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Lessons Learned: Successful Authorisation Under the Adequate Control Route

Use of DBP as an Absorption Solvent in an Industrial Process

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Helsinki, Finland

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Our Authorisation Journey

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Background

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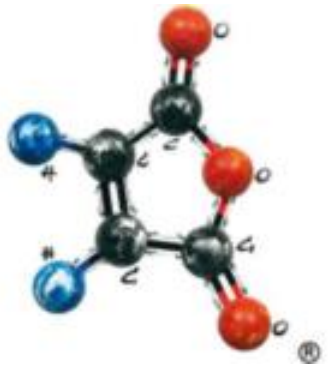
- Sasol-Huntsman is a 50/50 joint venture located in Moers, Germany, which produces only Maleic Anhydride (MA), using Huntsman technology.
- Huntsman is a U.S.-based global manufacturer and marketer of differentiated chemicals employing ~15,000 people at >100 facilities in >30 countries. Huntsman is a leading manufacturer of MA, catalyst for the manufacture of MA, and licensor of MA technology.



MA is a product of the partial oxidation of n-butane in air. MA is not a consumer product. Rather, it is a versatile building block chemical intermediate, essential to a broad spectrum of EU industry in hundreds of downstream uses.

MA Manufacturing Process
(the Use Applied For)

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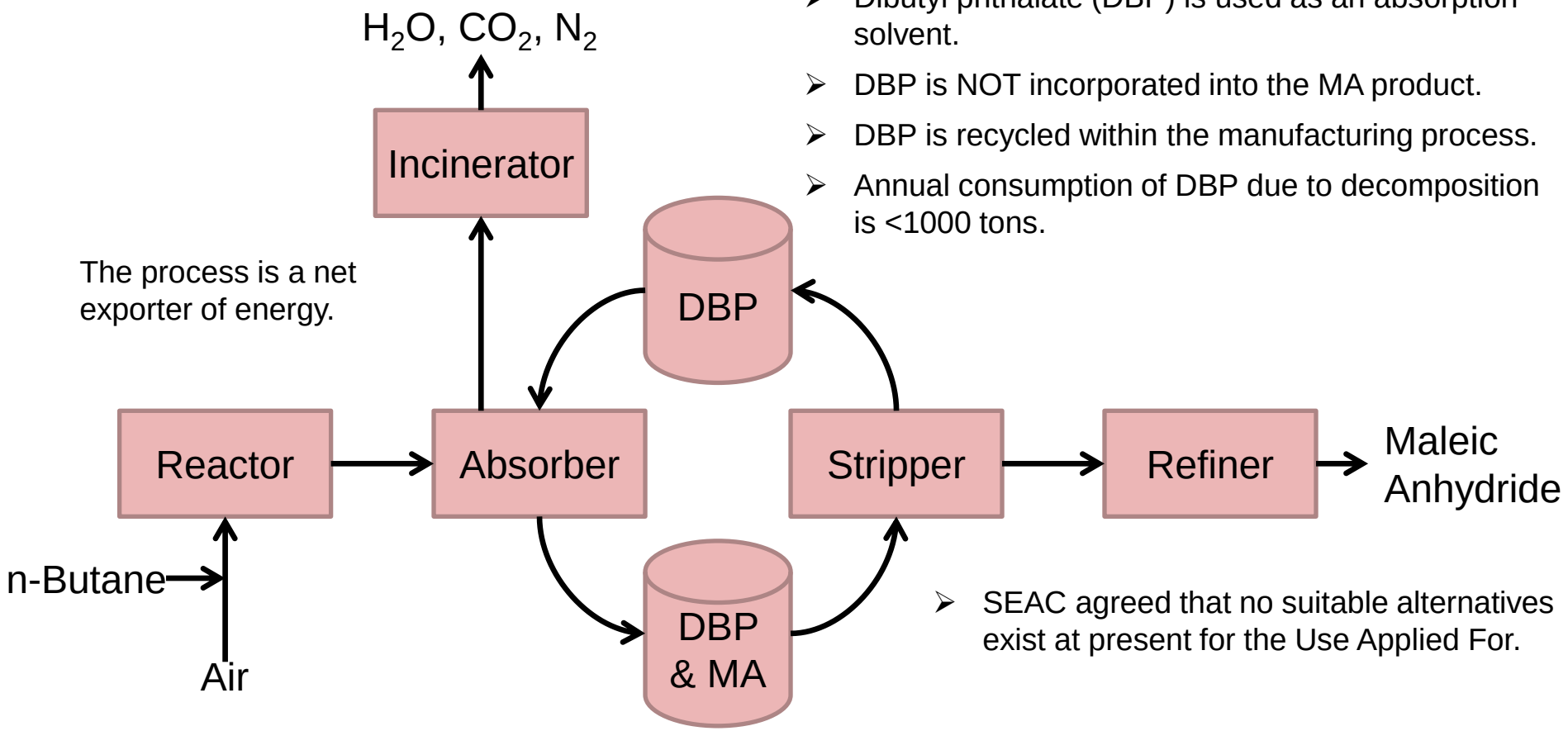

- Dibutyl phthalate (DBP) is used as an absorption solvent.
- DBP is NOT incorporated into the MA product.
- DBP is recycled within the manufacturing process.
- Annual consumption of DBP due to decomposition is <1000 tons.

- SEAC agreed that no suitable alternatives exist at present for the Use Applied For.

Our Application in Brief

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- Sasol-Huntsman applied as a Downstream User for the use of DBP as a solvent in the manufacture of maleic anhydride.
  - Deza (the EU's only DBP producer) also applied for the same use.
  - Sasol-Huntsman's AfA as a DU is redundant, but was motivated to protect the option to import DBP from outside the EU.
- Our Application for Authorisation demonstrated:
  - The Use Applied For is a closed industrial process. Potential exposure is strictly a workplace safety issue, which is expertly managed.
  - Despite clear evidence of Adequate Control, SEA was also performed to show the importance of MA to the EU economy.
  - Huntsman is actively engaged in research into potential substitutes, but DBP thus far remains the single best solvent for the Use Applied For.

Authorisation Timeline Highlights

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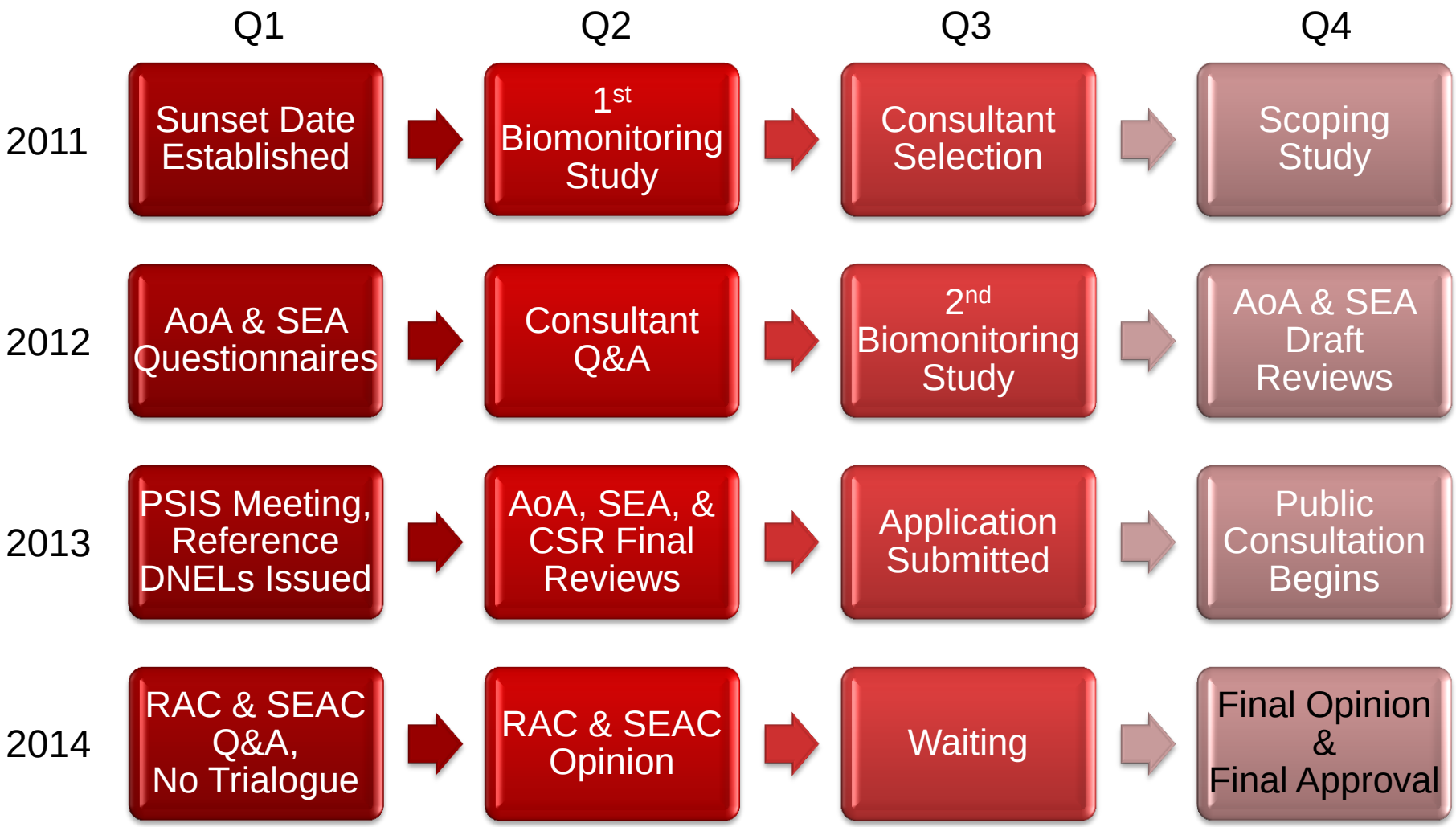

Facts & Figures

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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 >300 pages (AoA, SEA, CSR)
  - Simple, single use in a closed industrial process
  - 2 environmental contributing scenarios (ERC 4 & 7)
  - 3 worker contributing scenarios (PROC 1, 8b, & 15)
- Final approval by the European Commission on 18 December 2014
  - 12 year review period

Assuring Adequate Control

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- CSR exposure scenarios calculated by standard modeling tools showed Adequate Control.
  - We wanted validation of the models.
- 2011 screening study by German IPA confirmed workplace exposures to be safe. Patterns exhibited by different work groups illuminated opportunities for improvement.
  - Invited German Berufsgenossenschaft to inspect the plant and make independent recommendations.
  - Benchmarked DBP worker and environmental protection practices with two Huntsman MA plants in Florida and Louisiana.

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

BGW
Berufsgenossenschaft
für Gesundheitsdienst
und Wohlfahrtspflege

Workplace Exposure Benchmarking

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- Benchmarking amongst German and US plants revealed several “best practice” procedural and capital improvement opportunities:
  - PPE specifications and replacement protocols
  - Maintenance of DBP containing equipment
  - Sampling frequency
  - Closed loop sampling systems
  - Closed, back-flushing filters (2014 & 2015)
- 2012 follow-up biomonitoring study showed that median and 95th percentile exposures were reduced by more than half compared to 2011.
  - Commitment to minimizing potential worker exposures demonstrated by significant capital investment into additional improvements even after submission (and approval) of our Application for Authorisation.

Pre Submission Information Session

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- Don’t miss this opportunity for dialog.
  - Preview your dossier to ECHA to improve understanding of your key issues.
  - Clarify technical and procedural questions.
- Plan ahead.
  - Prepare questions in advance so answers can be properly considered and appropriate experts in attendance.
- Be prepared. ECHA will be.
  - We brought 8 team members.
  - ECHA was equally well represented.

Confidentiality

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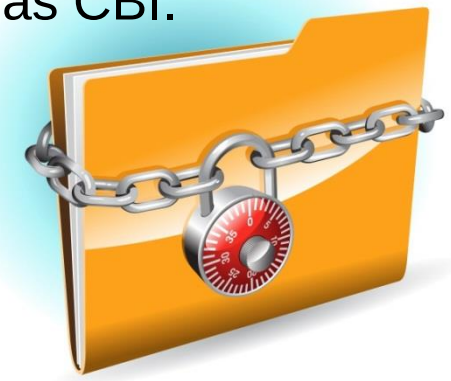
- Careful attention to identification of what is confidential, why it must be included in the AfA, and why it must be protected as CBI.
  - R&D (plans and patentable info not yet published)
  - Licensable intellectual property
  - Product cost basis
  - Customer/market information useful to competitors



- 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. Thus highly sensitive information should be included only if absolutely necessary and justification to protect as CBI is unquestionable.
- Our approach was to write first drafts without distinguishing between confidential and non-confidential information, then parse later.
  - Template structure disruptive to narrative flow, leading to redundancy in some cases and the appearance of unsupported leaps of logic in others.
  - Newer templates have already made substantial improvements.

Public Consultation

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- 8 January 2014 – public consultation closed
- 13 January – notified of 2 multipart comments
  - The same comments were made against Deza's analogous Application, plus a third comment, which was incomprehensible due to CBI exclusions.
- 20 January – notified of RAC & SEAC questions
  - 4 questions about alternatives, including details of calculations (requested spreadsheets)
  - 6 questions, multiple sub questions about exposure assessment details
- 5 February – deadline for all responses
  - No time to resolve confidentiality disputes. ATD not possible in time allowed, and request to delay was undesirable.

Decision Making

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- 5 February 2014 – responses to public consultation submitted
- 4 April – RAC/SEAC draft opinion issued
  - Recommended to approve, with 12 year review period.
  - 12 June deadline to comment; draft was promptly accepted.
- 11 April – final opinion of the RAC and SEAC
- Transparency and predictability lacking in subsequent decision steps
  - We were hopeful of attention by the REACH Committee at their June meeting, but waited until September.
  - REACH Committee opinion unanimously adopted 29 October.
    - One provision added to RAC/SEAC opinion, requiring documentation to be provided to authorities in German language.
  - "Commission Implementing Decision," dated 18 December, was recorded in the Official Journal of the European Union on 20 December.

Summary

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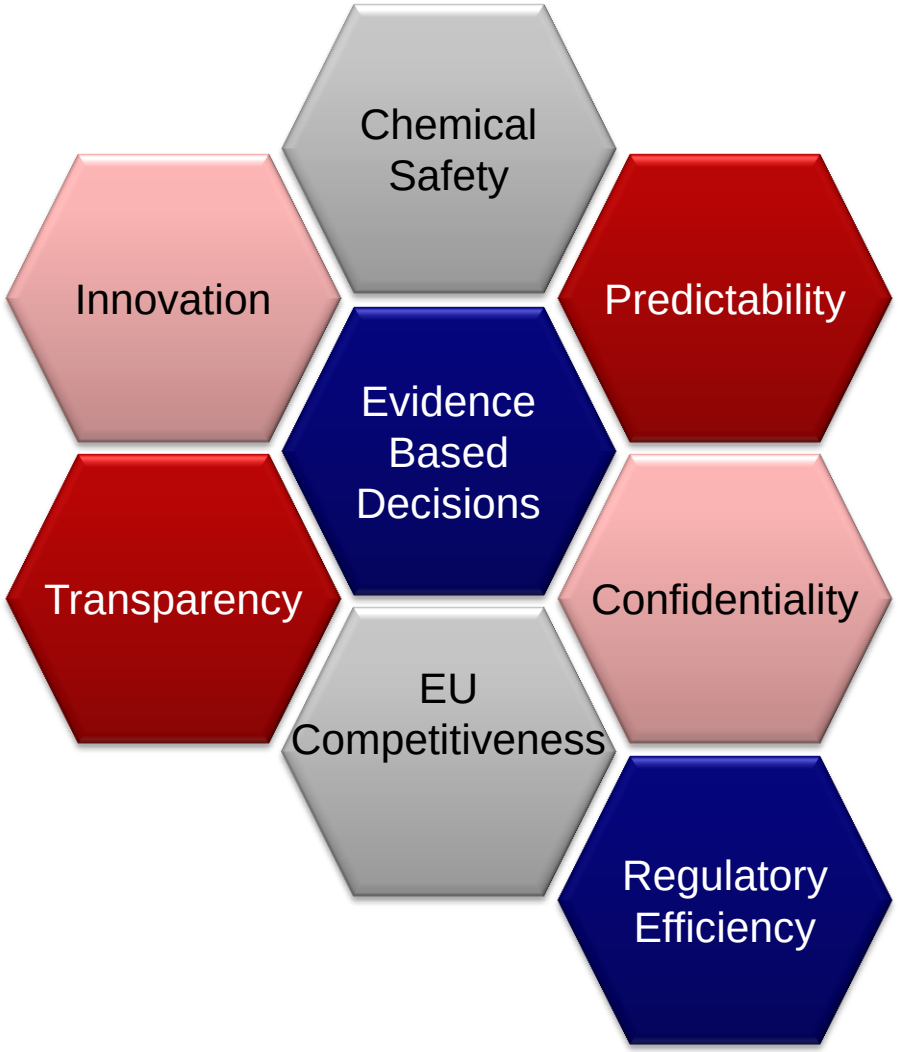
- Authorisation process is working and already adapting to early experience.
- Competing motivations (right) create ambiguity for Applicants trying to find a satisfactory balance.
- Continued focus areas include:
  - Confidential business information security and use.
  - Post public consultation period time pressures.
  - Commission decision-making process transparency.



Thank You

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