

How Industry Can Cooperate in Making an Application for Authorisation



8th Stakeholders' Day

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Cooperating for Authorisation

- ❑ Know your purpose
- ❑ Know your stakeholders
- ❑ Build a multiorganisational, multidisciplinary team
- ❑ Nourish the team
- ❑ Keep your eyes on the goal and the calendar



Introductions

HUNTSMAN

Enriching lives through innovation

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Enriching lives through innovation



SASOL
reaching new frontiers



Sasol-Huntsman

Huntsman is US based global manufacturer and marketer of differentiated chemicals employing ~12,000 people in 30 countries.

Sasol is a South Africa based integrated energy and chemical company employing more than 34,000 people in 38 countries.

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

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.

Socioeconomic Background

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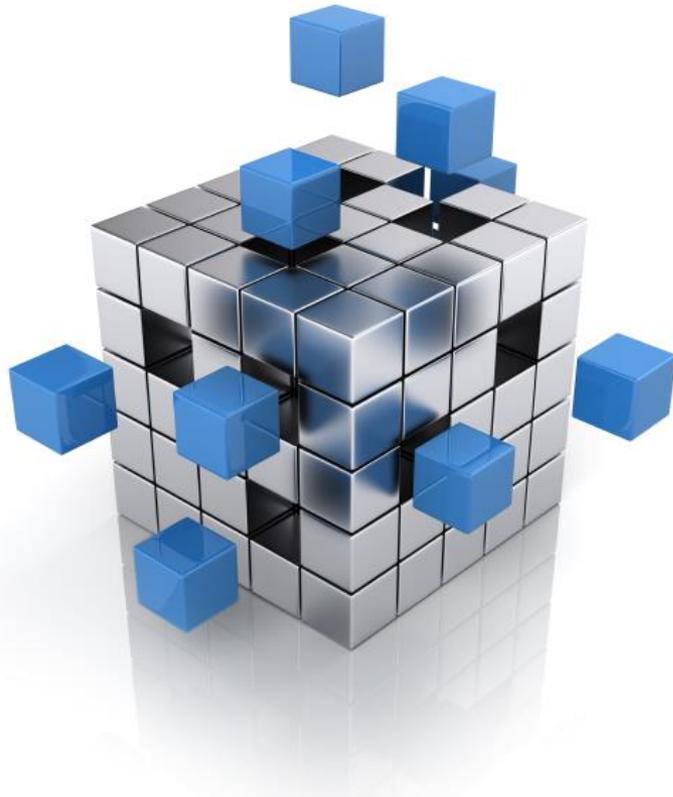
- ❑ MA is a versatile industrial intermediate essential to EU industry in hundreds of downstream applications
 - ❖ Half of EU MA goes into Unsaturated Polyester Resins (UPR). According to CEFIC, the EU UPR industry includes ~8000 companies and directly employs ~100,000 people. Value added to the EU economy is ~ €60 billion.
 - ❖ Other important MA uses include lubricants, paper chemicals, coatings, agriculture, and more
- ❑ Sasol-Huntsman is Europe's largest producer of Maleic Anhydride (MA)



Why Apply for Authorisation?

- ❑ Sasol-Huntsman will Apply for Authorisation to use DBP as a Solvent in the Manufacture of Maleic Anhydride
- ❑ Dibutyl Phthalate (DBP) is utilised as a solvent which is recycled within the manufacturing process
- ❑ DBP is not incorporated into the MA product
- ❑ DBP use as a solvent in the manufacture of MA is strictly a workplace safety issue, which is professionally and expertly controlled
 - ❖ Adequate Control is robustly demonstrated
- Our Application for Authorisation will show:
 - ✓ Our use of DBP clearly adds value to the EU economy
 - ✓ Risks related to this use are very small and well controlled

Diverse Resource Requirements



- ❑ Authorisation is a business critical project, not a health & safety department function
- ❑ Expertise must be engaged from across the business and extending to outside consultants
 - ❖ Engineering & Manufacturing
 - ❖ Process Safety
 - ❖ Product Safety
 - ❖ Product Applications
 - ❖ Sales & Marketing
 - ❖ Public Affairs
 - ❖ Senior Management
 - ❖ Legal & Regulatory
 - ❖ REACH

One Team – One Goal

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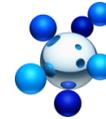
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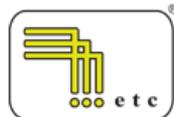
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RPA
Risk & Policy Analysts



BGW
Berufsgenossenschaft
für Gesundheitsdienst
und Wohlfahrtspflege



**EKOTOXIKOLOGICKÉ CENTRUM
BRATISLAVA s.r.o.**



FLEISHMAN[®]
INTERNATIONAL COMMUNICATIONS
HILLARD



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



Communication is Critical

❑ Central coordination is vital, but cannot become a barrier

- ❖ Technical experts
- ❖ Health & safety experts
- ❖ Customer-facing experts
- ❖ Business leadership
- ❖ REACH experts
- ❖ Public affairs
- ❖ Legal experts
- ❖ European Commission
- ❖ Member States
- ❖ ECHA



❑ Each actor has different needs and different outputs

❑ Interdependencies can impact schedule

How is it Working?

- ☺ **Excellent team dynamics**
 - ✓ Open communication
 - ✓ Organizational barriers minimized
 - ✓ Everyone is an owner
- ☺ **Competent consultants are critical and very helpful**
- ☺ **Good use of communication channels is essential**
 - ✓ Email
 - ✓ Telephone & teleconference
 - ✓ Face-to-face
- ☺ **ECHA has shown flexibility**
 - ✓ Seminars & workshops
 - ✓ PSIS meetings
 - ✓ Post-consultation dialogues

- ☹ **Template structure imposes too much redundancy and impairs clarity**
- ☹ **Lack of clarity in Authorisation decision criteria leads to excessive analysis**



Suggestions for Industry

- ❑ Don't underestimate the effort required.
- ❑ Involve actors beyond the scope of their individual roles to reinforce a sense of common purpose.
- ❑ Conduct regular teleconferences and progress meetings.
- ❑ Bring your consultants to your plant – and not just the managers. The individuals writing your reports should have an opportunity to see the world through your eyes.
- ❑ Manage the process to ensure a pro-competitive outcome



Suggestions for ECHA



- ❑ Improve the transparency of RAC, SEAC, and Commission decision-making processes
- ❑ Establish criteria framing how the RAC will judge the “suitability” of alternatives
- ❑ Establish criteria framing how the SEAC will weigh unrelated factors
 - ❖ Industry will be less inclined to produce 100-page analyses if it is known what is needed in the 10-page analysis ECHA wants
- ❑ Consider revising the definition of “Intermediates” to allow for the exclusion of uses which contribute to the manufacture of Intermediates

Conclusions - Preparing to Apply

- ❑ Start early
- ❑ Own the process
- ❑ Confirm that your use is important and its risks are small
- ❑ Build a team without silos
- ❑ Take advantage of ECHA's opportunities to interact



Thank You

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