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Streamlining Applications for Authorisation ECHA – European Commission workshop

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Experience from preparing an application for a process chemical with multiple applicants

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Key messages regarding « fit for purpose »

- Key figures on EDC an its uses:
  - ✓ EDC: considered as **non threshold carcinogen** (mainly based on default approach)
  - ✓ **Reference dose response relationship derived by RAC**
  - ✓ **99% of tonnage used as intermediate** and exempted from Authorisation: less than 3000 tonnes used as “normal substance” as extracting and process solvent in fine and specialty chemical industry
  - ✓ **Very short supply chain**: producer → (distributor) → downstream user [end-user] and limited number of plants concerned (less than 20 in EU)
  - ✓ **Very low number of workers potentially exposed to EDC**
  - ✓ **Production takes place within closed systems** and solvent is recycled where possible

Key messages regarding « fit for purpose »

- Key figures on EDC Authorisation Consortium:
  - ✓ **Consortium initially set up for jointly preparing a DU CSR** covering fine chemical industry uses as extracting solvent
  - ✓ As producers didn't decide to submit an AfA, **DU were requested to build Authorisation dossiers** → enlargement of the consortium
  - ✓ **3 main uses covered** within industrial facilities with high level of containment:
    - pharmaceuticals manufacture,
    - ion resin exchange manufacture,
    - de-waxing and de-oiling of crude oil fractions
  - ✓ **No joint Application for Authorisation** except for affiliate companies involved in the same use of EDC

Key messages regarding « fit for purpose »

CSR is key for demonstrating that risks are well controlled:

- Scope:
  - ✓ **Question regarding scientific R&D exemption**, including the status of quality control and laboratory testing activities
- Hazard assessment
  - ✓ RAC ERR will be used… even if it differs significantly from reference value (DMEL) mentioned in the SDS
- Exposure assessment
  - ✓ **Mainly based on quantitative personal measurements** based on long-term (functions) and short term (frequent tasks) Similar Exposure Groups (SEGs)
  - ✓ **Technical feasibility regarding measurements** (LoQ of analytical methods)
  - ✓ **Performing quantitative assessment for unusual tasks** (unloading, maintenance, sampling) is not so feasible
  - ✓ **Showing improvements may require to perform several measurement campaigns**
  - ✓ **Reasoning on mass balance is not straightforward**, as figures available to applicants are mainly based on estimations and often the substance is subject to transformation (breakdown)
- Risk characterisation:
  - For no threshold substances, **from which level of excess risks "well controlled conditions" will be achieved**...

- **Is there a need to develop in-depth CSR when the level of containment is very high** (corresponding to very well controlled conditions of use)?

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Key messages regarding « fit for purpose »

- Experience with AoA
  - ✓ Consumption of EDC is very low; purchases used to replenish process losses; where recycling undertaken, rates are high
  - ✓ Extensive R&D by applicants; up to 100's/1000's of chemicals may have been assessed
  - ✓ Uses are highly dependent on physico-chemical properties of EDC, hard to match → technically feasible alternatives are not available
  - ✓ Conversion to alternatives requires long time, downtime, radical equipment changes or plant rebuild
  - ✓ Regulatory requirements are important (variations of pharma Authorisations), re-qualification of sensitive uses (food contact/processing, nuclear, cosmetics, etc.)
  - ✓ Estimates of investment costs can be developed but operating costs harder to assess
  - ✓ Assessment of risks from alternatives really necessary if clearly technically infeasible?
  - ✓ How can a credible R&D plan for conversion to a yet unknown alternative be set out?

Key messages regarding « fit for purpose »

- Experience with SEA
  - ✓ Non-use Scenarios are similar: without EDC, EU plants would not be viable
  - ✓ Very low exposures to EDC, numbers of workers, environmental releases
  - ✓ EDC not present in products sold at concentration over 0.1%
  - ✓ **Monetised costs to health from continued use are extremely low**
  - ✓ Economic benefits to the applicant from continued use are much higher than human health costs → easy to demonstrated that Authorisation should be granted
  - ✓ Very high benefit/cost ratios but is it high enough? How much further should we go?
    - Monetisation of economic benefits to other actors on supply chain?
    - Monetisation of costs to citizens health from HvE exposure?
    - Quantification of social impacts on local communities?
    - Consultation with customers: little added benefit and high risk to business?
  - ✓ Setting out a review period is not always easy, if no promising alternative identified
    - Concept of investment cycles is not always compatible with how plants are operated
    - Plants may have been running for 20-40 years and can go on for another 40 or 50 years

Key messages regarding « fit for purpose »

- What may be the content of future AfA for EDC used as process and extracting solvent
  - ✓ A detailed CSR with emphasis on
    - Measured data
    - Demonstrating that worker exposure and environmental emissions are minimised as low as technically feasible
    - Describing actions planned for continuous improvement of exposure controls, if needed
  - ✓ A targeted AoA with a focus on describing
    - The process (also in the CSR) and setting clear technical feasibility criteria
    - Past and current R&D by applicant (and others), including targeted explanation of screening and shortlisting of alternatives
    - The technical feasibility of shortlisted alternatives against the pre-selected feasibility criteria
      - For alternatives that might potentially become technically feasible in the future, assess economic feasibility with a focus on investment costs
    - Risk assessment only for technically promising alternatives, and only if concerns over hazard profile
  - ✓ A targeted SEA with a focus on describing
    - The structure of the relevant upstream and downstream supply chain(s)
    - The "Non-use" Scenario(s) and a concise justification for their selection
    - The HH/ENV impacts from continued use (monetisation not necessary if clearly very low?)
    - The (monetised) economic benefits to the applicant (retained profit), including employment effects
    - A benefit/cost ratio of continued use that is very high (but how high is 'high'?)

Concluding remarks

- **Criteria for classifying a substance as a "process chemical" to be formalised**
  - ✓ Guidance on how to/whether criteria are met would be needed to control business risks
  - ✓ Embed process chemical into 'criteria' on justification of longer review periods
  - ✓ A "pre-qualification" process with ECHA to confirm Fit-for-Purpose approach suitable? (PSIS?)

- **What definition can be developed to be clear whether a Fit-for-Purpose approach can be used (level of containment?)**?

- **Is recycling necessary or demonstration of destruction of losses would be sufficient**?
  - ✓ **Mass balance not always possible to account for 100%** of substance for several reasons

- **Showing benefits>>costs from continued use can be done in a simplified manner** but achieving the desired result (specific review period of >>12 years) is more complex
  - ✓ Unless there is guidance on detail/proof required → very detailed impact analysis in attempt to make a convincing case and avoid business risk
  - ✓ Would a standardised method of showing R&D readiness help and also allow comparison between applicants? (Technology Readiness Levels (TRLs) and Manufacturing Readiness Levels (MRLs) for setting out how far a process is away from full scale implementation)

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