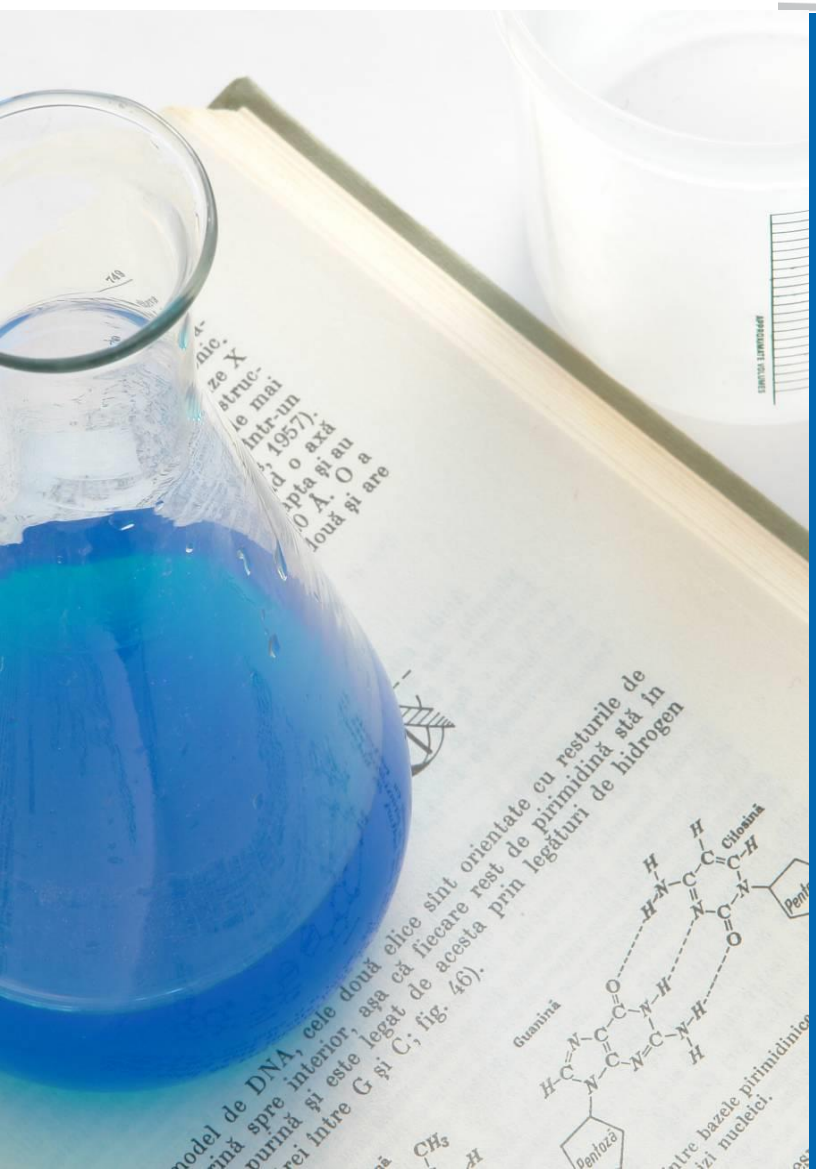

European Commission

Lessons learnt by authorities: Taking stock of received, processed and granted applications

Lessons learnt on
Applications for Authorisation
Helsinki, 10-11 February, 2015

Katarína Piršelová
Unit A3 - Chemicals
Directorate-General for Environment
European Commission

Where do we currently stand from the European Commission perspective?

- COM - decision-making stage (very end of the application for authorisation procedure)
- issues potentially accumulated throughout the whole procedure
- following the cases since very beginning
- still a learning stage
- so far only 2 decisions adopted (DEHP and DBP)

COM experience: authorisation decisions adopted so far (1)

- 2 authorisations granted, based on adequate control
- Straightforward processing of the applications and ECHA opinions and preparation of decisions :
  - effective demonstration that risk to human health or the environment from the use of the substance is adequately controlled,
  - well documented cases,
  - no alternatives at present,
  - applicants applying for their own uses,
  - uses specifically defined

COM experience: authorisation decisions adopted so far (2)

- Still, some issues along the way:
  - how to embrace the conditions for authorisation in the decision and the level of detail to go to
  - appropriate monitoring conditions in the decision – a summary of OCs and RMM in the language where the use takes place - tools for the enforcers but also downstream users adhering to the authorisation
  - an ad hoc WG to work on RMM and OCs in applications for authorisation – outcomes to be used for ECHA work with the applicants, ECHA committees and enforcement authorities
  - how to assign authorisation numbers (enforcers and downstream users adhering to the authorisation)

… and more to come with the cases currently being processed:

For example:

- adequate control of risks claimed in the applications but not demonstrated – are the SEA route arguments solid enough to grant the authorisations? Case-by-case BUT:
  - RAC/SEAC opinions not always explicit enough to reach a straightforward conclusion and express it in the decision
  - Not always possible to directly compare and judge on risks from the use
  - Applicants: In cases not a DNEL derived by RAC is used in the application, attention in describing the risks linked to the use for the purposes of the SEA route

… and more to come with the cases currently being processed:

Further examples:

- applications from the top of the supply chain, covering downstream uses (description and scope of uses applied for – positive or negative lists)
  - Balance between how large/general is the applied for use and how well the case can be argued by the applicant:
    - conditions and control of risks described
    - analysis of alternatives (suitability and availability for the applicant and for the DUs, meaningful consultation on BIU)
  - ECHA work with (future) applicants

… and more to come with the cases currently being processed:

Further examples:

- first cases of substances with no threshold or PBTs – "purely SEA route"
- interface with other legal frameworks (EU-wide or international)– e.g., for waste or POPs

……

cases where some/most of these points are cumulated together !

Outlook

So far – each case has been specific and particular, so the Commission continues:

- building its experience and this learning by doing

- reflecting on a way forward

Thank you

Disclaimer

All views expressed are purely personal and should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information provided.