REACH Authorization

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Outline

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2. State of Play
3. General Overview of Process
4. Who Can Apply
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   - Confidentiality
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   - Procedural Rights

What is Covered

Annex XIV substances

- SVHCs
  - Category 1A and 1B CMRs
  - PBTs
  - vPvBs
  - Substances raising equivalent level of concern.
- Taken from Candidate List

Marketing and Use in the EU / EEA

- Not manufacture of substance
- Application / Authorization will cover substance / use
- Annex XIV may exempt specific uses
- Intermediates exempted
- R&D exempted (no more than 1 ton)
- In addition, certain uses are exempted for specific categories of products

- Substance on its own
- Substance in mixtures
  - Subject to concentration limits
- Use of substance during manufacture of article in EU / EEA
- Not presence of substance in (imported) article
  - But beware of sunset date
  - ECHA to consider marketing and use restrictions

State of Play

Candidate List

- 144 substances included
- ECHA usually updates the Candidate List every 6 months

- Substances in the Candidate List may be included in Annex XIV
  - Prioritization based on
    - Hazardous properties (PBTs, vPvBs)
    - Wide disperse use
    - High volumes
  - Scoring system
- ECHA recommendation “at least” every 2 years

Authorization List (Annex XIV)

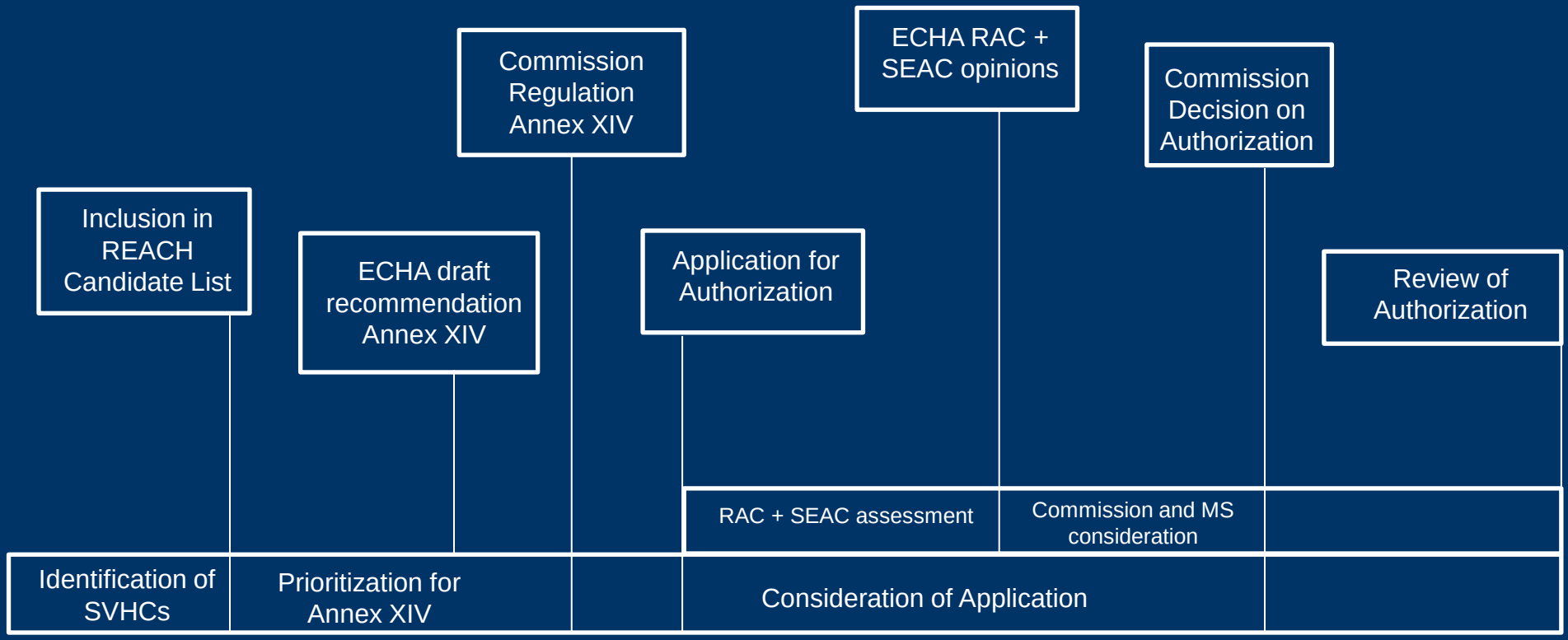
- 22 Substances included
- Last substances added:
  - 7 chromium compounds
  - Trichloroethylene
- Pending Recommendation to include 10 additional substances
- Consultation on 6 additional substances
- The large majority of substances included are CMRs

- Exemptions
  - Exemption for uses in the immediate packaging of medicinal products for the following substances:
  - Benzyl butyl phthalate (BBP)
  - Bis (2-ethylhexyl) phthalate (DEHP)
  - Dibutyl phthalate (DBP)

- Usually ca. 2 years between listing of a substance and application deadline
- 18 months between application deadline and sunset date

- 8 Notifications of intent to apply for authorization
- No applications yet submitted

General Overview of Process



Who Can Apply

• Manufacturer of substances	• Authorization will cover supply chain below:
	  • Use must be within authorization
	  • Downstream users must notify ECHA

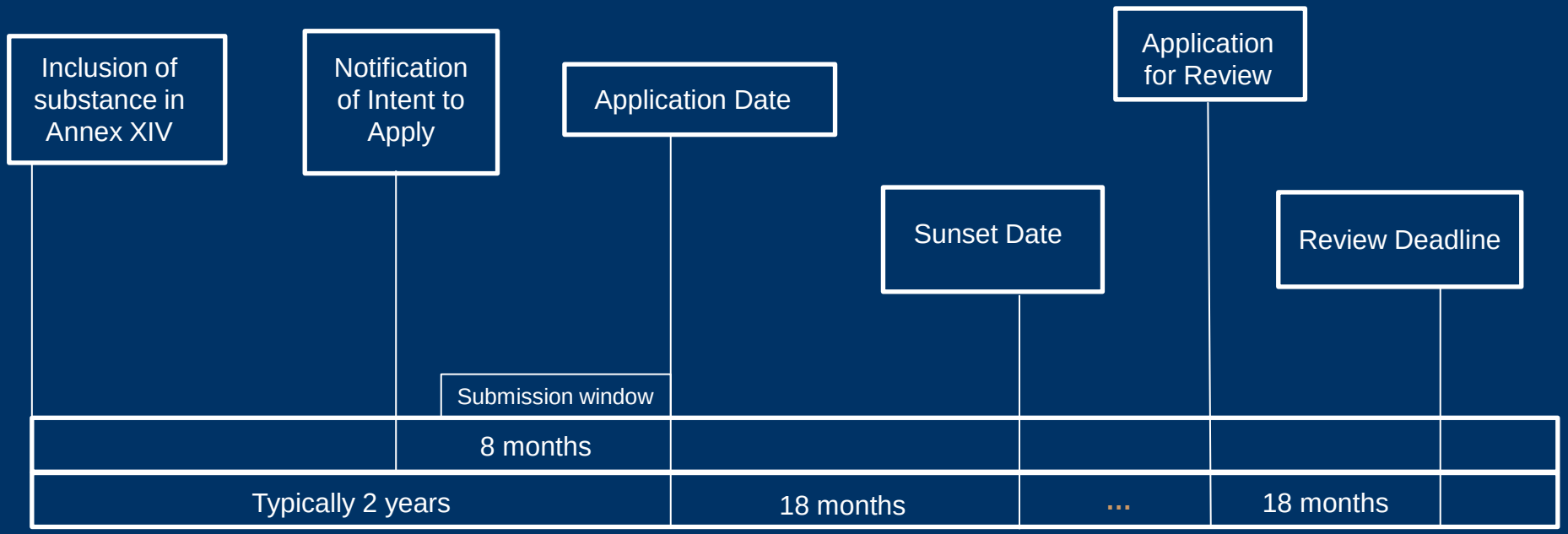
• Importer of substances and mixtures	
• Only Representative • Only Representative will become Authorization holder	

• Downstream User
  • Not Distributor unless he "uses" (e.g. repackaging)
	• Authorization will cover immediate supplier and supply chain below:
	  • Use must be within authorization
	  • Downstream users must notify ECHA

• Joint applications • May cover manufacturers, importers, downstream users and representatives	

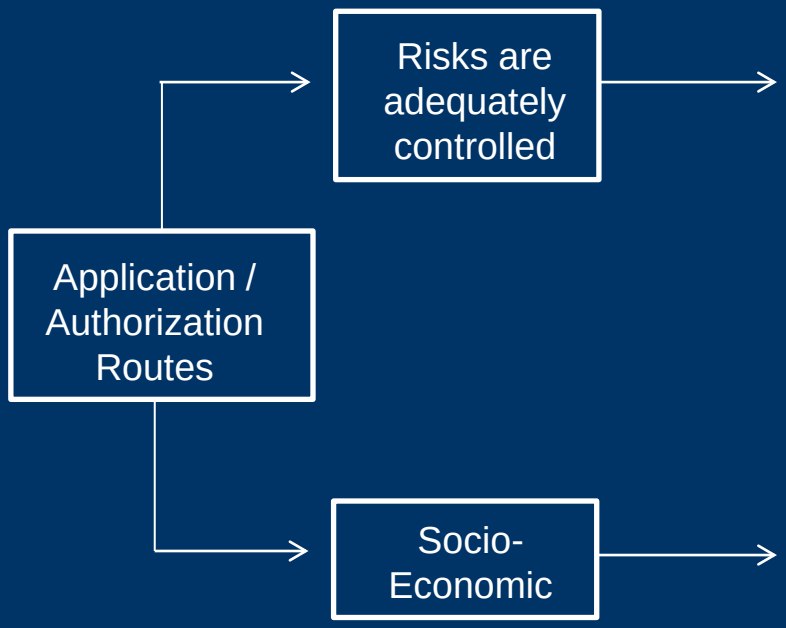
Application can cover substance or group of substances and different uses

Application Deadlines



- Possibility to apply after application and sunset dates
  - But use / marketing of substances is banned after sunset date and until authorization is obtained
- Application should be submitted during the “submission window” to ensure use / marketing of substance after sunset date (until decision is taken)
- Not possible to join another authorization application after its submission

Content of the Application



- Identity of Substance
- Contact details of applicant
- Uses for which authorization is requested

- CSR
  - Must show adequate control of risks
- AoA
- R&D plan if no suitable alternatives
- Substitution plan if suitable alternatives exist
- Socio-economic analysis (advised)

- CSR
  - Must show that risks are considered
- AoA
  - Need to show that no suitable alternatives exist
- R&D plan
- Socio-economic analysis
  - Must show authorization benefits exceed risks

- Payment of fee

Confidentiality Concerns

Joint Applications

- Sharing information on uses, alternatives, socio-economic impact, etc
- If precise use is too confidential, joint application might not be best option
- Also beware of antitrust concerns

Public Consultations

- ECHA will publish BIU for public consultation on alternatives
  - Applicant's name
  - Brief wording on BIU
    - Name of use
    - Conditions of use
    - Use descriptors
  - Public version of exposure scenario
  - Public version of AoA
  - Public summary of substitution plan
  - Public summary of socio-economic analysis
- Applicant is responsible for including confidential and non-confidential versions in application

Access to Documents

- Consider risk that ECHA may give access to information in addition to that published
- CBI v. Overriding Public Interest
- "Specific Use" and other deemed to undermine CBI
- Emissions to the environment are considered "overriding public interest"

Data Sharing

- There is no obligation to share data for authorization applications
- Latecomers may rely on data of previous applicants or authorization holders provided they obtain their permission
  - Chemical safety report
  - Analysis of alternatives
  - Substitution plan
  - Socio-economic analysis
- Contractual negotiations
- Beware of sharing data with companies from countries subject to trade sanctions

Procedural Rights

- Significant opportunities to comment
- Commission decision on authorization may be challenged before EU Courts
  - Company has standing to challenge inclusion of substance in Candidate List (Cindu Chemicals et al, March 2013)
    - Also inclusion in Annex XIV?
- But Courts' standard of review will be very high
  - Manifest error of assessment
  - Focus on procedural rights
  - Arguments should be made during the administrative procedure

Thank you

Questions?

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