



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Identification of insufficient dossier quality



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MS were asked within the course of the SCoPAFF meeting in July 2023 by the European Commission not to accept dossiers of insufficient quality.

- Insufficient dossier quality is a crucial point regarding delay in the evaluation
- Shortcomings often can not be identified by the validation assistant and in the formal completeness check



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Experience in other Member States and common understanding

- Common understanding of insufficient dossier quality should be discussed and criteria for the non-acceptance of dossiers should be specified
- Experience and proposals from other Member States?



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Experience in Germany

- The quality of reports generated in IUCLID still do not fulfill the criteria of Doc. M, N etc. so that applicants are obliged to submit those documents additionally („Further documents“).
- DE as RMS received dossiers with the following shortcomings:
 - Doc. M, N in a format that could not be edited (e.g. tables as pictures)
 - Materials/methods as well as study descriptions were partly missing
 - Results/tables with results and necessary parameters were partly missing
 - Study results were inaccurately presented
 - „Conclusions by the applicant“ were partly missing
 - Text was partly given in keywords, only
 - Studies were submitted to a wrong annex point so the the wrong OHT was used and data were not adequately presented



Thank you very much for your attention!

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