# Reduction of risk as a result of the authorisation requirement and the opinion development

## Implementation of REACH authorisation

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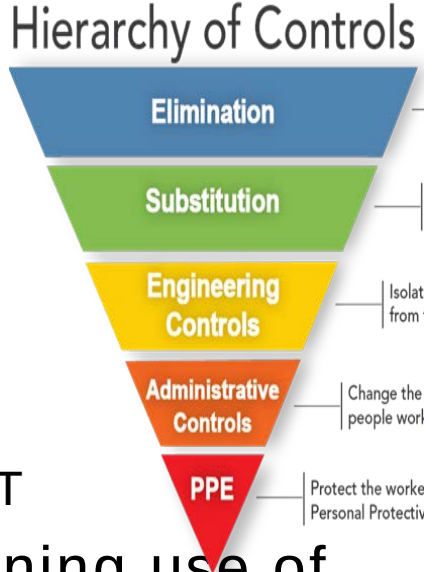
# Authorisation process starts with SVHC identification…

- Public Activities Coordination Tool (PACT) – lists 'substances of interest' and current RMOA activities
  - https://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/substances-of-potential-concern/pact

- SVHC identification (Candidate list) and prioritisation (Authorisation List) development

  → stimulus for the industry to analyse their chemical use and consider substitution possibilities

# Stimulus for substitution




- No applications submitted for 7/31 (23%) Annex XIV substances
  - musk xylene, MDA, DIBP, BBP, $As_2O_5$, TCEP, 2,4-DNT
- Only one application submitted for one remaining use of MOCA
  - Ca. 70% already substituted
- About 25-30% of applicants requested an authorisation as a 'bridge' to phase out the use
  - Innovation related to use of better, less harmful substances
  - Innovation related to production technology
- Applications are submitted for difficult-to-substitute uses

➢ **Overall reduction of exposure to SVHCs is observed**

# Increased awareness, resulting in changes at the workplace

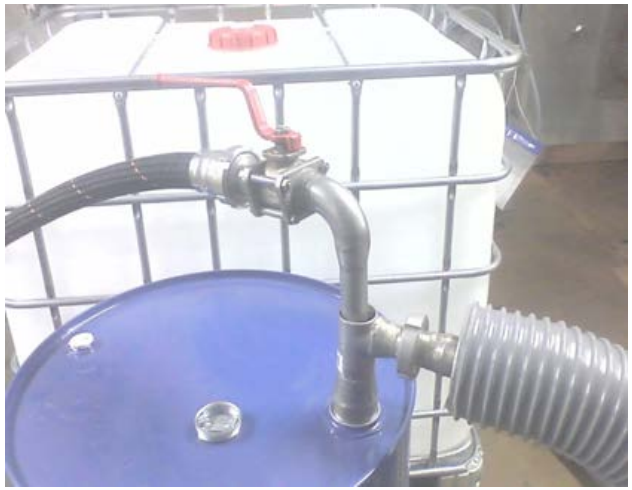
- Authorisation has stimulated fresh workplace exposure / emission investigations
  - Nearly all downstream applications report new (2013-2016) campaigns to measure exposure
  - Assessment of exposure increasingly based on measured data (including upstream ones):
    - More use of biomonitoring data when available
    - Less reliance on modelling at least for inhalation

- As a result of monitoring and re-assessment of the workplace, many applications describe:
  - Completed improvements to RMMs,
  - Implementation of new RMM's while preparing the application
  - Planned improvements

# RAC asessment of the applications…

- In approx. 75% of cases – additional conditions and monitoring arrangements are recommended to adress various concerns:
  - Uncertainties and lack of reprentativeness of exposure estimates
  - Appropriateness and effectiveness of RMMs implemented
- Conditions may require:
  - Periodic monitoring of exposure or emissions with further review of OC and RMM
  - Implementing / upgrading of specfic RMMs, to reduce exposure / emissions
  - Up-stream AfAs: developement of more representative ES, by DUs to measure their exposures and validate the effectiveness of OC and RMM

# Examples of RMM improvement?



# First observations related to review reports (1)

- A number of expiring authorised uses of HBCDD, DEHP, DBP, TCE, $As_2O_3$, lead-chromate pigments have not been re-applied for
- First (few) uses re-applied for:
  - Scope of the use has been narrowed down
  - Quantities used have decreased
  - Exposure estimates are now based on measured data

# First observations related to review reports 2

- The Article 66 DU notification process has started to function well in conveying specific information from the DUs to the upstream authorisation holders (and ECHA)
- ECHA expects that further reduction of risks will be observed with an increased level of certainty in the review reports via
  - the implementation of safer alternatives
  - improved OC and RMM leading to lower exposures

ECHA
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# Thank you!

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