Why should you apply for an authorisation?

Seminar on Applications for Authorisation

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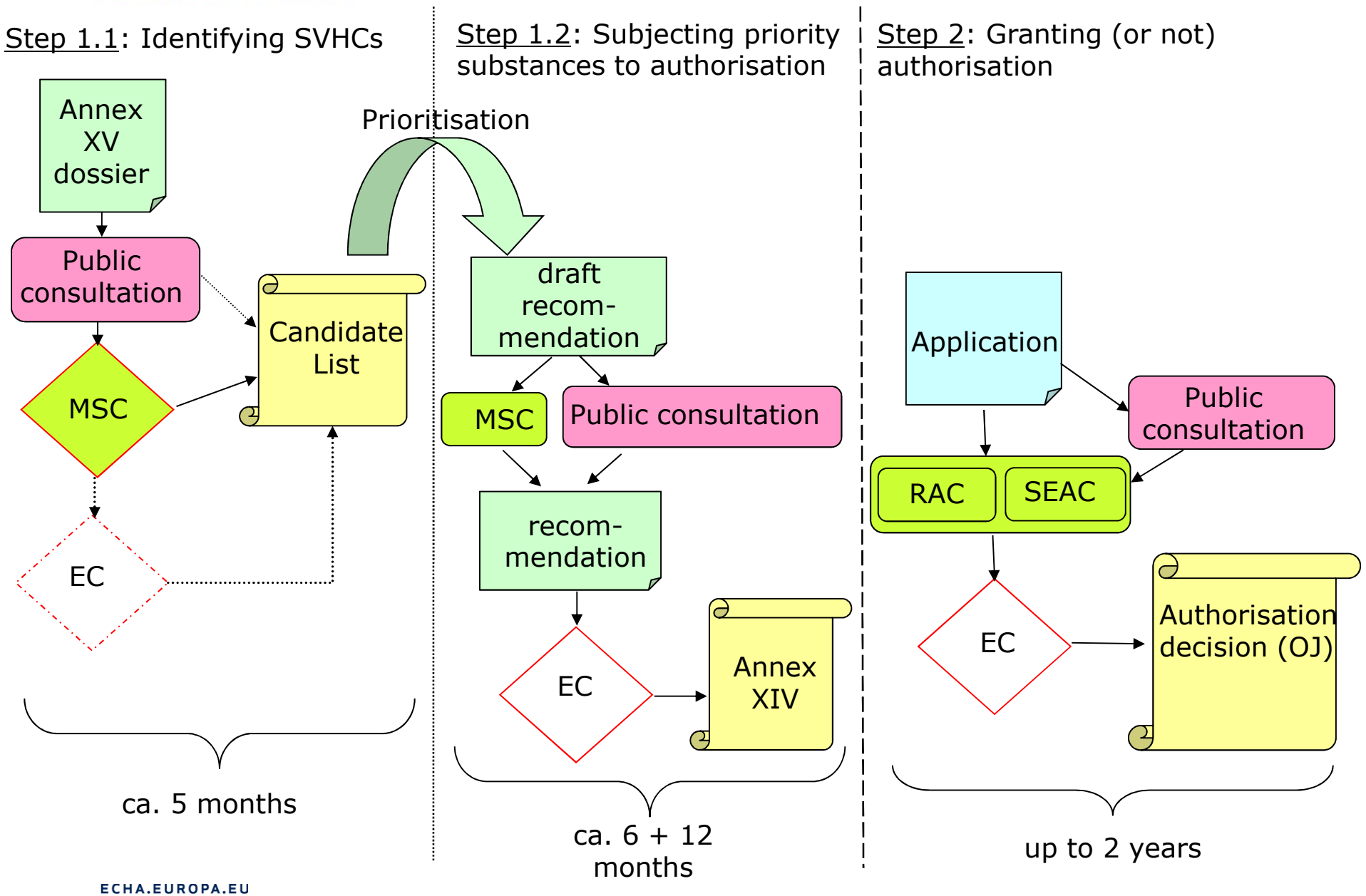
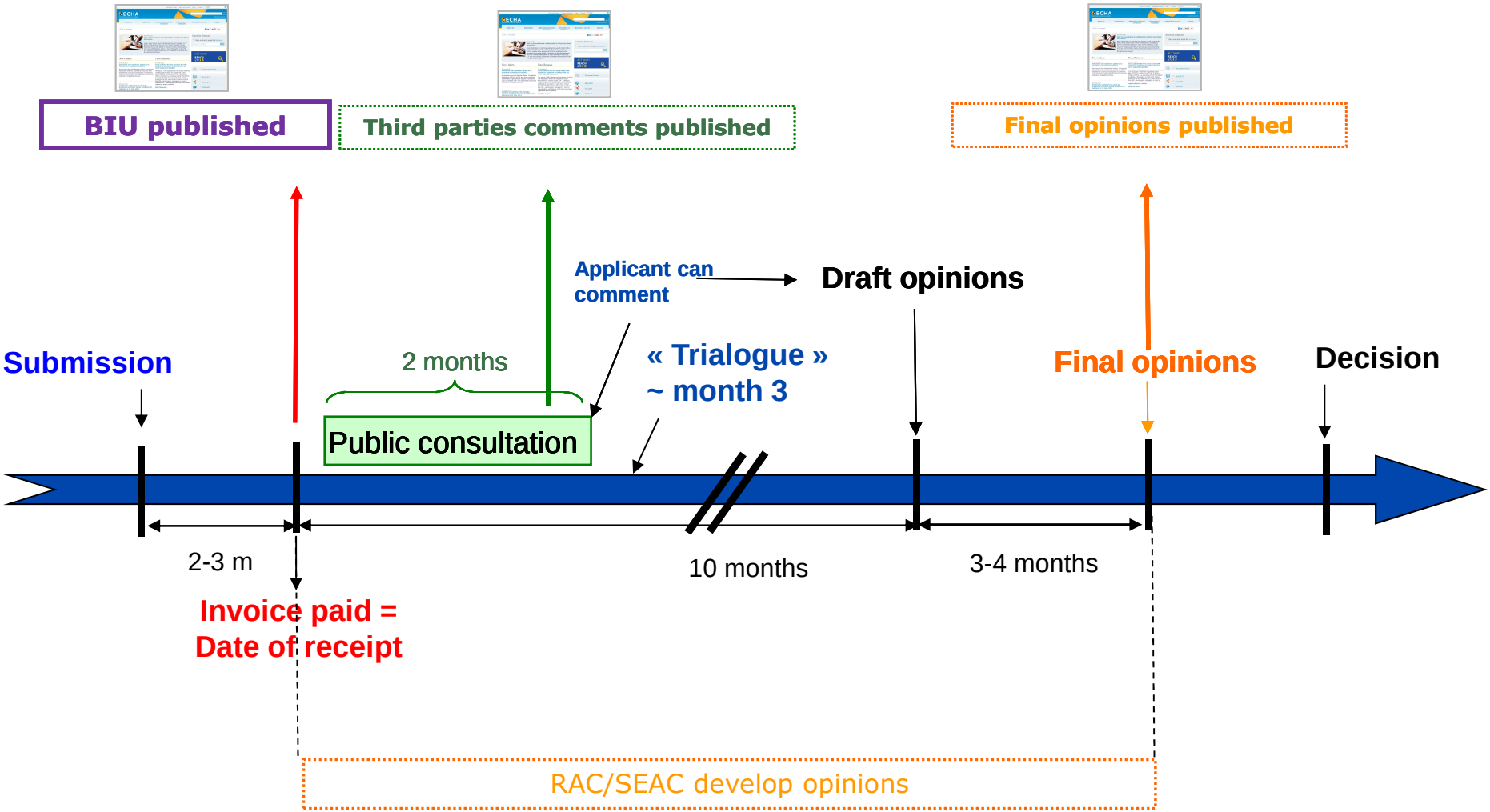
- Overview of process
- To prepare or not to prepare an application
- Take home messages

Overview of the process

Autorisation: Overall procedure



Overview of publication of information in the AfA process



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_2, 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**

Click Here To Apply!

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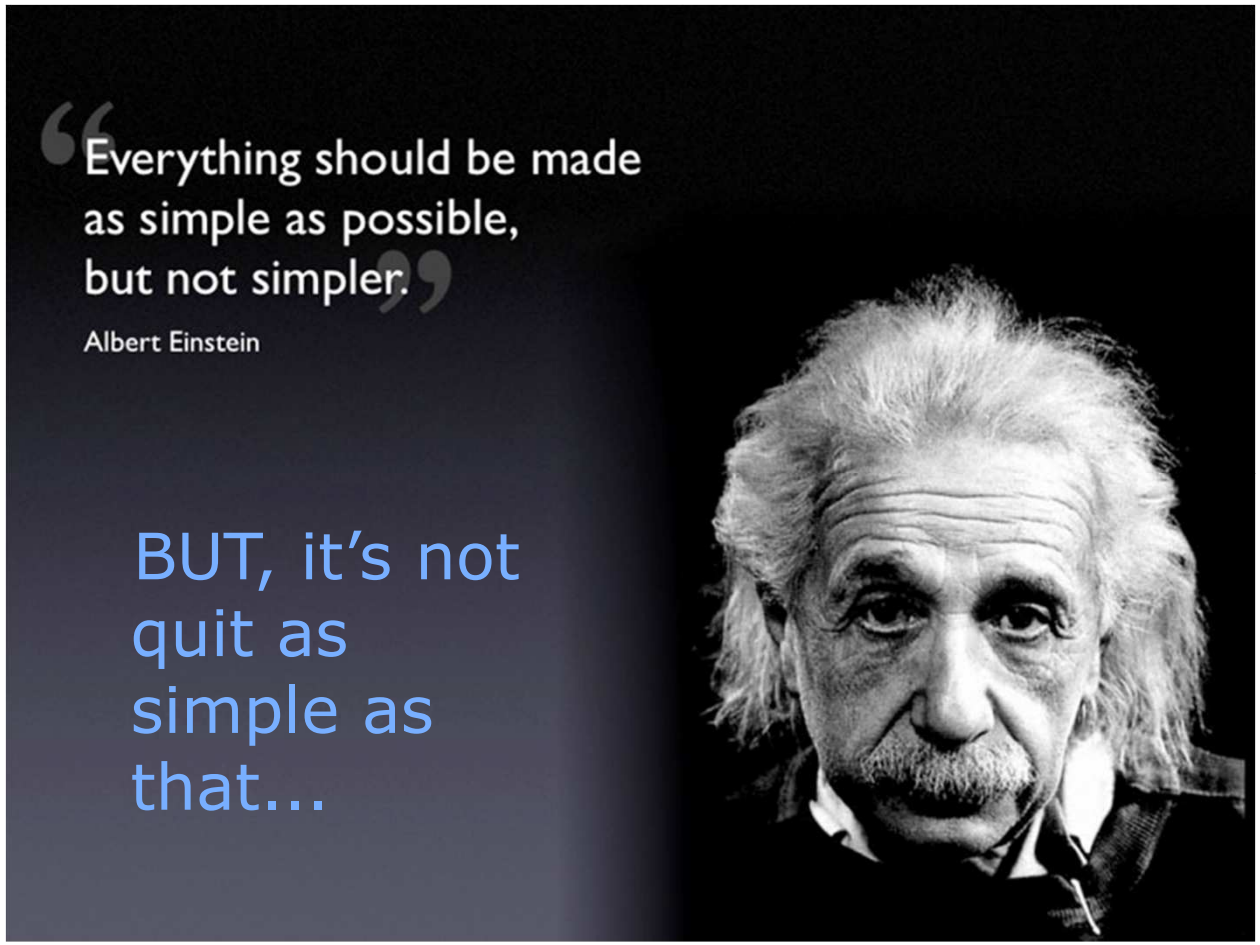
⇒ **And you have the analysis you need for your application**

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



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

Advice

- 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.

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Thank You!