEMICALS AGENCY

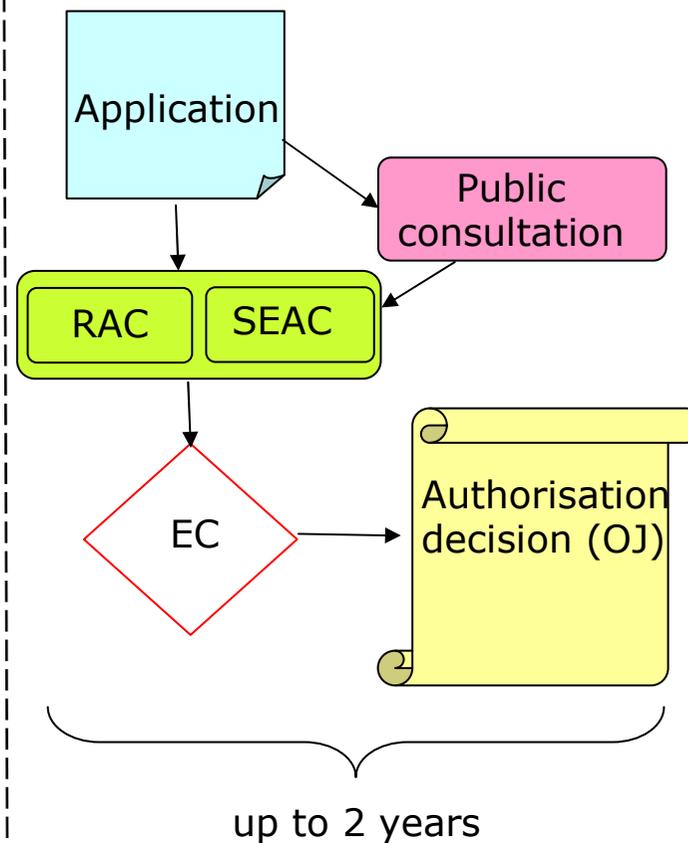
## Step 1.1: Identifying SVHCs



## Step 1.2: Subjecting priority substances to authorisation



## Step 2: Granting (or not) authorisation



## Step 2: Applications for authorisation

- An applicant can be:
  - a manufacturer,
  - an importer,
  - a downstream user,
  - an only representative,
  - any combination of these.
  
- An application for authorisation can be submitted:
  - for one or several uses
  - for one or a «group of» substance(s)

# To prepare or not to prepare an application



## Why should you apply?

### You should apply

- if the use of the substance clearly adds value in the European Union and the risks related to its use are very small...



### You should not apply

- if the use of the substance does not add a lot of value in the European Union and the risks are relatively high...

## The key question to you

- For identifying the impacts of a substance being listed in Annex XIV and being subject to authorisation
- For assessing whether the impacts of authorisation would be bigger or smaller than the benefits
- For deciding whether you should apply for authorisation or not
- If you manufacture the substance, import it, use it in your processes, if it is present in the products you produce, or in products you use

⇒ **What will be the impact on my business if the substance can no longer be used in the EU?**

## 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 environmental or H&S compliance**

## 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**

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

1. You might estimate that existing environmental and health risks are greater than the costs of alternative options
  - ⇒ You have found that authorisation is unlikely to be granted and you have saved the application costs
2. You might identify viable alternatives
  - ⇒ You have found an option which is cheaper and/or better than authorisation (and saved application costs)
3. You might find that the costs of alternatives exceed the current risks
  - ⇒ You have a case for authorisation
  - ⇒ **And you have done the analysis you need for your application**

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## Analysis of alternatives template

- List of possible alternatives
- Description of efforts made to identify possible alternatives
- Research and development
- Data searches
- Consultations
- Alternative 1: Substance ID and properties/Description of technique
  - **Technical feasibility**
  - **Economic feasibility**
  - **Availability**
  - **Reduction in overall risk**

## Socio-economic analysis template

- Definition of “applied for use” scenario
- Definition of “non-use” scenario
- **Human health and environmental impacts**
- **Economic impacts**
- Social impacts
- Wider economic impacts
- Comparison of impacts
- Distributional impacts
- Uncertainty analysis

## Analysing options and impacts tells you whether you have a case for authorisation

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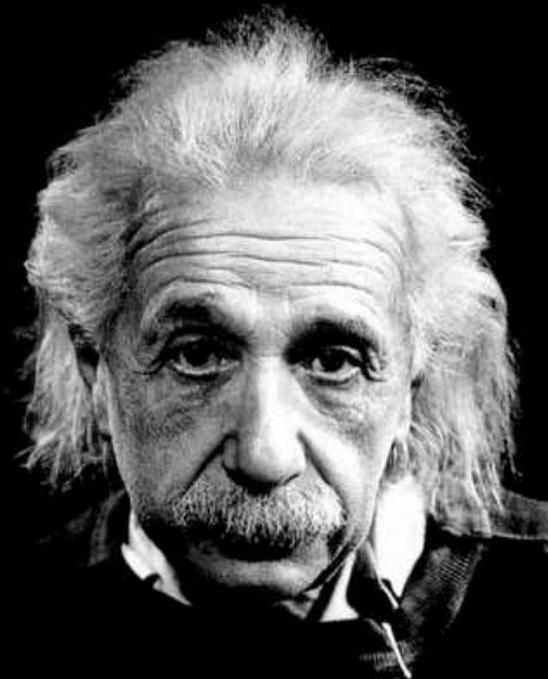
⇒ **And you have the analysis you need for your application**

⇒ **And if you have done your analysis right, RAC and SEAC should agree with your assessment**

“Everything should be made as simple as possible, but not simpler.”

Albert Einstein

BUT, it's not quit as simple as that...



## There is a world outside your business

- A substance might be critical to your business, but is it also critical for your suppliers, customers, competitors?
  - You might not identify any viable alternatives, but third parties might (through public consultation)
  - You might control risks to your environment and health, but the substance might also generate risks to your downstream users and customers
- ⇒ **You need to look wider than your immediate (commercial, technical, environmental) context**
- ⇒ But it might help your case as well (e.g. higher costs for downstream users)

## Other factors affecting the application decision

- Compiling an application might still require significant staff and other resources
- The application fee is not insignificant and only guarantees an opinion, not authorisation
- Authorisation is temporary – application costs have to be incurred again and again, and justifying the authorisation might get harder over time
- Competitor, supplier and market trends – if everyone else is substituting, will you get left behind?

# Take home messages



## Key messages

- You should apply if the use of the substance clearly adds value and the remaining risks are small
- The first question is not *how* you apply for authorisation; it is *what will happen to my business if the Annex XIV substance can no longer be used in the EU?*
- Authorisation concerns your 'core business': Own it! Do not leave it to your environment department or consultants
- Think outside your business to find the right scope for your assessment: commercially, economically and environmentally
- A strong case for authorisation probably means an easier application; the more marginal the case becomes, the more resources, time, analysis etc the application will need

- Start to prepare early enough
- Involve your supply chain (up and down)
- Get familiarised with:
  - Guidance Documents (content / procedure)
  - submission tools and user manuals
  - formats (and in particular IUCLID) and templates on ECHA's website
- Be « use-oriented »
- Notify ECHA, and request for a « *pre-submission information session* » (6-7 months before), if needed
- Ask ECHA for technical advice (eg. through Helpdesk), make suggestions, too.

**Thank You!**

