

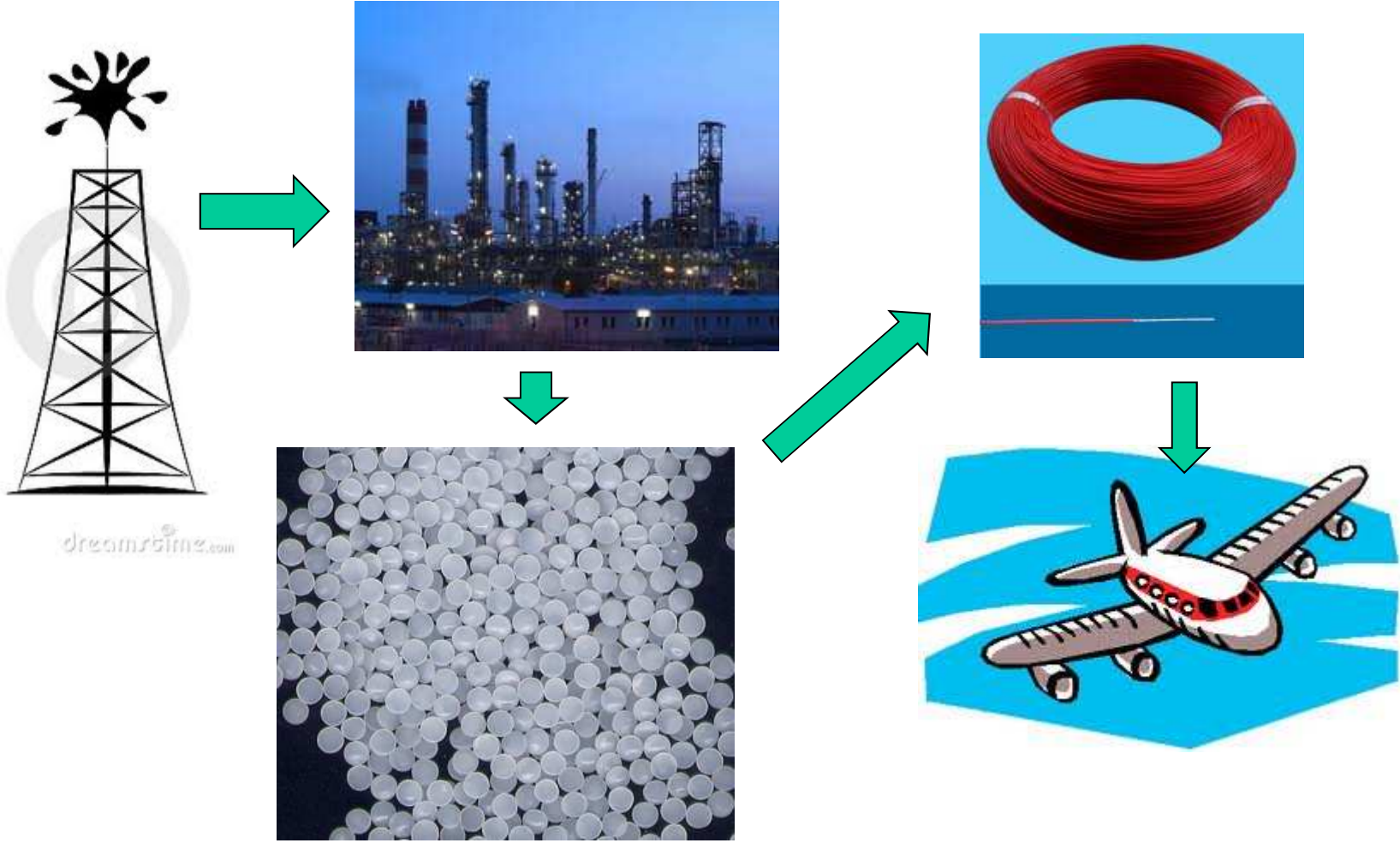
Exposure scenarios and communication in the supply chain in REACH

– key issues for downstream users 23 January 2013
Workshop on Airworthiness and REACH Authorisation

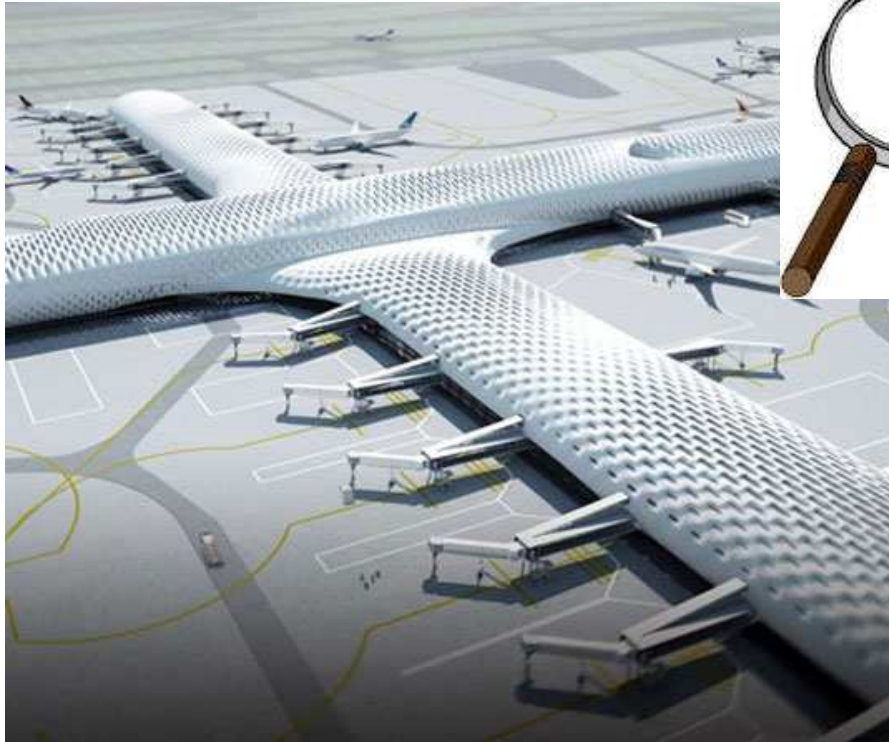


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Complex communication in supply chains



Complex communication in supply chains



REACH in a nutshell



- A producer/importer **registers** a substance and pays a registration fee and letter of access (no data, no market)
- Information is **disseminated** on the ECHA website, except confidential information
- **For all uses** (covering the entire supply chain) up to end-of-life
- These uses are covered by the **chemical safety assessment** (if substance > 10 ton per year)
- If substance is dangerous **exposure scenarios** (ES) must be worked out (including operational conditions (OC) and risk management measures (RMM))
- These ES will be added to the **extended safety data sheet**
- The Agency and Member States can **evaluate a substance**
- Substances of very high concern can lead to an **authorisation** process and and with the ultimate aim of substitution
- Substances with unacceptable risk to human health and environment can go into **restriction** of their allowed uses

Chemical safety assessment



- According to the volumes manufactured or imported different information requirements are asked for substances
- This information is used to make a chemical safety assessment of that substance
- Different aspects are considered in the hazard assessment
 - Human health (e.g. acute toxicity, carcinogenicity)
 - Environmental (e.g. toxicity for fish)
 - Physico-chemical (e.g. flammability)
 - PBT – vPvB (e.g. accumulation in nature, persistence)

Chemical safety assessment



- All these aspects are compared with the rules of classification to conclude whether a substance is classified in a certain hazard category or not
- This information is used as well to find the safe concentration where no negative effects are seen for human health or the environment
- In some case it is not possible to derive safe concentrations (e.g. for non-threshold carcinogens and PBT/vPvB)

Chemical safety assessment



- If a substance is hazardous, then the exercise goes further with a risk assessment
- Every use of the substance has to be checked to estimate what is the exposure to
 - Humans
 - Workers
 - Consumers
 - Environment
- The use is considered adequately controlled if the exposure is below the safe concentration
- If this is not the case, additional layers of protection have to be added to ultimately come below the safe concentration

Safety data sheet and exposure scenario



- The outcome of this chemical safety assessment is communicated in the chemical safety report
- This very scientific document is « simplified » in the exposure scenario and the safety data sheet
 - The safety data sheet contains this information in a structured form and is already mandatory in the EU since 1991
 - The exposure scenario gives information, use by use what are the operational conditions and the risk management measures to be taken in order to guarantee no negative effects for human health and the environment

Safety data sheets for mixtures



- The manufacturer of a mixture (e.g. a lubricant) is using the safety data sheets (and since REACH the exposure scenarios) from the individual substances to establish a safety data sheet for the mixture (if hazardous or containing certain hazardous substances)
- REACH is only adding more information on substances, a more uniform approach **and the obligation to implement the safety requirements mentioned in the safety data sheet, otherwise you are not allowed to use the substance or the mixture**

Differences between REACH and previous legislation



- As a downstream user you have to check the operational conditions and risk management measures communicated in the safety data sheet and implement them
- If you don't have them in place you have different possibilities:
 - Implement them
 - Persuade your supplier that your use is adequately controlled and he updates his eSDS
 - Prove that your situation is still adequately controlled and inform ECHA
 - Stop using the substance/mixture

And for authorisation?



- **For substances identified as substances of very high concern, and prioritised and taken up in the authorisation Annex, an authorisation is needed to continue the use in the EU**
 - **As a substance**
 - **As a substance in a mixture**
- **The chemical safety assessment will be looked at in much more detail**
- **Applicants may consider to define their uses more precisely than under the registration; this may result in different exposure scenarios**
- **But some uses remain very comparable**
- **Downstream users have to notify their use after granting the authorisation**

And for authorisation?



- **Is there a difference between chromium plating of an aeroplane and a car? Or any other article?**
 - **Some fundamental questions need to be answered:**
 - **Are you using the same operational conditions and risk management measures?**
 - **Is the exposure to workers, consumers and the environment the same?**
 - **If so the socio-economic impact may still be different**

Unique?



- **Before REACH every use of every substance was unique, confidential and should have been handled separately**
- **Since REACH and the related costs, confidentiality is now used for real confidential uses**

One key message



- **Look what you have in common and find allies, rather than being unique in the world and hence confronted with all costs yourselves. Find the subtle equilibrium!**



Thanks for your attention