IUCLID for microbial active substances

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Issues with MS intake

- Additional questions arise at completeness check
  - studies cannot be found by MS
  - Request for changes because .....
  - Request to divide over ´grey points` (also see IBMA presentation november)

Studies to be found

- Studies/information moved or duplicated to point 11

Previously used documents now obsolete, kept until April 2024

Study title

Is this fate & behaviour?
no it is residue
Title should indicate datapoint or ???
If the author shows confidential in IUCLID how to make sure it can be found

Issues with MS intake

- Additional questions to dossier issues with IUCLID
  - Absence of data that are required under the UP of 2011
    - Not foreseen in the TOC
    - UP 2011 part II are replaced in 2022 to our opinion
      - Example: “Information regarding the potential interference with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC should be addressed in the applicant's dossier. This is a specific decision-making criterion for the authorisation of plant protection products containing microorganisms (see uniform principles in Commission Regulation (EU) No 546/2011).”
    - In commision regulation(EU) 2022/1441 of 31 August 2022 this requirement no longer occurs

Dossier and DAR/RAR

- Applicants are still requested to submit OECD format summary documents
- Applicants are requested during the evaluation process to update not only IUCLID but also the summary documents
- Applicants are requested to solve issues coming from report generator as it does not fit with MS templates for DAR/RAR

WE ARE DOING DOUBLE WORK CONSTANTLY

Application submission

- MS ask applicants for full dossier outside of IUCLID

  (in MS word format)

Example message
in our opinion IUCLID is still not working sufficiently well to allow for a decent evaluation of a dossier. Therefore, an OECD dossier (old format) is required together with the IUCLID submission from which we can start when we draft the DAR.

- Note from EFSA: for Microorganisms there is no DAR template indeed.
- However, the question also comes for biologicals that fall under the chemical assessment requirements as well

IUCLID

- Confidentiality
  - ✓ The update of confidentiality issues takes more time than scientific update
  - ✓ Contrary information received; different people come with different answers
  - ✓ Requested at different stages in the process so you redo multiple times

  - ✓ And than at the very end you have the portalino which is extremely detailed and costs a lot of time

➢ Issues with existing dossiers

- ✓ The algorithm applied when system changes are implemented seems not appropriate.

- ✓ Studies did not only end in obsolete but additionally in other sections. Some studies can be found multiple times at unlogic sections and headers.
  - See the issue on studies ending in section 11

Conclusion

- MS attitude against IUCLID system has to/must change
- Applicants cannot continue to do double work
- The update of two dossiers each time MS want a change is undoable

- The result of the current approach is that the dossier ends up in a mess where for applicant but also for EFSA it is hardly possible to end with a decent dossier for the approval process of a.s. at EU level which suits as start for the product approvals (renewal of)

Conclusion

-For applicants each service update of IUCLID causes issues

- the burden is hughe, the costs multiply

version control requirement stressed again

-Turnaround time of dossiers must be shortened to avoid multiple updates

Thank you!

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