# Specific issues from RAC and SEAC

Workshop on Streamlining Applications for Authorisation

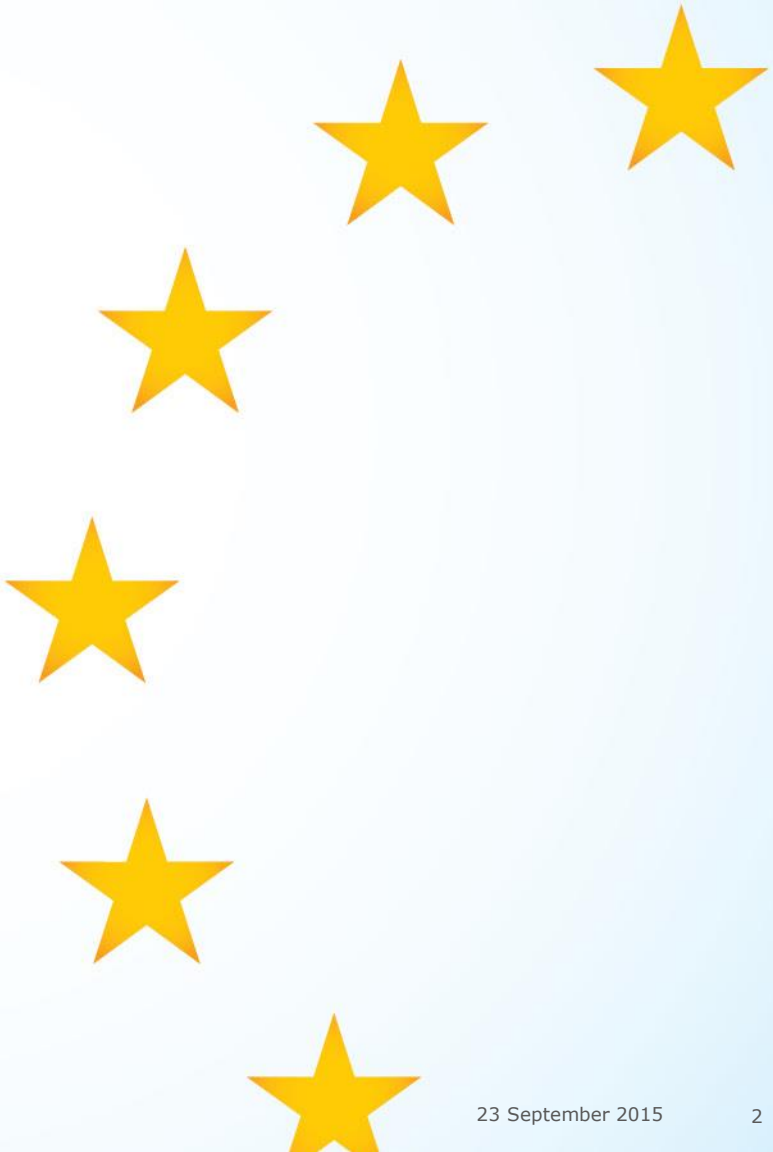
17 November 2015

*Tim Bowmer*

European Chemicals Agency, Helsinki

# Outline

- Summary of RAC experience
- Summary of SEAC experience
- “Fit-for-purpose” applications

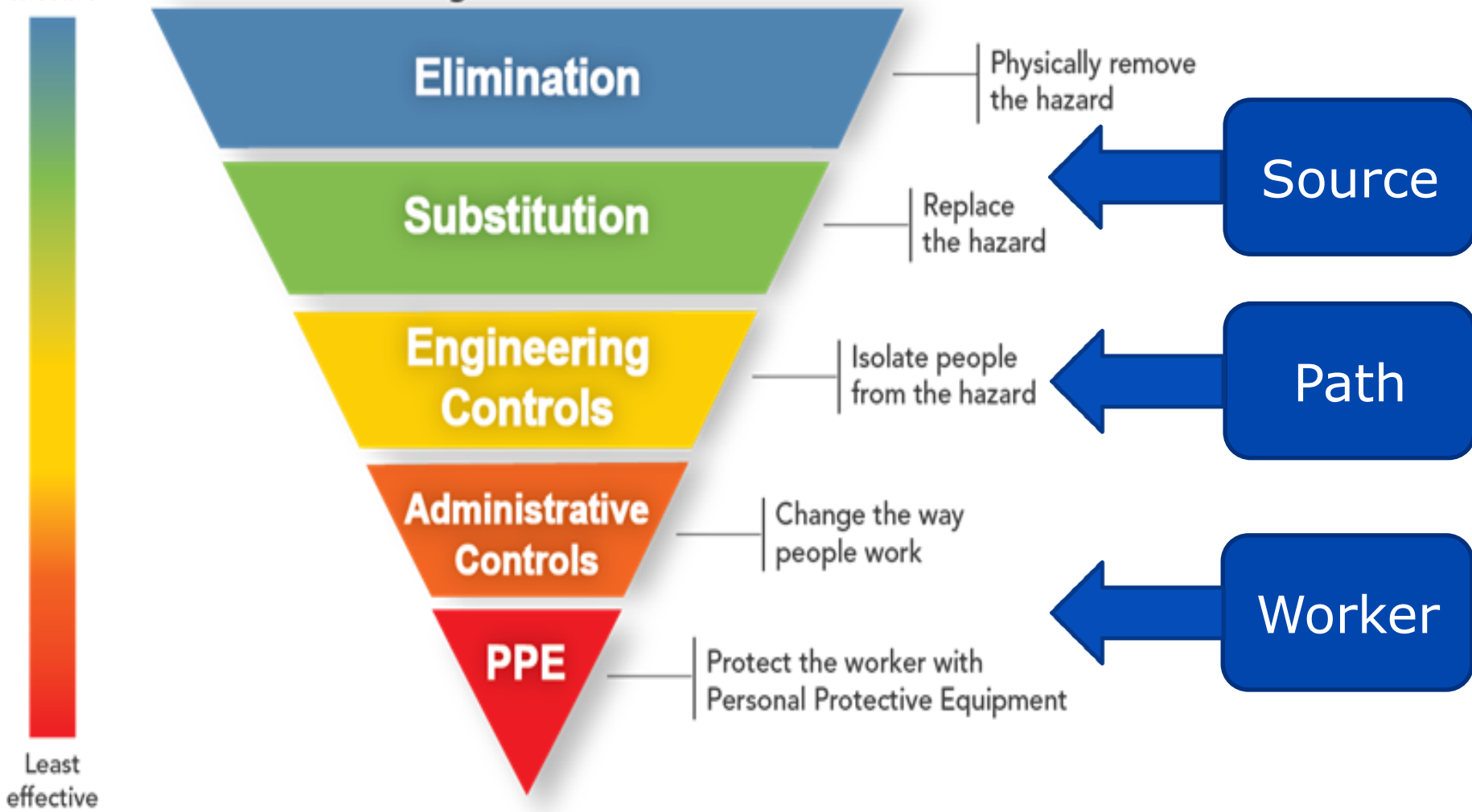


# Summary of RAC experience

# General findings

- Essential safety information in CSR **should not** be claimed as confidential – hinders evaluation
- Deviations from RAC Reference DNELs or dose-response curves have not generally been well justified
- Information on the hazard and especially the risk of alternatives often only poorly developed

# Hierarchy of Controls




Source: NIOSH

# It is critical that RAC understands the process(es) and the respective RMM's

- Include descriptions, diagrams, photographs & videos– do not assume prior knowledge
- Address all relevant exposures e.g. inhalation, dermal, exposure via environment
- Describe the frequency, duration and overall sequence of activities / tasks
- Who performs each of the tasks – is there potential for shift-long, combined, exposure?
- Identify and clarify situations where the usual RMMs may not work (e.g. maintenance, cleaning, sampling, laboratory …)

# Operating Conditions & Risk Management Measures 1

## Engineering controls

- Use of closed (and automated) systems:
  - Often claimed - but not always substantiated based on monitoring. May still need to be combined with other RMMs to ensure control of exposure (e.g. types of ventilation, enclosure)
  - Do manual tasks still occur with potential for exposure?
- General and Local Exhaust Ventilation (LEV): is not always sufficiently described (e.g. location, effectiveness, maintenance, exhaust treatment)

# Operating Conditions & Risk Management Measures 2

- **Administrative and organisation controls**
  - Training, maintenance, supervision, access restriction, hygiene
- **Use of Personal Protective Equipment (PPE)**
  - Justification for the selection of specific PPE not always provided – filter type / glove type
  - Over-reliance on high-efficiency PPE equipment (is it feasible to work in for long stretches and effective?)
  - Is PPE properly maintained and replaced as necessary?

# Exposure assessment

- Exposure measurements preferred
  - often sparse – contextual information is often missing or incomplete
  - LOD/LOQ, number of samples, duration of sampling, task performed during sampling, static or personal, uncertainty (mean vs 90$^{th}$ percentile)
- Exposure modelling - useful and could have improved several cases considerably
  - Often reported insufficiently (input parameters missing / incomplete)
  - Overreliance on Tier I (screening) models
- Biomonitoring useful where an appropriate method is available
- Express exposure and risk with and without PPE
  - if only with PPE, then specify and document the efficiency of the equipment

# Reality check…

*Identify and clarify situations where the usual RMMs may not work (e.g. sampling, maintenance, cleaning, laboratory …)*

# Summary of SEAC experience

# General

- Applicants are increasingly focusing on the business reasons for applying in their AoAs and SEAs
  - When the key business drivers are clear to SEAC, this facilitates the evaluation
- Most applicants have used the RAC reference values
  - Simplified the applicants' work and facilitates SEAC when evaluating the health impact assessment and valuation
- Many have carried out a full cost-benefit analysis and provided the spreadsheets
  - Helped SEAC to evaluate and draw conclusions for their opinion
- There are still transparency issues around data sources, assumptions and methodology, particularly in relation to the assessment of costs in the non-use scenario
  - SEAC should be able to trace data and reproduce the results

# Analysis of alternatives (AoA)

- The analysis of the existing alternatives should be based on the applicant's context, in terms of technologies, markets etc.
- Identification of alternative substances and technologies
  - Some applicants have not explained
    - how the short-list of alternatives was derived
    - if the function of Annex XIV substance could be replaced
    - why some "sub-uses" could be substituted while others not
- Assessment of alternatives
  - Time and resources to transition to an alternative not sufficiently well justified
  - Commercially available alternatives sometimes not included in the analysis
- AoAs were not always used as the basis for defining the non-use scenario in the SEA

# Socio-economic Analysis (SEA)

- The non-use scenario did not always seems credible
  - "Shut-down" or "complete relocation" not analytically supportable
  - Include a discussion of the applicant's options – what would be the impacts of changing to an alternative?
- Some applicants have not focused on net costs
  - If an operation is closed down, there will be "savings" as well
  - An alternative could be more expensive but result in some gains (e.g. in energy consumption or quality)
  - Double counting of costs along the supply chain should also be avoided
- Some applicants have estimated the cost of unemployment based on lost salaries
  - But the freed up labour cost can be spent on other economic activities. For the truly involuntary unemployed, social cost is less than wage
- Some applicants have estimated the loss of revenues
  - This would inflate the losses (as the expenditure would go down too). Loss of e.g. net margin or net operational profit would be a more accurate comparator.

# Concluding on impacts

- Impacts were not always analysed from society's perspective
  - The use of a substance might be critical to one company, but its suppliers, customers or competitors might easily do without it
  - Lost revenue of someone in the supply chain may be compensated by increased revenue of those supplying or using the alternatives
- Assumptions and uncertainties not always recognised
  - Uncertainty does not in itself invalidate the conclusions but they need to be described and, where possible, minimised
  - An uncertainty analysis tests whether different assumptions or estimates could affect the conclusions and, if so, how significant this effect may be.
- Many applicants have justified their review period requests
  - SEAC looks at every application with the "review process" firmly in mind
  - Linked to availability of alternatives and timeline for substitution
  - Recommend a short review period where there are significant uncertainties in CSR, AoA or SEA

# “Fit-for-purpose” applications

# How the committees derive review periods

- RAC assesses the risks and the uncertainties of the CSR. To a large extent, RAC's message to SEAC is concerned with the uncertainties
- SEAC accounts for the uncertainties highlighted by RAC and those from the SEA and AoA in their opinion, mainly in the recommendation on the length of the review period.
- The normal review period is 7 years
- Large uncertainties in the RAC and/or SEAC evaluation lead to a shorter review period. Too large uncertainties could result in rejection or non-evaluation.
- Less uncertainty combined with a clear motivation can lead to a long review period

# What might be considered a ”fit-for-purpose” analysis?

- Balanced and fact-based – conclusions are well justified
- Focuses on the factors that are likely to make a difference
- Not overly complicated, especially when the risk/benefit ratio is high and robust
- Uncertainties are recognised, described and their consequences are analysed
- Sufficient information is provided to reproduce estimations and calculations

# Fit-for-purpose in RAC

- Provide clear descriptions and illustrate the process and the worker activities covered in the exposure scenarios
- Describe all RMM in place to control/minimise exposure
  - OC, RMM: engineering, administrative and PPE, effectiveness where appropriate
- RAC has a strong preference for measured data
  - Supplement limited measured data with modelled values - try and corroborate
  - Include contextual information alongside monitoring data and all input parameters for modelling

# Fit-for-purpose in SEAC

- Descriptions of technical functions in AoA should be concise and meaningful for non-experts
- Briefly describe any shortlisting criteria and process
  - No need to list thousands of substances
  - Equally or more hazardous alternatives in general should not be shortlisted
  - Include alternative substances and technologies used by competitors
- A comprehensive risk assessment of an alternative is not needed except where the alternative is technically and economically feasible (but riskier)
- The economic feasibility assessment can be based on typical costs within a sector. Detailed specifications for new plants are not required.
- Describe your substitution efforts to substantiate the requested review period

# Fit-for-purpose in SEAC

- The analysis of alternatives should be the basis for developing non-use scenarios but adopting an alternative does not need to be the most likely non-use scenario
  - The joint AoA/SEA format supports the link between the two reports
- Justify the selection of the most likely non-use scenario and focus the analysis of socio-economic impacts on that
  - The key arguments should be clear without lengthy text
  - Calculations should be clear to SEAC, e.g. by providing spreadsheets
- Focus on demonstrating that the benefits of continued use outweigh the risks
  - The lower and more certain the health and environmental impacts of continued use are, the less effort is required when estimating costs

# Making a recommendation on an application…

***Adequate control route*** (threshold substances)

- *The risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled (RCR<1)*

***Socio-economic route*** (non-threshold substances or adequate control not supported)

- *The socio-economic benefits outweigh the risks to human health or the environment, and*
- *no suitable alternative substances or technologies are available*

# What do RAC and SEAC evaluate?

**RAC formulates its recommendation on the basis of:**

- The risks posed by the use (and the alternatives), including the hazard and exposure assessment
- Appropriateness and effectiveness of risk management measures (RMM) in place
- Achieving adequate control or minimisation

**RAC may recommend:**

- Additional conditions
  - Related to continued use of the substance e.g. review and/or improvement of RMMs
  - Related to the review report, e.g. monitoring

**RAC communicates its concerns regarding the risks and the uncertainties to SEAC**

# What do RAC and SEAC evaluate?

**SEAC evaluates and formulates its recommendation on the basis of:**

- Whether the socio-economic benefits of authorisation outweigh the risks of continued use (when the risks are not adequately controlled)
- The technical and economic feasibility and availability of alternatives
- The length of the time-limited review period requested by the applicant

# Outcomes: in a worst case

- RAC and/or SEAC may not be able to evaluate an application
  - Has already occurred
- RAC may decide that there is no adequate control – SEA route follows and exposure minimisation
  - Has already occurred
- SEAC may not support the granting of an application for authorisation
  - Not yet the case, but some applications have had recommendations for shorter review periods than 4 years

# Fit-for-purpose in RAC:
## Upstream/umbrella applications

- May cover one large business or multiple unconnected businesses
- Usually cover multiple sites and workplaces
- One use may cover wide variations on the same process in terms of scale (size, workforce and geography), technology and RMMs
- Difficult to evaluate without representative exposure scenarios
- Representative data is needed to cover the scale, process technology and the diverse RMMs in place
- Explain how the data provided adequately represents the expected variability in exposure
- In short, address the uncertainties adequately

# Thank you

Subscribe to our news at echa.europa.eu/subscribe

Follow us on Twitter
@EU_ECHA

Follow us on Facebook
Facebook.com/EUECHA