Experience from ECHA

Workshop – Shared experience on Applications for Authorisation

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Outline

- Pre-submission
- Submission
- Opinion making
- Key messages

Pre-submission

Pre-submission (1/2)

- **Notifications to submit**
  - For ECHA to better anticipate resources for upcoming applications
  - Opportunity to request a Pre-Submission Information Session (PSIS)

- Experience from ECHA
  - **56 notifications** since 2012
  - All 'current applicants' have notified ECHA
  - All notifications accompanied by a PSIS request
  - Gave good visibility and helped ECHA to better plan the work and nominate Authorisation teams

Pre-submission (2/2)

- **Pre-submission Information session (PSIS)**
  - Aimed to clarify technical/regulatory issues and discuss the Broad Information on Use (BIU) package
  - Pilot project for the first batches of applications
  - **16 PSISs** since 2012 and more to come!

- Experience from ECHA:
  - All applicants but one have requested a PSIS
  - Overall very positive feedback from applicants
  - ECHA find them useful to solve basic technical issues and to identify/anticipate quality issues
  - Resource demanding. ECHA to evaluate how long this process can be maintained

Submission

Submission (1/3)

- **Applications for Authorisation (AfAs) received**
  - **12 AfAs** received with a total of **33 uses** applied for
  - Several types of AfAs and applicants
    - [One applicant; one substance; one/several uses]
    - multi-applicants AfAs
    - multi-substances AfAs (DEHP/DBP; Pb/Cr pigment)

- Experience from ECHA:
  - Timing:
    - almost all AfAs submitted within the windows and all before the latest application date
    - 2.5 months for ECHA to process and applicants to pay seems to be OK
  - Business rules checks
    - almost all AfAs have passed the checks during the first submission
    - minor technical failures and issues
    - → Instructions developed by ECHA seem to be clear. Read them carefully

Submission (2/3)

- **Invoice**
  - Fee determination parameters (FDP) are based on the number/ size of applicants, number of substances and number of uses
  - All current applicants are non-SME companies (except one)
  - Tight deadlines (3 weeks max) for the payment

- Experience from ECHA:
  - ECHA was able to clearly set the FDPs
  - ⚠ Additional fees based on additional exposure scenarios !
  - All applicants have paid on time despite expected difficulties

Submission (3/3)

- **Broad Information on Use (BIU)**
  - Set of information published by ECHA for the public consultation
  - Difficult trade-off between transparency and meaningfulness

- Experience from ECHA:
  - Concept has been overall understood by applicants
  - A few technical problems with the files (encryption/protection, confidential watermarks on public versions…)
  - Transparency:
    - 65% public and 35% confidential but not visible from the current templates structure
    - Information overlaps between public and confidential info, and part A of CSR confidential → ratio probably more close to 80/20
    - ATD requests received
    - One applicant provided a 100% public set of information
  - Meaningfulness: difficult to draw clear conclusions but reasonable number of meaningful comments received

Opinion making

Opinion making (1/6)

- **Conformity check**
  - Prepared during the submission pipelines activities
  - Agreed by the Committees at the beginning of the opinion making phase
  - It is rather a content/formalistic check than a real quality check

- Experience from ECHA:
  - All received applications have been found to be in conformity
  - All received applications included a SEA
  - ECHA clarified that wide scope AfAs and/or safety net AfAs (e.g. when the use is not clearly exempted) cannot be rejected at the conformity check stage

Opinion making (2/6)

- **Public consultations**
  - One consultation per combination of [applicant-substance-use]
  - Scheduled every mid-February, May, August and November
  - Duration = 8 weeks
  - 3 batches of public consultations have been held

- Experience from ECHA:
  - Comments received mainly at the end of the period
  - Different types of submitters (NGOs, competitors, academics…)
  - Variability in the number of comments received per AfA
  - Comments on alternatives and on exposure assessment
  - Reasonable proportion of meaningful comments
  - All applicants took the opportunity to respond to comments

Opinion making (3/6)

- **Additional questions from RAC/SEAC**
  - Additional information to bring the AfA in conformity
  - Written questions to clarify essential points in the application
    - description of uses/tasks and exposures
    - substitution and socio-economic issues

- Experience from ECHA:
  - RAC and SEAC rapporteurs have sent questions for all applications
  - Normally one round of questions. Second round for some AfAs
  - Good basis for further discussions in the trialogue
  - Relatively high level of scrutiny by rapporteurs
  - Very tight deadlines!
    - for applicants to answer
    - for rapporteurs to digest additional information before the trialogue

Opinion making (4/6)

- **Trialogues**
  - To discuss in an interactive manner issues related to the case
  - ECHA organised 5 sessions (3 additional scheduled in May)
  - Take place ~ 4-5 weeks after the end of the public consultation i.e. mid Feb, May, Aug, Nov
  - All stakeholders can attend (RAC/SEAC members and STO observers, third-parties who commented on alternatives)

- Experience from ECHA:
  - Webex seems to be the most convenient format
  - Not easy to plan and combine many sessions within a 2 weeks time slot
  - Trialogue organised for almost each AfAs (canceled if the case is clear)
  - Have been useful to clarify RAC and SEAC issues
  - STOs including third-parties have been active during the Q&A session
  - Most of the discussions handled in the observed session
  - ECHA to streamline the organisation if many AfAs are received

Opinion making (5/6)

- **Opinions development – RAC/SEAC plenaries**
  - Common approach available on ECHA's website
  - Delivered within 10 months from the date of payment of the fee
  - 2 'fast tracked' opinions delivered within 4 months

- Experience from ECHA:
  - All plenaries discussions took place in observed sessions
  - Hazard assessment: in most cases applicants have used RAC's reference DNELs which facilitated to a great extend the work of the Committees
  - Exposure assessment: applicants have used both modelling and (bio)monitoring not always in combination. If modelling is used RAC would also like to see supporting (bio)monitoring data
  - Alternative assessment: to ease the setting of review periods applicants should clearly describe their efforts to identify safer alternatives and make them available

Opinion making (6/6)

- **Opinion development / Experience from ECHA:**

  - ECHA received 'generic' and 'specific' AfAs
  - Applications submitted by DUs at company level are relatively straightforward to evaluate compared to AfAs covering many DUs
  - The use description and the scope of the assessments are keys
  - Communication in supply chains (up and down) is critical:
    - Generic AfAs: good representativeness of exposure levels and suitability of alternatives for a large number of unidentified DUs potentially covered
    - Specific AfAs: supply chain disruptions if upstream actors have not secured their uses
  - Criteria to recommend monitoring arrangements and additional conditions to be further developed

Key messages

Key messages to applicants

- The AfA process works!
- Technical aspects: read carefully ECHA's support webpages and instructions
- Quality aspects: everyone on a learning curve
- Public consultation: be as transparent as possible
- Need to find the break even point between generic and specific AfAs

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Thank You!