Authorisation
Practical considerations for companies
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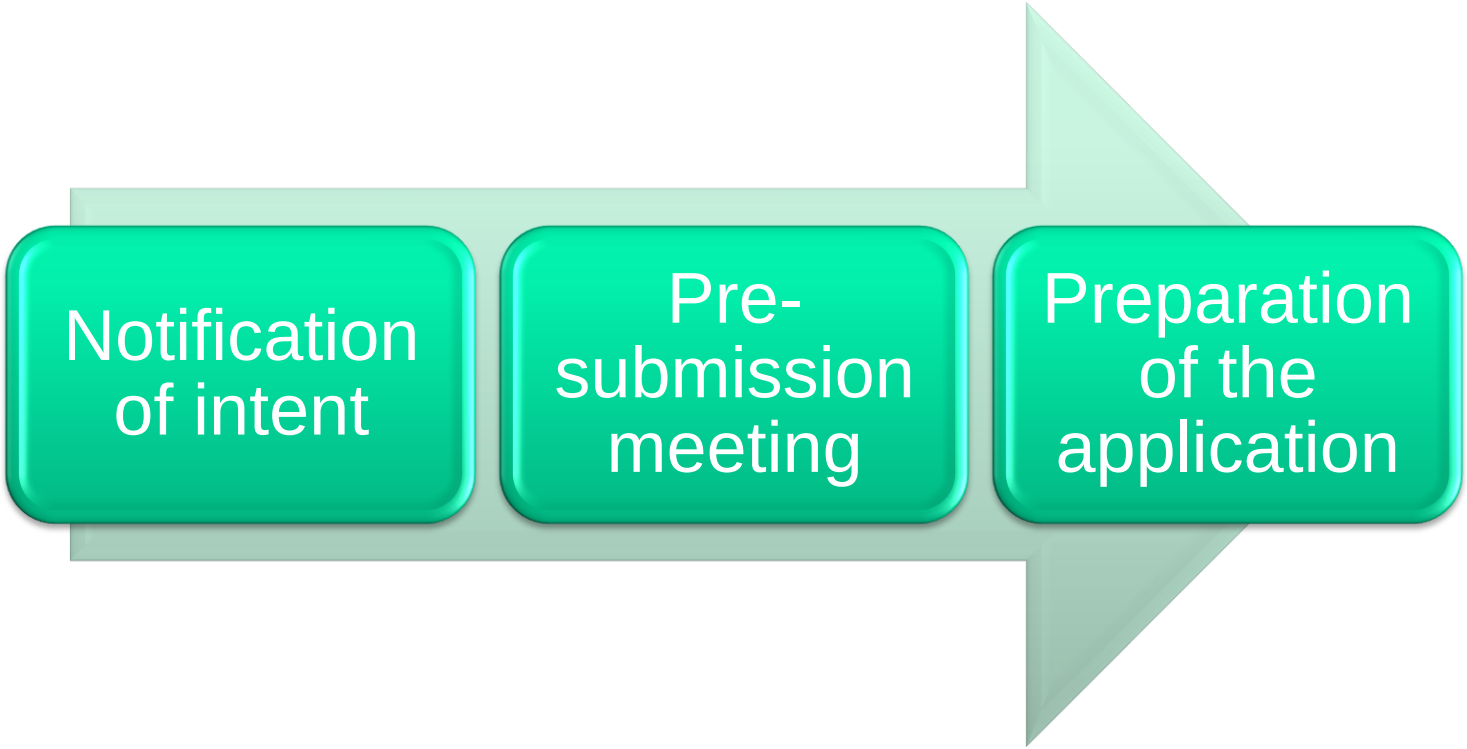
List of abbreviations

AoA	Analysis of Alternatives
CBI	Confidential Business Information
CSR	Chemical Safety Report
DU	Downstream User
ES	Exposure Scenario
OJ	Official Journal
RAC	Risk Assessment Committee
SP	substitution plan
SEA	Socio-Economic Analysis
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum

The first steps in the process



- **Allows a better planning by ECHA**
- **Indicates for which substances and which uses**
- **Request for pre-submission meeting to focus on the technical requirements of the dossier, no discussion on the content of the application**

Preparing an application

Who?

- Manufacturer, importer or DU or joint
- Joint application is not a legal obligation!
- Does a DU have sufficient info to apply individually?
- Differring agenda's depending on position in the supply chain

For What?

- One or more uses, one or more legal entities, one or more substances if fulfilling definition of a group (annex XI, sect 1.5)
- Exchange of CBI, potential competition law, legal advice required!
- How to share costs of preparing the application?
- Role for existing consortium/SIEF?

Costs?

- Fee integral part of the application, calculated by use(s), by substances, by size of company
- Joint invoice: how to distribute costs? Advanced payment by one company unlikely?!
- http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_fees_en.asp

Content of the application

- Application is structured by use

Applicant(s)

USE 1	CSR/ES	AoA	SP	SEA
USE 2	CSR/ES	AoA	SP	SEA

- Options / possible outcomes

Adequate control no suitable alternatives	Adequate control suitable alternatives	Socio-economic advantages > risks
CSR AoA	CSR AoA SP	CSR AoA SEA
SEA	SEA	

Content : some reflections

USE

- Use descriptor system as a basis
- More case specific details may be required
- Contact DU?

CSR/ES

- CSR of registration dossier
- For DU potential issues to get access
- Letter of Access may be required?

AoA

- Risks, technical and economical feasibility to be considered
- CBI & Comp law
- What if only little information on (eco)toxicity of alternatives?
- Contact DU?

SP

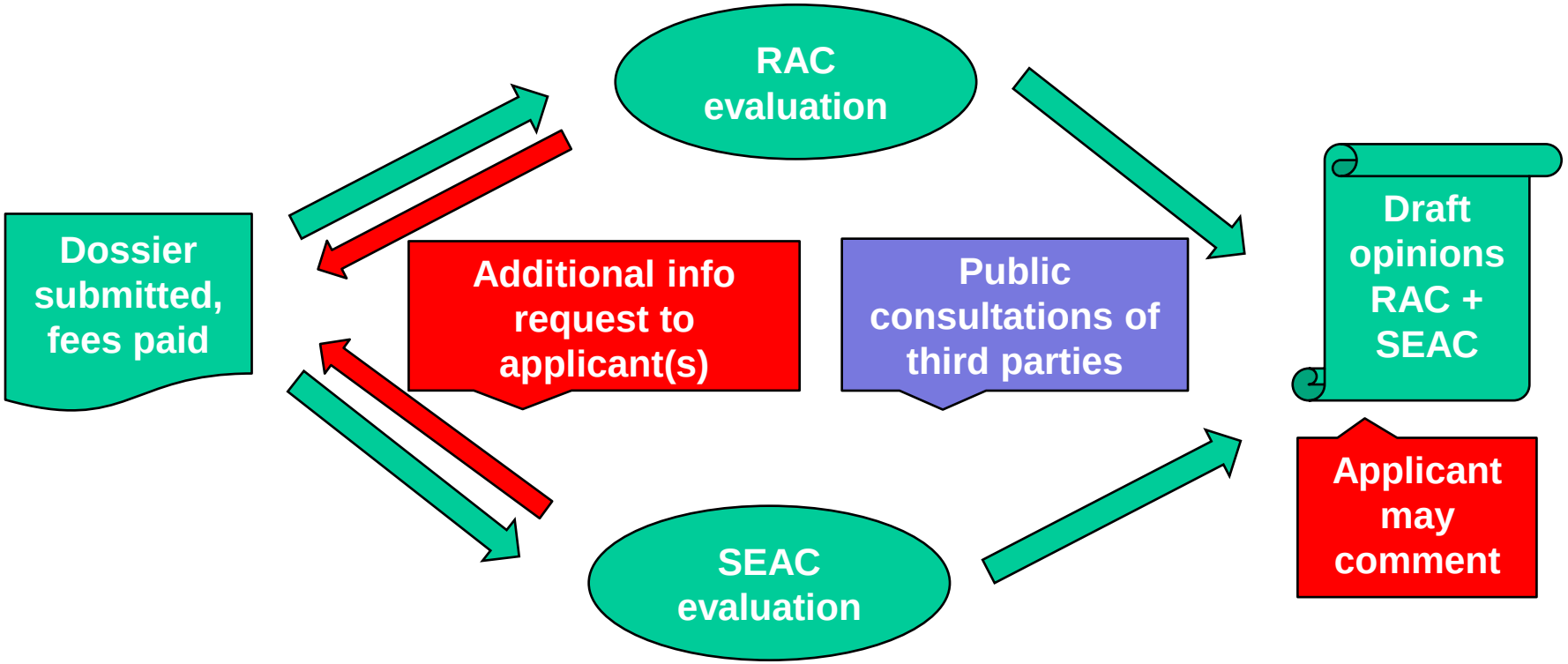
- Ultimate goal is substitution
- Realistic timing!
- Key to determine time of validity of authorisation
- Contact DU?

SEA

- Mandatory only for SE route but sometimes advisable for other routes as well
- Little expertise available
- Resources potential issue!

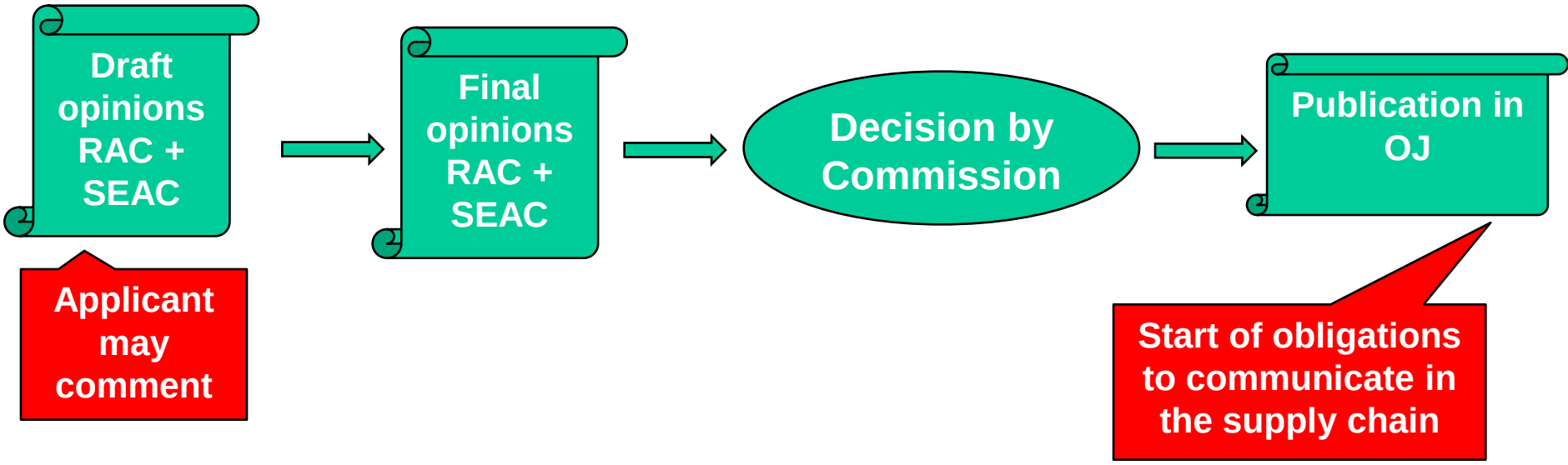
High level of detail required! Start preparing early!
Highly regulated sectors : substitution is a long process

Steps after submission



If alternatives identified by third parties during consultation :
(too) late to react!
Try to be as exhaustive as possible in the AoA
Will third parties be exhaustive on the suitability of alternatives?

After submission



Open questions: What if authorisation is refused?
What to do with stocks already in the supply chain?

Timing is critical

Minimum time = 17 months
Time between ultimate application date and sunset date = 18 months
Start early and submit as early as possible!
Make use of ECHA's preferred submission slots!

Some further considerations

- Authorisation = lengthy, costly and labour intensive with a large degree of uncertainty
  - Alternatives available for all applications?
  - Can you (and your customers) switch before the application date? (concerted action → need to consider competition law issues)
  - If not, do you want to continue this business in Europe? Cost vs benefit?
  - Communicate with your customers / suppliers
  - ‘Living process’: authorisation granted for a limited time → re-submission

Conclusions

- Applying for authorisation is new to everyone
- Data sharing not a legal obligation
- Large risk of infringement of anti-trust law
- High level of detail required in the application dossier
- Early start recommended!
- Make use of opportunities to communicate with ECHA

Thank you for attention!
Any questions?