9th PSN-IUCLID

Non-paper on making available studies submitted in previous dossiers - Regulation (EU) 2020/1740

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The challenge

- Content of the application for renewal - Article 6(3) of Regulation 2020/1740 -
  - Applicants shall make their best efforts to obtain access to and provide the full text of each test or study report and summaries thereof, which were part of the approval dossier or subsequent renewal dossiers.
  - The Member State, that acted as rapporteur for the previous approval and/or subsequent renewal dossiers, or the Authority shall endeavor to make available such studies where the applicant provides evidence that its attempts to obtain access from the study owner have failed".
- Few cases expected where applicants do not submit old studies as part of the renewal application
- Data protection status of studies does not impact the possibility to make studies available
- More legal background – Non-paper (non-binding, not a legal instrument)

European Commission

The proposed options/solutions

- RMS manages the process directly – IUCLID (re)submission
  - RMS gives 30 days for the owner of the studies to reach an agreement with the applicant otherwise studies are made available to **the applicant** after a 30 days period for the sanitisation of personal (EU-GDPR) or confidential information (data owner to identify - Art 63(2) of PPPR). The redacted version of the studies will be made available to the applicant for IUCLID submission (to be flagged as non-confidential).
- A consultant manages the process – IUCLID inherited template
  - RMS gives 30 days for the owner of the studies to reach an agreement with the applicant otherwise studies are made available to a **hired consultancy*** after a 30 days period for the sanitisation of personal information (EU-GDPR) and confidential information (Art 63(2) of PPPR). Both original and redacted versions of the study will be made available to the **consultancy** for IUCLID submission (to be flagged as confidential and non-confidential respectively).

*costs would need to be covered by the applicant for the renewal

Timing and derogations

- Ideally before notification of studies pursuant to Article 3 of Regulation 2020/1740
- Allowing sufficient time to reach an agreement with data owners
- The admissibility of the renewal application should not be precluded if certain studies cannot be submitted. In this case study summaries available from previous evaluations can be used in its evaluation (Article 11(3) of Regulation 2020/1740)
- Member States may also develop or use other possibilities to make studies available - the non-paper can be reviewed and updated in the future.