

ECHA workshop on authorisation

Authorisation applications:
a) manufacturer perspective
b) confidentiality considerations

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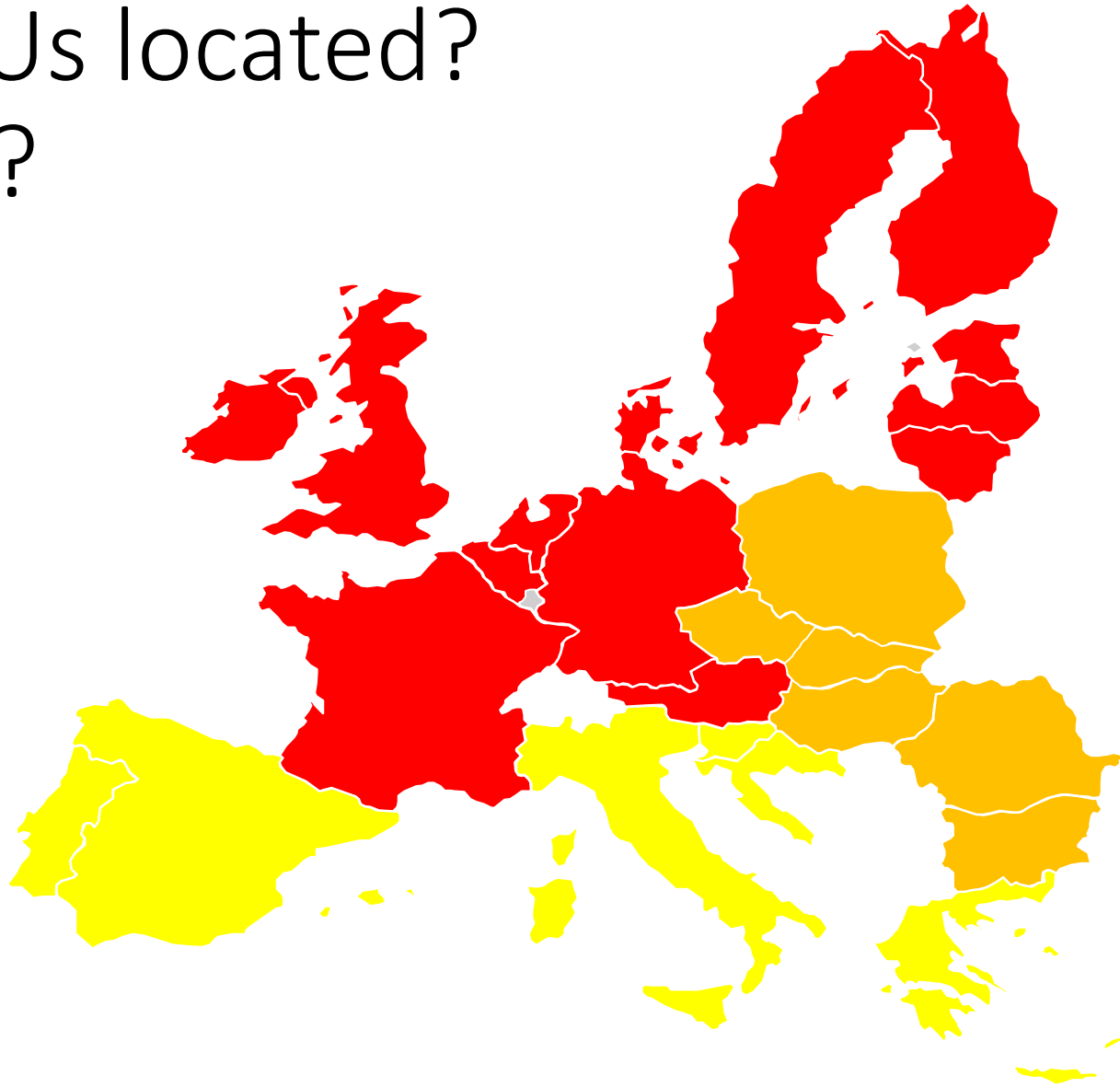
1. Competition law and Confidential Business Information
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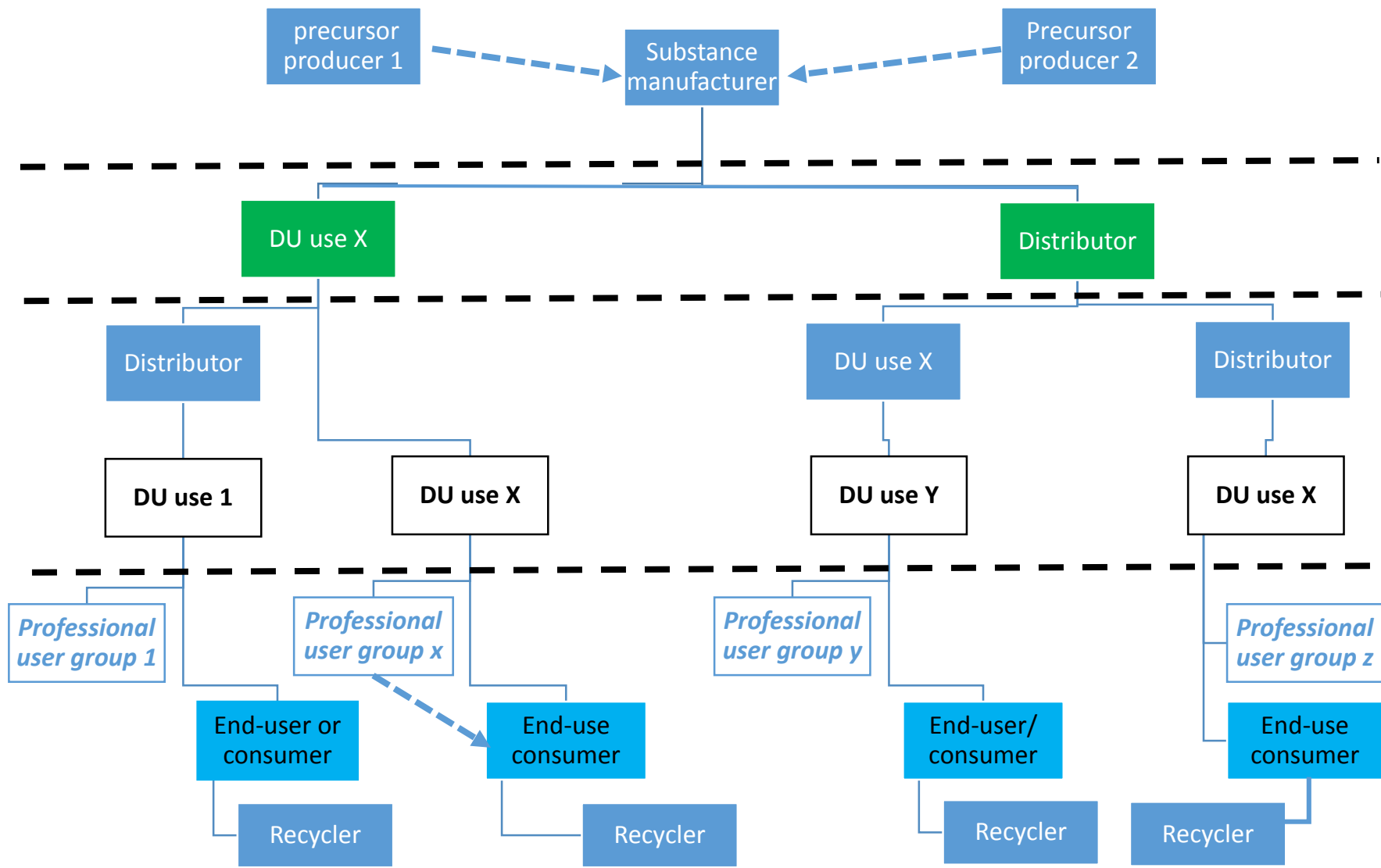
Manufacturer applications for authorisation – why apply?

1. The length and complexity of the supply chain
2. Where/which sectors are your major user groups?
3. Knowledge of your market is key – what is the perspective of the SMEs in your DU market?
4. For all applicants a go-no-go decision depends on: Confidence in the process of authorisation, a strategic analysis of the market and the Regulation and Guidances.

Where are the DUs located? Who is impacted?

- REACH awareness varies
 - By region
 - By sector
 - By company size
- Who is impacted?
- What is the perspective of the SMEs?





Supply chain communication –

Communicating with those who are impacted:

- Communication with customers
- Getting further downstream
- Bottom-up approach
- Performance and safety specifications
- Using public fora
- Effective supply chain communication



The use of a use

1. Uses are based on the Guidances
2. Uncertainty at different levels about industrial processes
 - different expectations about how a use should be described
3. A substance that is broadly used (ie used in a range of industrial applications, article parts and end-products) does not mean the same as a use definition that is too broad
4. Uses and articles (if the substances ends in consumer/professional articles)
5. In authorisation, the use up to the point of incorporation into an article is relevant; articles are not authorised
6. Professional and consumer exposure to those articles containing the substance must be taken into account in the authorisation CSR

Authorisation and confidentiality

Confidentiality considerations common to all applications

- Competition law and Confidential Business Information
- Confidentiality and authorisation
- Confidentiality in the application for authorisation
 - the SEA (Socio-Economic Analysis)
 - the AoA (Analysis of Alternatives)
 - the CSR (Chemical Safety Report)

Competition Law / CBI



From a competition law perspective, issues are more sophisticated



Authorisation is not pure “regulatory” area:
it covers sensitive and individual commercial aspects



Joint preparation of the non-sensitive parts of dossier but dossier completion and **submission on an individual basis**
(= safest approach)

Confidentiality and authorisation

- Why claim NO information as confidential?
 - unique reasons per application
- Why claim information as confidential?
 - the nature of the information obtained from the supply chain
 - the value of CBI in an application
 - your company procedures
 - confidential information must be supported by properly justified arguments
 - the use of data by others

Confidentiality in the application for authorisation

- Confidential information in the Socio-Economic Analysis (SEA) and the Analysis of Alternatives (AoA):
- SEA requirements are specific and reasonably detailed; the requirements of the SEAC are just starting to become clearer
- Analysis of Alternatives:
 - 2 perspectives
 - the input of DUs is required by the process
 - few lessons to date

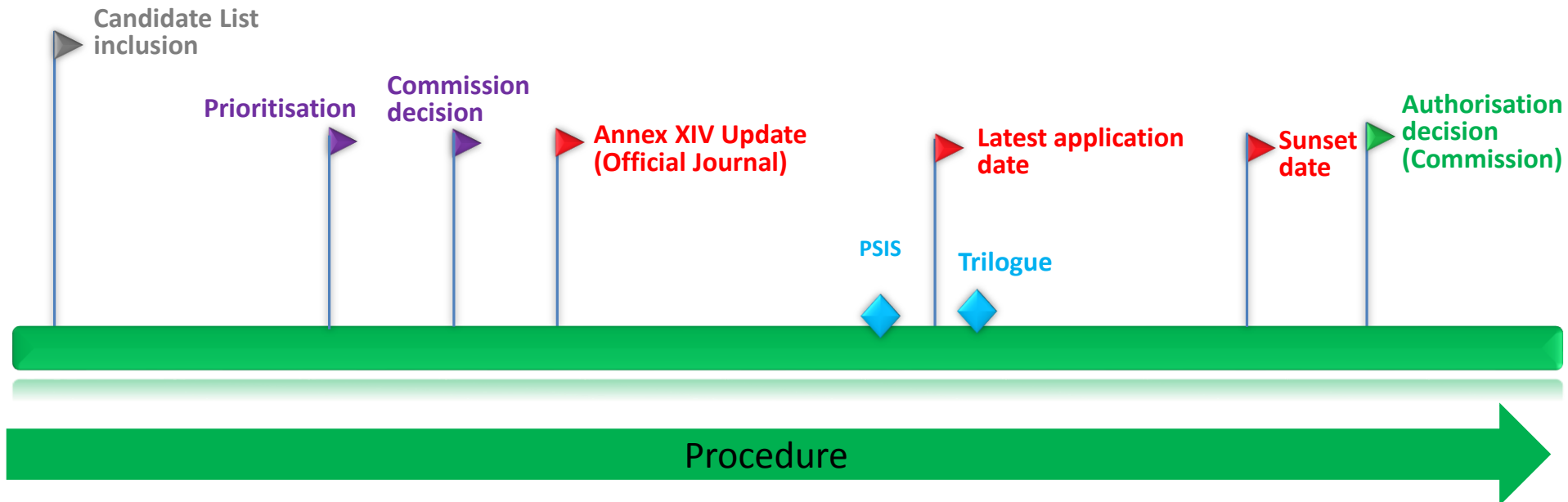
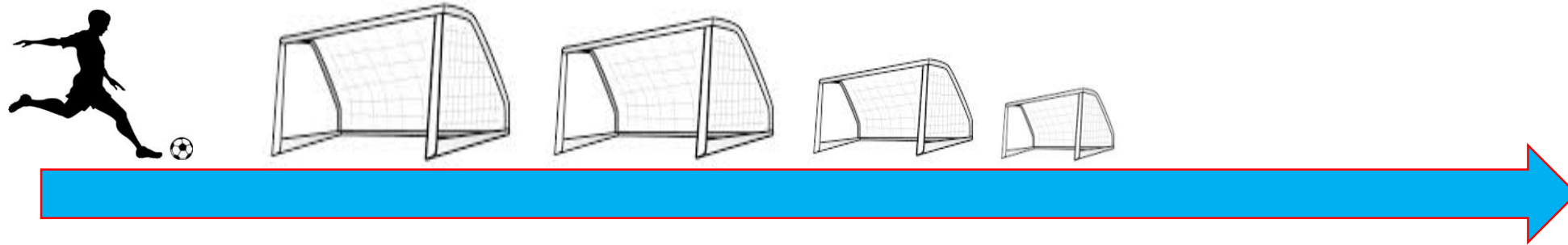
Confidentiality and the Chemical Safety Report (CSR)

- Registration CSRs for registrant applicants
- What is disseminated via the Dissemination Portal
- Authorisation CSRs – registrant vs non-registrant applicants
- Is there a middle road regarding confidentiality and CSRs?
Yes, quite possibly

Confidentiality continued

- Confidentiality and the Trialogue
- Confidentiality, CBI and Access To Documents (ATD)
 - ATD and CSRs
- There is no Board of Appeal (or equivalent) for authorisation
- Clarity is needed from the outset as to why information is confidential

Confidence in the process



Thank you