Welcome to Today's Webinar:

An Overview of the REACH Authorisation Procedure and Preparatory Activities by IAEG WG5

26 January 2017

Today's webinar - aims

- Provide an overview of the REACH Authorisation procedure
- Set out the typical practical options for actors in the supply chain
- Provide a brief overview on the contents and requirements of the specific documentation that must be submitted
- Explain the challenges faced by the aerospace sector
- Outline the activities IAEG WG5 is undertaking, explain why we are undertaking them and why we need your support!

Who are we?

IAEG
INTERNATIONAL AEROSPACE ENVIRONMENTAL GROUP®

- Trade association formed by major aerospace companies – formally incorporated June 2011
- Focussed on the multitude of global laws and regulations impacting health and the environment
- Formed to address the complexity and variability of these requirements and associated impact on the Aerospace industry (Civil & Defence) and its supply chain

WG5 Members

Airbus	Embraer
Airbus Helicopter	GE
BAE Systems	Honeywell
Boeing	Raytheon
Bombardier	Rolls Royce
Cobham	Textron
Dassault Aviation	Thales Group
Gulfstream	UTC - PW
Mitsubishi Aircraft	UTC - UTAS
Northrop Grumman	

IAEG at a glance

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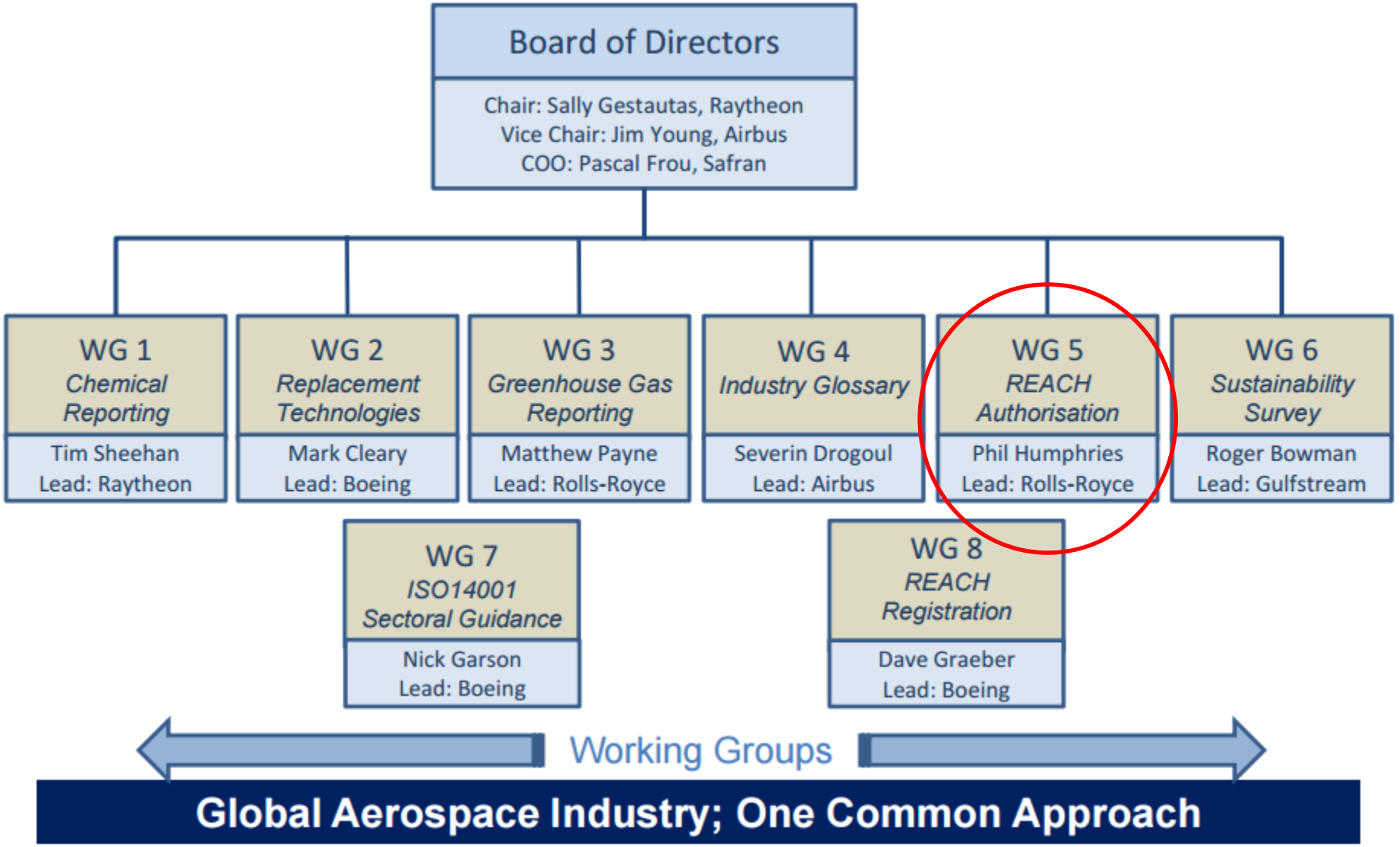


REACH Authorisation process

TITLE VII

AUTHORISATION

CHAPTER 1

Authorisation requirement

Article 55

Aim of authorisation and considerations for substitution

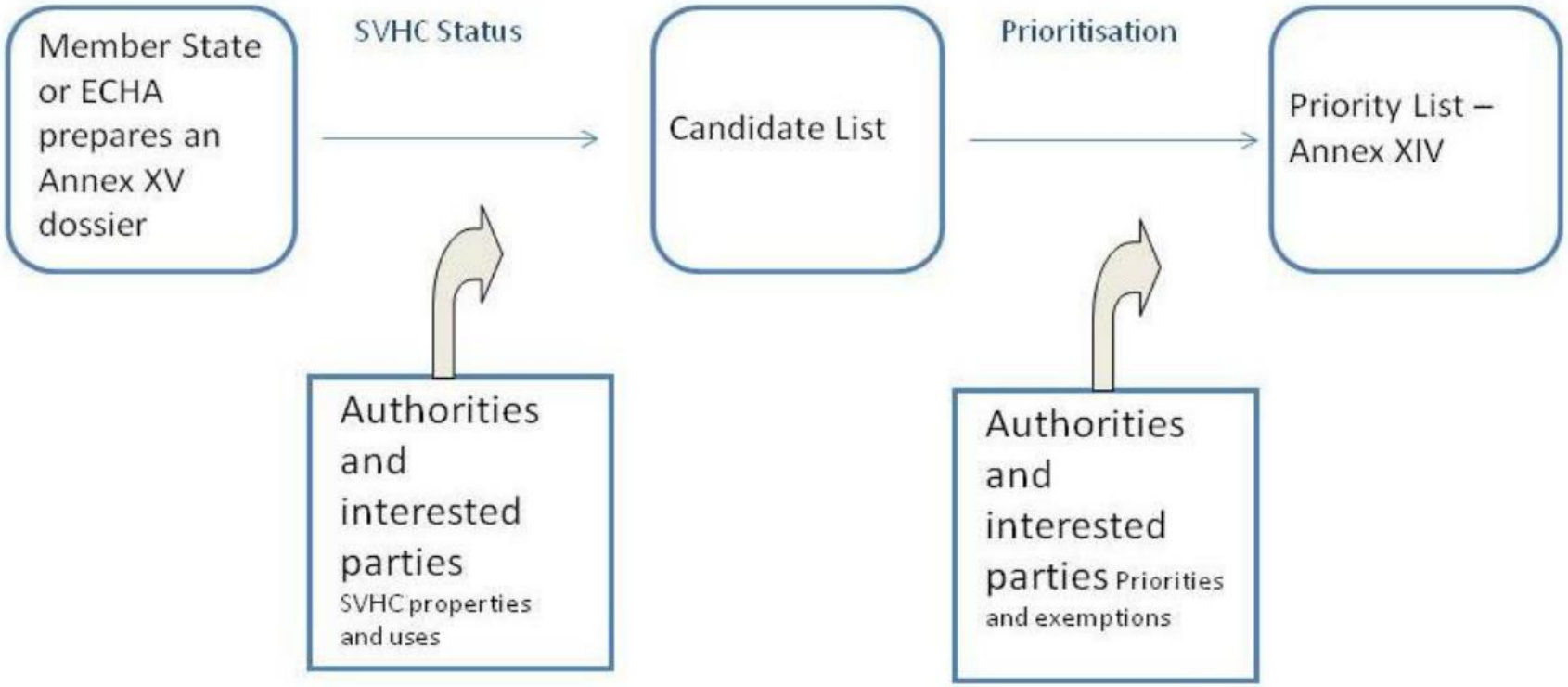
The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

- Authorisation is one of the core REACH processes for managing the risks of hazardous substances
- Aims to ensure that the risks from SVHCs are properly controlled and that these substances are progressively replaced

REACH Authorisation process

- After a two-step regulatory process, SVHCs may be included in the Authorisation List
- These substances cannot be placed on the market or used after a given date (the ‘Sunset Date’), unless an authorisation is granted for their specific use, or the use is exempted from authorisation
- Authorisation list = **31 substances**
- Candidate list = **173 substances**
- Authorisations are time limited (typically 4, 7 or 12 years) and review reports are required. They are granted per substance and per use

Journey to Annex XIV



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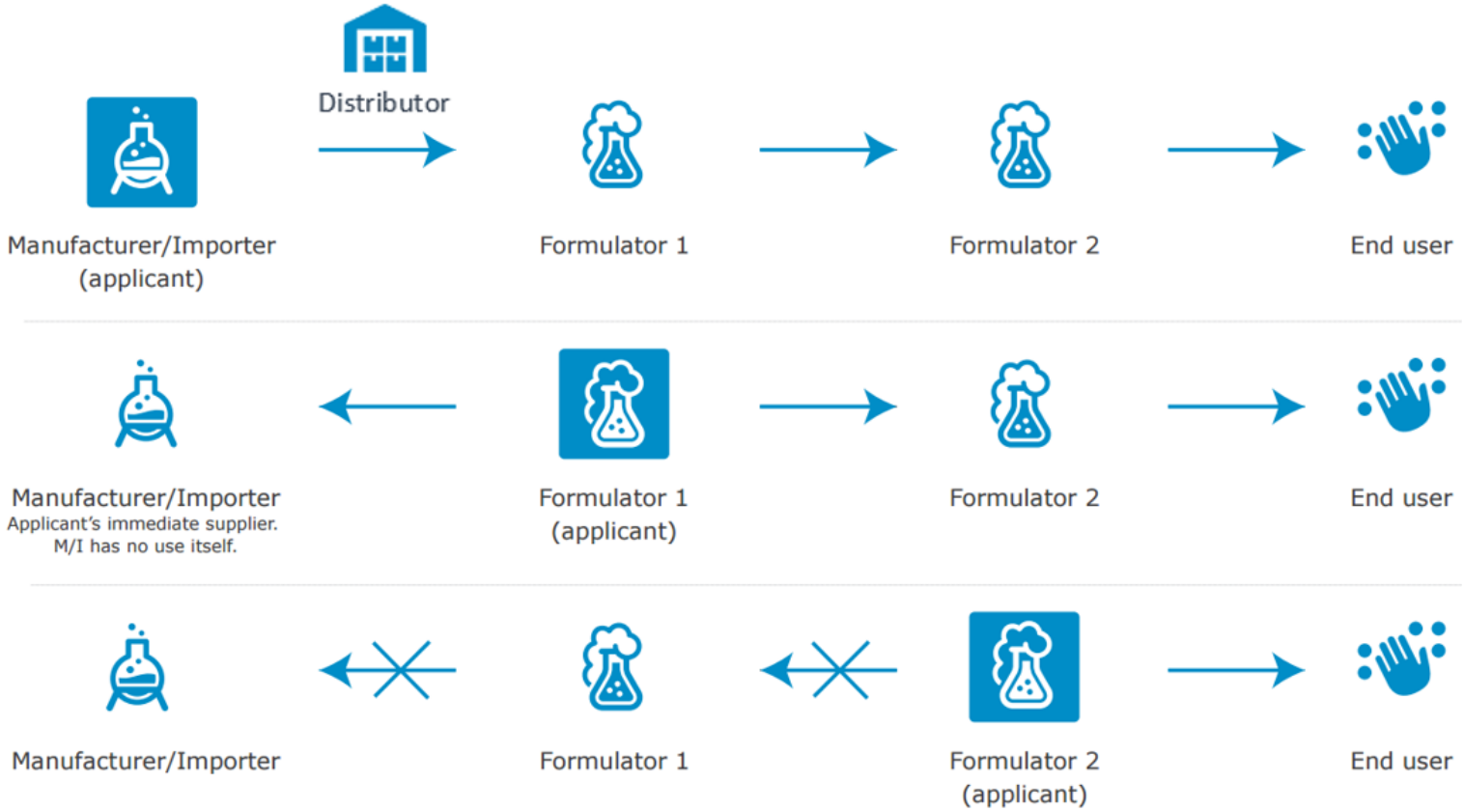
Supply chain coverage

- Use coverage is top-down, not bottom-up – there is a potential for supply chain disruption
- ‘The best’ way: substance manufacturer or importer submits application (all supply chain can be covered if uses are included)



Components of an Authorisation dossier

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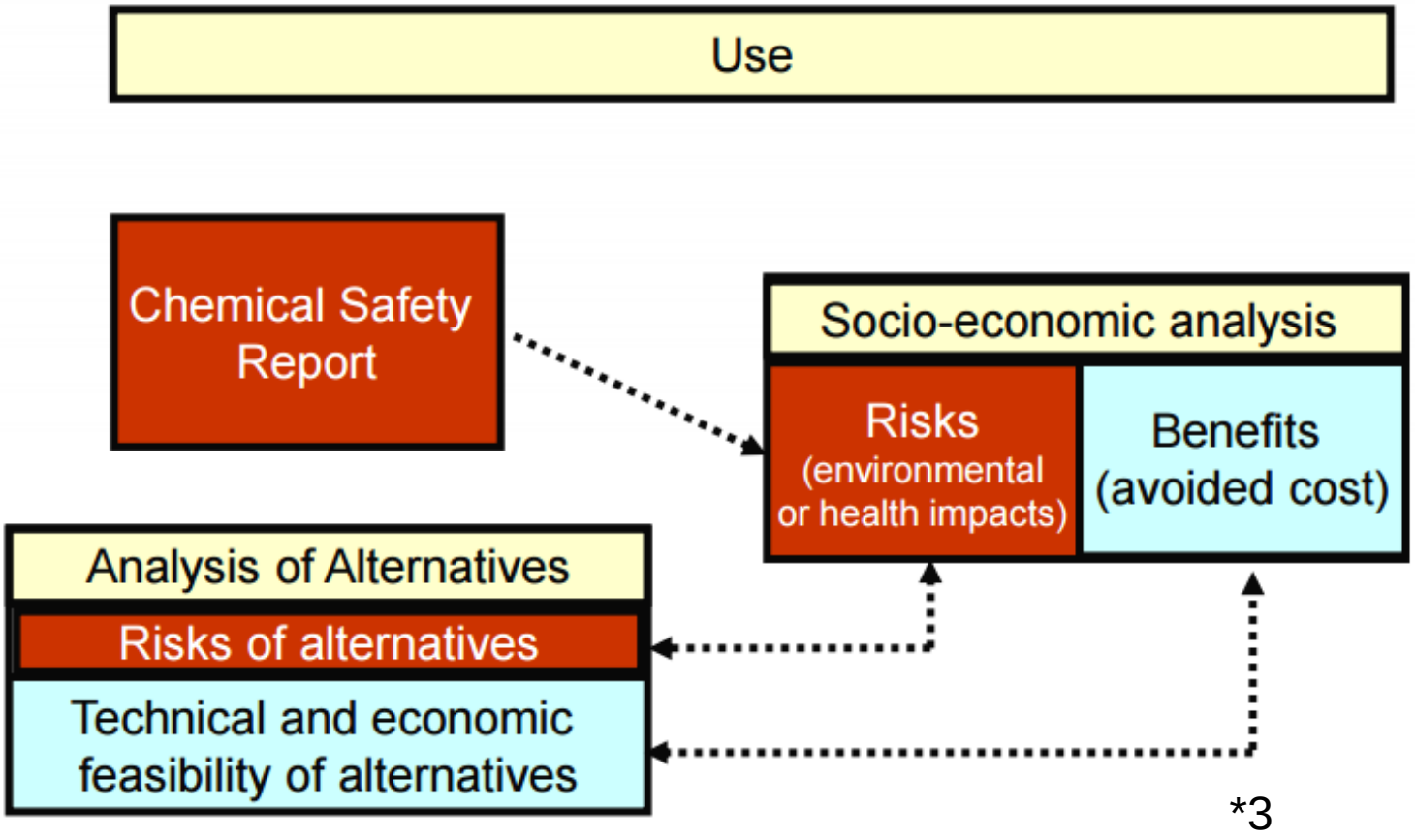
CSR, AoA and SEA



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Components of an Authorisation dossier - CSR

- A REACH Authorisation CSR is different from a Registration CSR
- An Authorisation CSR includes:
  - The hazard part, addressing critical effects; and
  - An exposure evaluation and risk characterisation for the uses
- Low risks provide good arguments in the cost-benefit analysis, undertaken in the Socio-economic Analysis
- ECHA has a strong preference for measured data

Components of an Authorisation dossier - AoA

- A critical and compulsory part of an Application for Authorisation
- The applicant must demonstrate that no technically feasible, economically feasible and suitable alternatives exist
- Major AoA sections include:
  - Analysis of substance function
  - Identification of possible alternatives
  - Assessment of the suitability of alternatives

Components of an Authorisation dossier - SEA

- ‘Applied-for use’ scenario (typically, business as usual) compared to the ‘Non-use’ scenario(s)
- There may be more than one Scenario depending on the options being considered
- The Scenarios need to be realistic and justified and should reflect the results of the AoA

An evolving process…

- Templates and guidance materials can change
- As do committee evaluation methods
- ECHA holds regular workshops
- Authorisation Q&A's regularly updated
- Important to stay on top of the current 'best practises'

Given that large dossiers can take 2 years+ to develop, applicants must be ready to exhibit flexibility in their approach to Authorisation

Authorisation from a business perspective

- A complex and challenging process
- Requires businesses to make strategic decisions

1. Replace the substance with a suitable alternative or adapt your process to avoid its use

2. Switch to products (articles) that avoid the use of the substance.

3. Consider applying for authorisation.

4. Ensure your use is covered by another authorisation.

5. Cease use in the EU.

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Challenges for the aerospace sector

- Industry's dependence on certain SVHCs to meet functional requirements, in particular high standards of safety over long product lives
- Reg. 216/2008 on qualification, etc. of alternatives
- Relatively small volumes of chemicals used by sector or its suppliers
- Complexity of the supply chain

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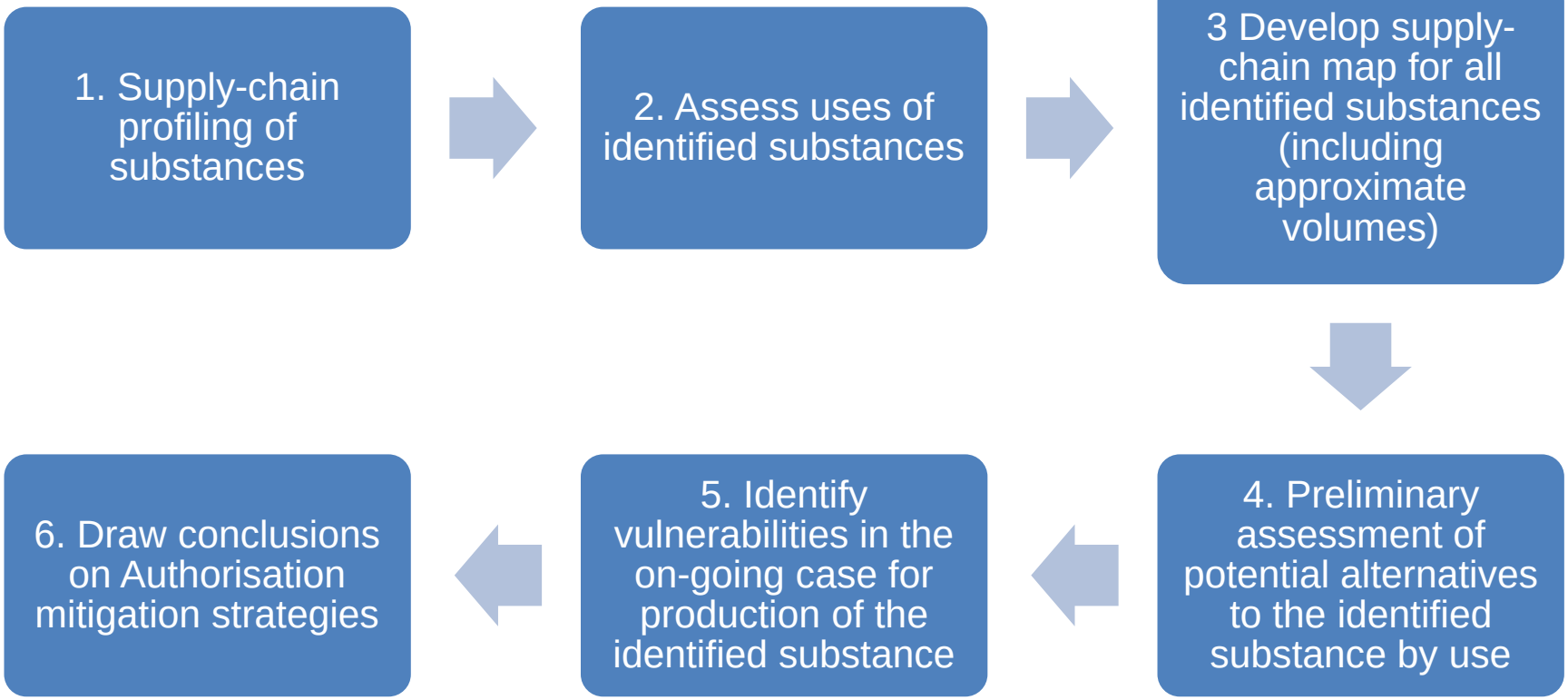
Although complex, such aspects are not a disadvantage…

- Similar nature of issues facilitates development of upstream Application for Authorisation
- Long service lives, high costs of retrofitting and intense requalification processes mean there is the potential for long review periods
- High economic and political risks of not authorising uses

Supply chain mapping – process overview



Supply chain surveys

- Survey being undertaken for cadmium and cadmium compounds
- A short (one page) initial questionnaire to help with use identification
- A more detailed follow-up questionnaire to obtain key information
- **Information is collated and treated confidentially** (cannot be linked back to individual respondents)

Your support is essential!

- Please complete and pass on our short questionnaires
- The more information we receive, the better the picture of the supply chain → This will allow for a more informed, structured and comprehensive approach to potential future Authorisation activities
- Respondents will receive a summary of conclusions and instructions on how to keep track of developments
- Outside the EU? Authorisation can still affect you!

References

***1**. Nickel Institute (2012): The REACH Authorisation Process – Key Questions and Answers. Available at http://www.nickelconsortia.eu/assets/files/consortia/Authorisation%20QA%20May%202012.pdf.

***2**. ECHA (2013): Factsheet – Applications for authorisation under REACH. Available at https://echa.europa.eu/documents/10162/13637/factsheet_applications_authorisation_en.pdf.

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***4**. ECHA (undated): Getting started – Distributor. Available at https://echa.europa.eu/support/getting-started/distributor.

***5**. ECHA – EASA (2014): An elaboration of key aspects of the authorisation process in the context of aviation industry. Available at https://echa.europa.eu/documents/10162/13552/aviation_authorisation_final_en.pdf.