

Application for Authorisation

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- 29th April 2014
- ECHA workshop on sharing experience on applications for authorisation

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Authorisation Lessons Learnt

- The authorisation submission requires you to use IUCLID and REACH IT – familiarise yourself with both
- The RAC and SEAC do not have prior knowledge of Aerospace safety and certification requirements and how they control the introduction of alternatives
- CSR's may need updating
- Monitoring data will need updating
- You must distinguish clearly between data that is Public or Business Confidential – the default position is Public
- Use the pre-submission information session (PSIS) – you get to meet your case management team and clarify issues
- Keep your SEA clear and as simple as possible
- Distinguish clearly between an alternative and a substitute



Public Consultation

- Every stakeholder in a consortium will want their voice heard
- The applicant will not necessarily be familiar with the DU's AoA
- The applicant will definitely not be familiar with the DU's SEA
- AoA's may be confidential to individual DU's which creates problems for maintaining confidentiality during Q&A
- Each DU may have a number of different functions that need to be involved
 - Eg. Legal, Supply Chain, Manufacturing, Design, Laboratories, HSE, Technical Consultants
- The existing Trialogue process is unlikely to work for large consortium applications
- It may not be feasible to respond in 2 weeks with multiple stakeholders
- It might be better to move to a purely written Q&A process
- Independent consultants will probably be needed to filter AoA Q&A's and protect BCI.

