



**Royal
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Enhancing Society Together

Caught in a pincer

*The apparent do's and don'ts in EU risk
assessment and their scientific merit*

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Agenda

- The pincer
- Our case
- The hazards and their assessment
- Risk
- Exposure assessment
- Conclusion

Caught in a pincer

- Risk assessment is a two step process
- Step 1: hazard assessment,
 - Assess if a substance is hazardous
 - Determine dose effect relationship
 - Determine limit value
- Step 2: exposure assessment
- The Pincer:
 - Authorities overestimate hazard
 - Exposure models overestimate emissions and underestimate effectiveness of risk management measures

Our case PY.34 and PR.104

- Lead & Hexavalent chromium → cause for concern
- 2010: Harmonized classification as CMR based on read across from highly Lead Chromates
- February 2012: Placed on Annex XIV of REACH, → authorization needed for further use inside EU after sunset date
- November 2013, Authorization dossier submission
- February – April 2014, Public consultation
- May 2014 Trialogue
- June – November 2014 RAC & SEAC discussion
- Draft opinion anticipated mid December
- Final recommendation Q 1 2015
- Expected MS decision Q4 2015

Our case PY.34 and PR.104

Authorisation process

- Analysis of alternatives
Show that no alternatives are available
- Hazard assessment
Determining relevant limit values
- Assess level of control & exposure
- Socio-economic analysis
Show that benefits of use outweigh benefits of non use scenario

Our case: PY.34 and PR.104

- Very poor solubility of lead-sulfochromate pigments
 - Industrial & professional uses only
 - Specific technical function → no one on one replacement
 - Well known supply chain
 - Anticipated level of control high
 - Volumes used are known
- Convincing case seemed plausible

The hazard

- No epidemiological smoking gun for C.I. PY 34 & C.I. PR 104
- Fight on classification long since lost
 - Authorities do not apply basic read across rules
“when in doubt, choose the highest hazard”
- Cr(VI) & Pb deemed non threshold → no safe exposure, Derived Minimum Effect Level (DMEL) needed
- REACH → registrants assess hazard, derive DMEL
 - Allows the use of all scientific data
 - In authorization RAC assess the risk → stipulate dose-effect relationship
 - Separate DMELs for Cr(VI) and for Pb⁺⁺

The hazard - ChromiumVI

- 2 possible mechanisms
 1. CrVI → enters cell → reduced → CrIII → genotoxicity
CrVI → reduced → CrIII → cannot enter cell → no genotoxicity
 2. Very poorly soluble respirable particles
→ long clearance time → massive # particles → inflammation → cancer
- Mechanism 1
 - Chromates associated with human lung cancer are all highly soluble
 - Solubility is key to bioavailability → conservative assessment factor 40
 - Rapid reduction of CrVI
in lung interstitial fluid / gastro intestinal tract is likely
 - Higher DMEL is justified
 - not accepted by RAC
- Mechanism 2
 - our suggested DMEL & respirable fraction → 5000 respirable particles / day
 - Deutsche Forschungs Gemeinschaft set health based OEL,
biopersistent respirable particles → 0.3 mg/m³
→ 4,500,000 respirable particles

The hazard - Lead

- Wide variety of health effects
- Adult worker accepted blood level 40 $\mu\text{g}/\text{dl}$ male workers
20 $\mu\text{g}/\text{dl}$ female workers (reprotoxic effect)
- Children BMDL01 developmental neurotoxicity
 - Blood-Pb level = 12 $\mu\text{g}/\text{dl}$
 - DN(M)EL of 5.8 $\mu\text{g}/\text{m}^3$
 - women of childbearing age

Conclusion hazard

- Scientific arguments for higher DMEL, leading to decrease of risk ignored or not accepted
- Additional oral cancer risk for mucociliary clearance of non respirable Cr(VI) included by RAC
- Dose response curves overestimate the risk
- DMELs Cr(VI) set at additional risk of 10^{-6} / year (overestimated value)

Risk

Individual worker risk

- Exposure x Duration → individual risk

Population

- Individual risk x Population exposed → Population risk

Exposure assessment

- No usable exposure measurements available
 - Lack of contextual information → OC and RMM
 - No information on activities performed
 - No information on volume handled
 - Some biological test result (in blood)
 - All indicating no or very limited exposure (within bandwidth general population)
 - Usefulness limited
 - no information on frequency & duration of exposure
- Exposure modelling

Modelling exposure

- Advanced REACH & MEASE tool used
 - Detailed description of operational conditions
 - Allows for application of hierarchy of control
 - Realistic conservative effectiveness of Risk Management Measures, e.g. containment, ventilation
 - Select the percentile → 90th
 - Dustiness information
 - Particle size & effectiveness of RPE applied outside of models
- Modelling results
 - Individual worker risk minimal (10⁻⁷ and 10⁻⁹ per year)
 - Additional EU population risk < 10⁻⁴ per year
 - Level of protection for spraying & manual handling dust heavily dependent on RPE (APF of 40 - 200)

End result

- Risk assessment seems acceptable
High APF problematic
- We are convinced that risk is overestimated
- Shown generally accepted risk is achievable when applying good working practices
- Increase of level of protection of EU workers
- Huge benefit to society if authorization is granted

