Experience in the Committee for Risk Assessment

Lessons learnt on Applications for Authorisation

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What do RAC and SEAC do with Applications for Authorisation?

RAC and SEAC decide on conformity

RAC recommends:

- on adequate control for threshold substances
- on whether the operational conditions (OC) and risk management measures (RMM) in place are appropriate and effective in limiting the risks from non-threshold substances
- on additional conditions such as monitoring arrangements

RAC advises SEAC:

- on any need to alter the review period from the standard, primarily due to remaining risk concerns (SEAC makes the final recommendation)

Making a recommendation on granting an authorisation…..

Adequate control; 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,

No adequate control, e.g. non-threshold carcinogens, PBT/vPvB

- The socio-economic benefits outweigh the risk to human health or the environment, and
- no suitable alternative substances or technologies.
- An evaluation of *"the risks posed……, including the appropriateness and effectiveness of the risk management measures proposed"*

What does RAC look for in an evaluation?

- The hazard of the substance – intrinsic properties from Art. 57 a-f (see RAC Reference Values below)
- A description of the industrial process and its operational conditions, in the context of representative workplaces
- The risk management measures currently in place
- Review the exposures - who is exposed to what, where, for how long and how often (inhalation and dermal)
- Review the risk estimates presented by the applicant
- The risks of alternative substances or technologies – usually using comparison of hazard as a surrogate

RAC Rapporteurs experience: General

- It is critical that RAC can understand the process (see next slide) – diagrams, photographs, videos, all help
- Evaluation of applications was complicated by unrealistic confidentiality claims (90% of some CSR's)
  - ECHA's security practices unnecessarily triggered, preventing printing (solved in the meantime) etc.
  - Where the RAC Reference values (DNEL's/DR curves) were not used – the justification for other values was insufficient, e.g. not in line with ECHA Guidance
- Information on the hazard and risk of alternatives was often lacking or only poorly developed
- Trialogues have been useful in clarifying details - occasional new information
- Timelines are short, for the applicants and for RAC

RAC Rapporteurs experience: OC and RMM

- Closed systems
  - often claimed but not always substantiated
- General and Local Exhaust Ventilation (LEV)
  - Is not always specified in terms of siting, and effectiveness
- Description of the overall sequence of activities
  - Essential but often incomplete
- Good practice documentation for the (relevant parts of the) process
  - can help but was often lacking
- Use of Personal Protective Equipment (PPE)
  - Routine use vs last resort – over-reliance, e.g. on high efficiency equipment (effectiveness not always substantiated)
  - Evidence of periodic check-ups of collective PPE equipment?
  - RAC prefers exposure and risk to be expressed with and without PPE (if only with PPE, state efficiency of the equipment)

RAC Rapporteurs experience: Exposure

- The applications are sometimes very general and lack focus on exposure to the Annex XIV substance
  - Process descriptions and sequence of process steps often vague
  - How many people are involved in doing a particular task, where and for how long per shift?
  - What are they doing the rest of the time which could lead to further exposure to the same chemical?
- Relevant exposure measurements often very sparse
  - The Annex XIV substance (inhalation, dermal)
  - Analogous substances if compatible
- Exposure modelling
  - sometimes lacking, or insufficiently documented, whereas it could have improved several cases considerably
- Biomonitoring to identify high exposure tasks

Corroborate the evidence where possible

Exposure: what have we received?

- Exclusively measured data (air monitoring and/or biomonitoring)
- Exclusively modelled data
- Literature data (mostly measured) including industry surveys, epidemiology studies, etc.
- Evidence of compliance with thresholds set by voluntary industry agreements
- Various combinations of the above

RAC has a strong preference for measured data

- If modelling is the only option, corroborate with at least some measured data - this enhances the RAC evaluation
- We have seen monitoring programmes initiated just prior to and during the preparation of several applications – the results helped build the cases and are very relevant for re-application

Finding the right scale for an application (1)

Compact applications, e.g.:

- a single workplace
- several workplaces, e.g. a discrete formulator – pre-fabricator - product chain
- one to many, very similar workplaces, e.g. a formulator - professional use DU's (…borderline)

Operational conditions, task-based activities and RMM affecting exposure of workers in the context of each workplace need to be clearly described and very similar

Finding the right scale for your application (2)

Manufacturer/upstream applications – also large DU consortium applications - may be efficient, but can have other drawbacks:

- Tendency to rely on generic data (e.g. open literature or voluntary emission standards):
  - *Difficult/impossible to evaluate without the source material*
- Operational conditions and RMM still need to be described:
  - *Well described examples of 'representative' work-places (with justification) are needed for the evaluation*
- Several applications were broadly trans-national:
  - *An indication of geographical variability is necessary, e.g. data on trends in operational conditions/RMM with location*

RAC's recommendations

- Adequate control of risks is demonstrated by the applicant:
  - Generally, so far, no conditions additional to those proposed in the application (occasionally conditions for a possible review)
  - No recommendation to SEAC on the review period
- Adequate control is not demonstrated or the risks are not adequately limited – the degree of failure is critical to next steps:
  - If OC and RMM are not adequately described, recommend specific conditions and or additional RMM
  - Include monitoring arrangements
  - Recommend a short review period to SEAC
- Application cannot be evaluated
  - Rejection, or stringent conditions in special cases

We have used all of the above except rejection (so far)!

A long-term view based on RAC's experiences

- While allowing time for substitution - adequate control or appropriate limitation of the risks form Annex XIV substances need to be maintained
- The Committee's therefore look at every application with the review process firmly in mind
  - Recommend a short review period where there are remaining uncertainties with regard to the exposure assessment
  - Encourage applicants to work on the weaknesses of their first application
  - Where necessary, apply monitoring arrangements – the data can be inspected by enforcement authorities and should be tailored for use as part of any review by the Committees
  - Make evaluation on review simpler, clearer and more efficient

Hazard assessment: RAC reference values

- RAC has provided DNEL and dose-response relationships on a pilot basis for almost all substances so far
- A background report is prepared by a consultant to ECHA and a Reference Value note is prepared for agreement in RAC
- A large majority of the applications to date have used the RAC reference values
- We think that this has saved up to 30% of the rapporteurs time in preparing the opinion and the Committee's time in plenary. It can save substantial time for the applicants.
- At the start, we were late in publishing the notes – we listened to your feedback and now publish much earlier
- We would like to continue the programme but would appreciate your views

Thank you

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