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?

- 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  
Airbus Helicopter  
BAE Systems  
Boeing  
Bombardier  
Cobham  
Dassault Aviation  
Gulfstream  
Mitsubishi Aircraft  
Northrop Grumman

Embraer  
GE  
Honeywell  
Raytheon  
Rolls Royce  
Textron  
Thales Group  
UTC - PW  
UTC - UTAS
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.

**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.
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

Member State or ECHA prepares an Annex XV dossier → SVHC Status → Candidate List → Prioritisation → Priority List – Annex XIV

Authorities and interested parties
SVHC properties and uses → Authorities and interested parties
Priorities and exemptions
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

CSR, AoA and SEA

Chemical Safety Report

Socio-economic analysis
- Risks (environmental or health impacts)
- Benefits (avoided cost)

Analysis of Alternatives
- Risks of alternatives
- Technical and economic feasibility of alternatives

Use

*3
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
• ‘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.
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

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

1. Supply-chain profiling of substances

2. Assess uses of identified substances

3. Develop supply-chain map for all identified substances (including approximate volumes)

4. Preliminary assessment of potential alternatives to the identified substance by use

5. Identify vulnerabilities in the on-going case for production of the identified substance

6. Draw conclusions on Authorisation mitigation strategies
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!


