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Sasol-Huntsman

Blazing the Authorisation Trail

Finding our way through the Application for Authorisation process

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Helsinki, Finland

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Our Authorisation Journey

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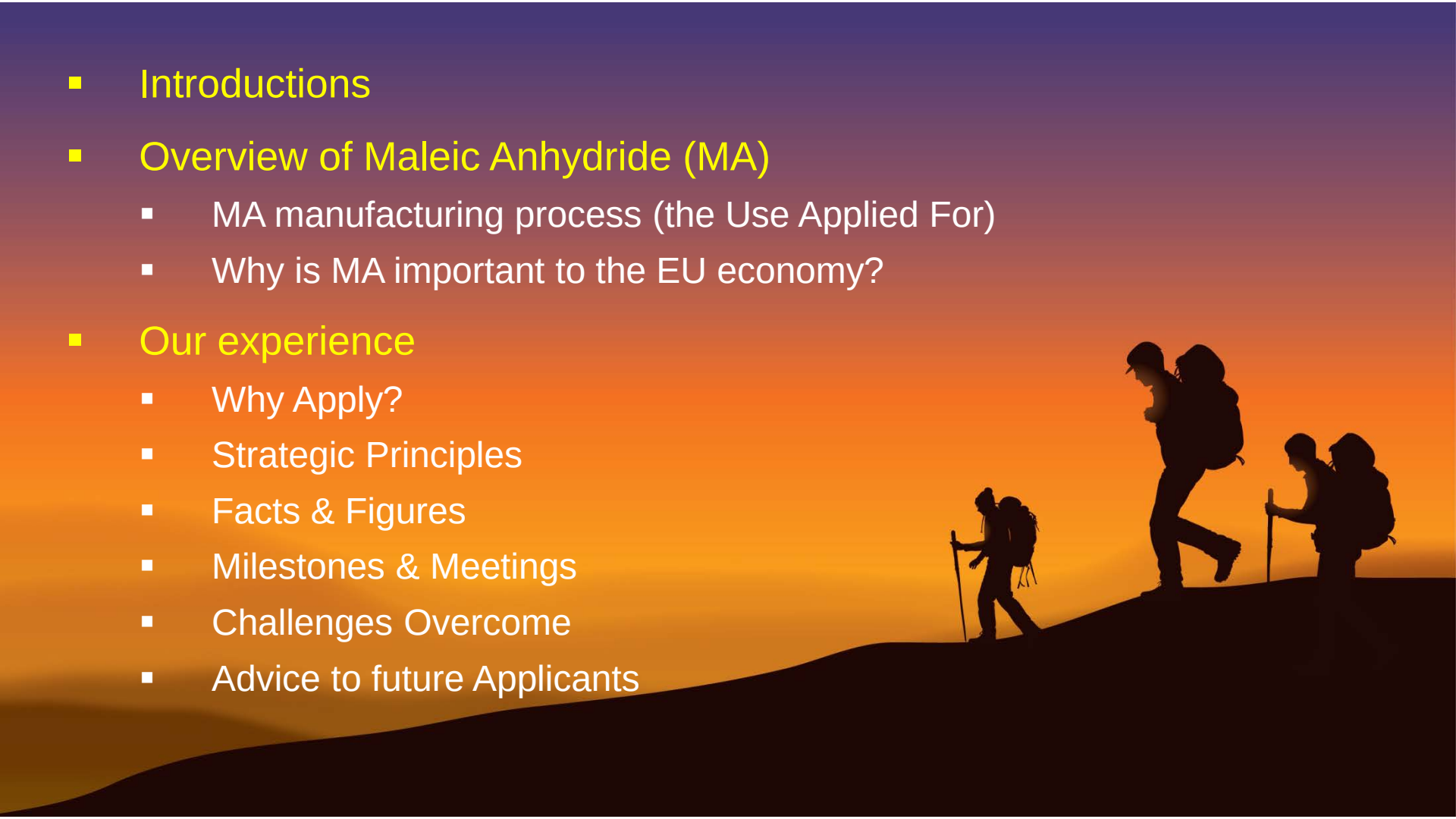
- Introductions
- Overview of Maleic Anhydride (MA)
  - MA manufacturing process (the Use Applied For)
  - Why is MA important to the EU economy?
- Our experience
  - Why Apply?
  - Strategic Principles
  - Facts & Figures
  - Milestones & Meetings
  - Challenges Overcome
  - Advice to future Applicants



Introductions

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Huntsman is a US based global manufacturer and marketer of differentiated chemicals employing ~12,000 people in >30 countries. Huntsman is one of the world's leading producers of refined Maleic Anhydride (MA) and licensors of MA technology.

sasol
reaching new frontiers

Sasol is a South Africa based integrated energy and chemical company employing more than 34,000 people in 37 countries.

Huntsman and Sasol are committed to high standards of safety in all their worldwide operations and affiliated businesses, including embracing the regulatory framework of each host country.

Sasol-Huntsman

Sasol-Huntsman is a 50/50 joint venture located in Moers, Germany which produces only Maleic Anhydride, using Huntsman technology. Sasol-Huntsman is Europe's largest manufacturer of Maleic Anhydride.

What is Maleic Anhydride?

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- MA is a highly versatile building block chemical which is essential to EU industry in hundreds of downstream applications
  - Approximately half of EU MA is used to produce Unsaturated Polyester Resins (UPR). According to CEFIC, the EU UPR industry includes ~8000 companies and directly employs ~100,000 people. Value added to the EU economy is ~€60 billion annually.
  - Other important uses include lubricants, paper chemicals, coatings, and agriculture.
- Sasol-Huntsman, with a nameplate capacity of 105,000 tons annually, supplies about 35% of EU requirements.

MA Manufacturing Process
(the Use Applied For)

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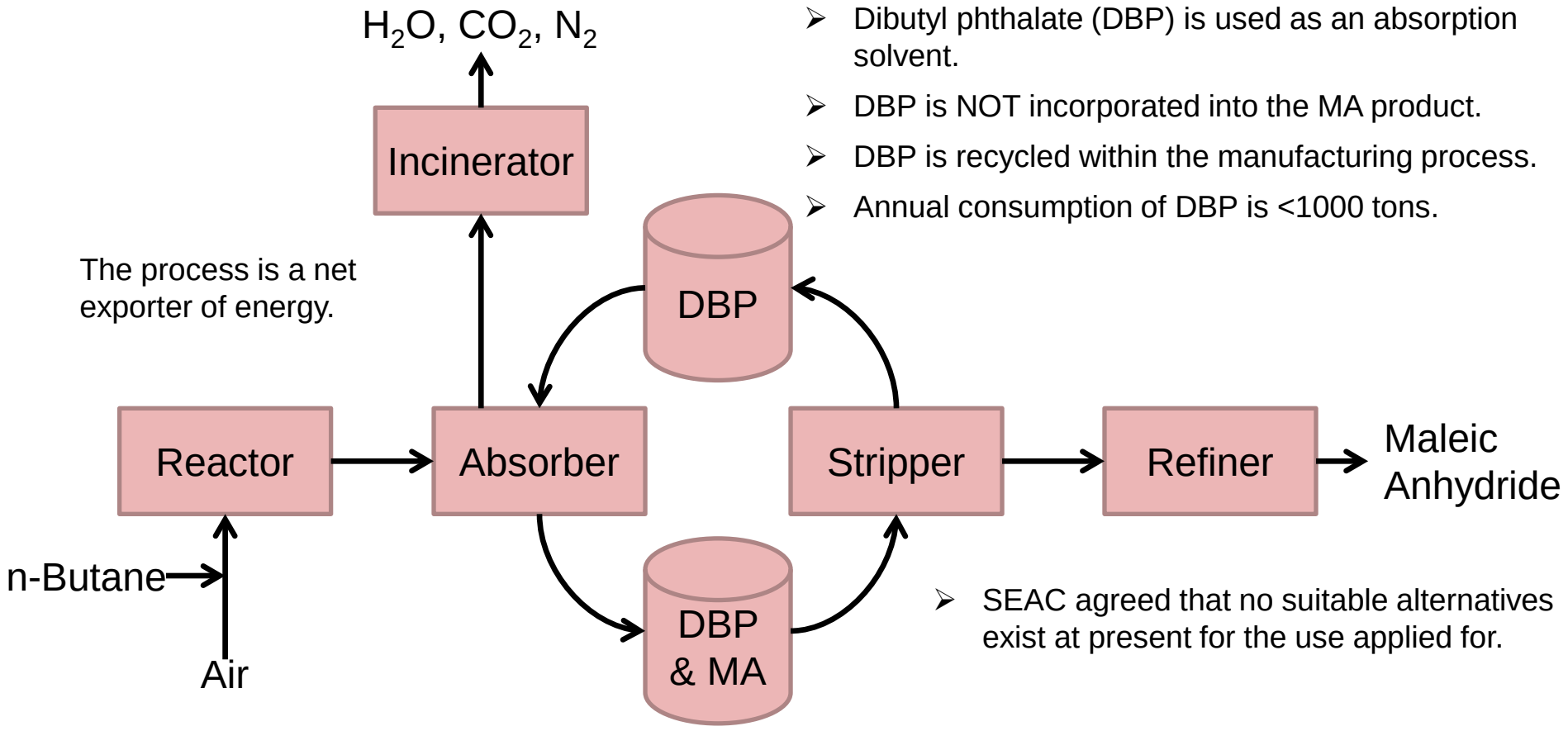

The process is a net exporter of energy.

- Dibutyl phthalate (DBP) is used as an absorption solvent.
- DBP is NOT incorporated into the MA product.
- DBP is recycled within the manufacturing process.
- Annual consumption of DBP is <1000 tons.

- SEAC agreed that no suitable alternatives exist at present for the use applied for.

Why Apply for Authorisation?

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- Sasol-Huntsman is the only EU downstream user (DU) of the Use Applied For.
- The EU DBP manufacturer also applied for Authorisation of the same use.
- Sasol-Huntsman's Application for Authorization (AfA) as a DU is redundant, but was motivated to protect the option to import DBP from outside the EU.

Strategic Principles

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- Given that the Authorisation process was new and there was no prior experience to learn from:
  - Maximum transparency
  - Proactive
  - Thorough
- Despite clear evidence of Adequate Control, SEA was also performed to document the importance of MA to the EU economy.

- Information and communication tools are powerful, but face to face meetings were also utilized to maximize understanding.
- Team included members with knowledge of EH&S, technology, and market impacts.

Facts & Figures

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- Core Working Team of 8 People
- From May 2011 to July 2013
  - 18 team meetings in 7 cities & 5 countries
  - Monthly senior management reports
  - Regular presentations to Board of Directors
  - Dozens of teleconferences, hundreds of phone calls, & countless emails
- Completed Application Dossier (CSR, AoA & SEA) >300 pages

2011 Major Events

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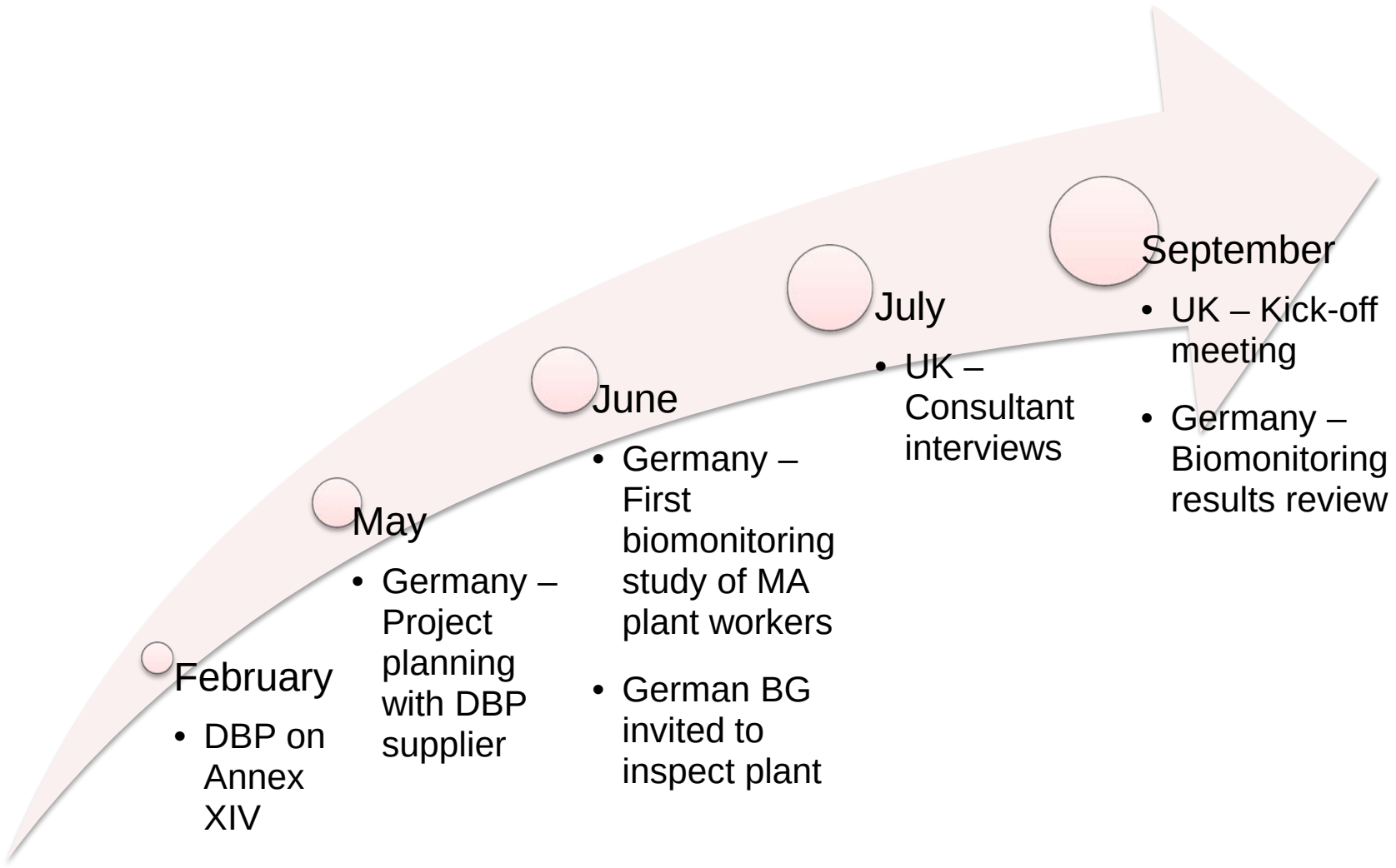

2012 Major Events

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April

- Czech Republic – Presentation of Sasol-Huntsman use of DBP to DBP supplier's senior management
- Czech Republic – Tour of DBP plant
- Germany – Team meeting to answer AoA & SEA questions

June

- UK – Review of AoA first draft
- Germany – Team meeting to answer AoA & SEA questions

July

- Germany – Meeting with German IPA to commission follow-up biomonitoring study

October

- Finland – ECHA workshops on AfA, AoA,and SEA
- Germany
  - Review SEA first draft
  - Review 2nd biomonitoring study results
  - MA plant tour for project team

Biomonitoring 2011

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- CSR exposure scenarios calculated by standard modeling tools.
  - We wanted validation of the models.
- 2011 screening study by German IPA confirmed workplace exposures to be safe and also illuminated opportunities for improvement.
  - Benchmarked with Huntsman MA plants in the US.
  - Invited German Berufsgenossenschaft to inspect the plant and make improvement recommendations.

IPA
Institut für Prävention und Arbeitsmedizin
der Deutschen Gesetzlichen Unfallversicherung
Institut der Ruhr-Universität Bochum

BGW
Berufsgenossenschaft
für Gesundheitsdienst
und Wohlfahrtspflege

Biomonitoring 2012

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- Numerous procedural changes implemented and capital investment in minor equipment improvements.
- 2012 follow-up study to measure the benefit achieved by procedure and equipment changes.
  - Median and 95th percentile exposures reduced by more than half relative to 2011 study

2013 Major Events

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January

- Finland – PSIS meeting

March

- UK – AoA and SEA 2nd draft reviews
- “Reference” DNELs issued by RAC, major rework of CSR begun
- Finland – 8th Stakeholders Day

April

- The Netherlands – AoA and SEA final team reviews
- ECHA revises submission dates

July

- AfA submitted to ECHA

Pre Submission Information Session

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- Don’t miss this opportunity for dialog.
  - Preview your dossier to ECHA to help them understand your case.
  - Clarify technical and procedural questions.
- Plan ahead.
  - ECHA wanted our questions to be submitted in writing one month in advance of the meeting, as it may not be possible to properly address impromptu questions. In practice, the discussion was not so rigid.
- Be prepared. ECHA will be.
  - We brought 8 team members.
  - ECHA was equally well represented.

Public Consultation

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- 8 January 2014 – public consultation closed
- 13 January – notified of 2 multipart comments
- 20 January – notified of Committee questions
  - 4 questions about alternatives, including details of calculations
  - 6 questions, multiple sub questions about exposure assessment details
- 5 February – deadline for all responses
  - Response to public consultation comments – 6 pages of text
  - Response to Committee questions
    - Extensive explanations
    - CSR revised
    - Spreadsheet calculations
    - Voluntary documentation of workplace studies

Challenges – Public Consultation

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- Calculations – asked clarification what was needed
  - ECHA's answer was to not do any new work, just send our spreadsheets. We chose instead to create clear, new spreadsheets useful for 3rd party study.
- Multiple AfAs in public consultation at same time
  - Time pressures on all contributors responding to multiple inquiries on multiple Applications all at the same time.

Challenges – Document Control

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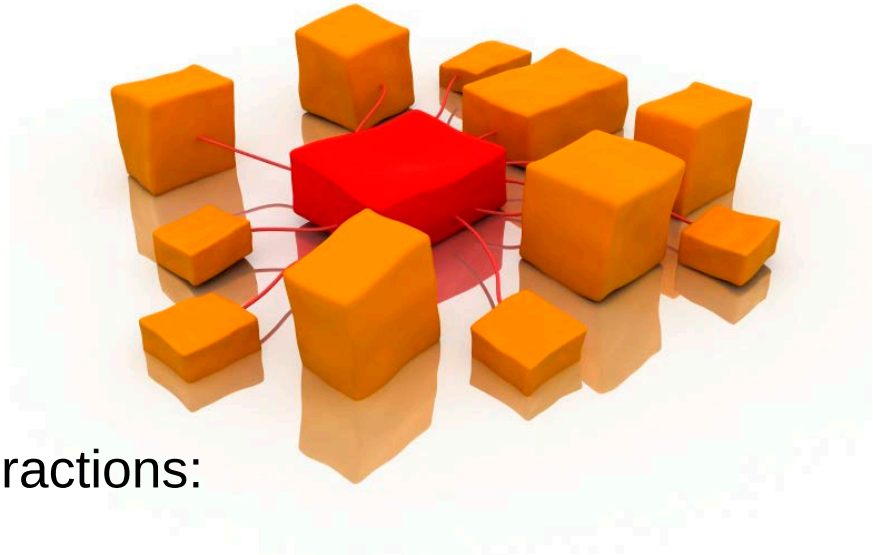
- Application dossier docs incorporate inputs from a wide variety of contributors:
  - Engineering
  - Commercial
  - EH&S
  - Legal
  - 3rd party consultants



- Set clear expectations of team interactions:
  - Primary penholder
  - Gatekeeper for sifting inputs – must speak to the penholder with one voice
  - Timeliness of feedback
- Help contributors to efficiently locate relevant and frequent changes within very large reports

Challenges – Confidentiality

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- Allow time for identification of what is confidential, why it must be included in the AfA, and why it must be protected as CBI.
  - R&D (plans and patentable info not yet published)
  - Licensable Intellectual Property
  - Product cost basis
  - Anything contrary to competition law
  - Customer/market information useful to competitors

- ECHA can disagree with confidentiality justification.
  - The sheer number of people who have access to confidential documents creates intrinsic risk in the practical assurance of CBI protection.
- Our approach was to write first drafts without distinguishing between confidential and non-confidential information, then parse later.
  - Is disruptive to the logical flow of the narrative, leading to redundancy in some cases and the appearance of unsupported leaps of logic in others.

Key Takeaway Ideas

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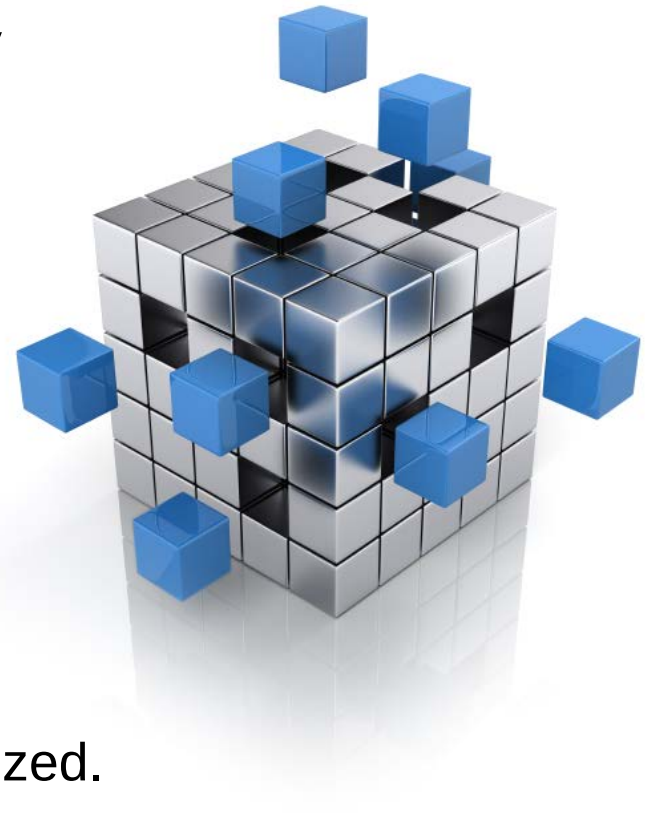
- Authorisation is a marathon, not a sprint.
- Clearly define the Use Applied For and why it is important.
- Treat as business critical.
  - Don’t outsource leadership
  - Commit appropriate resources
- Make strategic decisions early:
  - Adequate Control, SEA, both
  - CBI definition and handling
  - Transparency and depth of details
- Keep supporting documentation well organized.
- Assure resource availability for the post public consultation Q&A.



Thank You

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