8th meeting of the PSN IUCLID sub-group
22 November 2023

IUCLID – LATEST NEWS & UPDATES

Chiara MACCHI

EUROPEAN FOOD SAFETY AUTHORITY

IUCLID SUPPORT [1/2]

- Two updated IUCLID manuals have been published and the remaining will be online by the end of the year
  - MRL Application manual (https://zenodo.org/doi/10.5281/zenodo.4630193)
  - Micro-organisms Mini manual (*https://doi.org/10.5281/zenodo.10118202*)
  - All links will be available in the Applicants Toolkit
- Two new trainings available on EU Academy:
  - IUCLID for Applicants - https://academy.europa.eu/courses/iuclid-for-applicants
  - IUCLID for Evaluators - https://academy.europa.eu/courses/iuclid-for-evaluators
    - Application requires EFSA's approval

IUCLID SUPPORT [2/2]

- Administrative guidance
  - The plan is to circulate with Member States for commenting mid-December → mid-January
  - EFSA will address the comments
  - Guidance to be published in spring 2024
- "Virtual Tour of the Member States" continues
  - 6 meetings held so far (AT, DK, GR, FR, NL, IT)
  - Very fruitful exchanges
  - We will resume in January 2024

RECOMMENDATIONS TO APPLICANTS ON IUCLID DOSSIERS

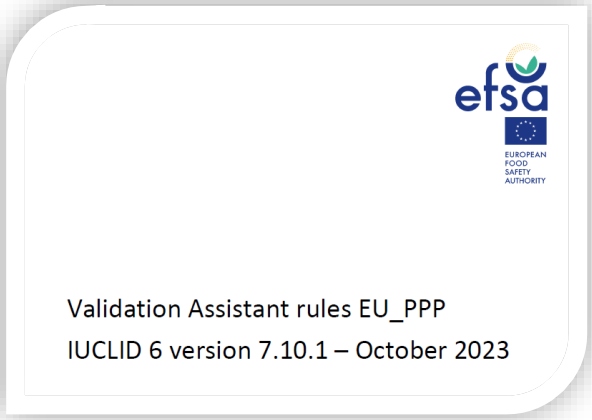
- Appropriate name to be given to the dossier, considering it will be published too
  - Dossier name must be provided!
  - ISO name of the substance / ISO name + crop(s)/various crops for MRL
  - Indication on NAS/AIR if wanted
  - AVOID details on (re)submissions, versioning, dates, etc
- Carefully check CBI elements before submitting
  - Dissemination preview + filtered dossier available
  - Issues with e.g. Doc J sanitisation
  - Only the applicants/data owners can establish/verify CBI
- No draft DAR/RAR/ER to be included in the dossier

GUIDANCE ON WHEN TO ADDRESS NEW VALIDATION ERRORS

- During the **admissibility phase** new Validation Assistant (VA) rules added after the initial submission date of a dossier may not be addressed unless:
  - The RMS/EMS identifies the missing/incorrect data as critical for risk assessment and completeness of the dossier
  - The error is a Business Rule (BR) and must be resolved to successfully resubmit the dossier during its life cycle
- During the **risk assessment phase**, VA rules can be left unresolved if they are not BRs unless requested otherwise by the relevant regulatory authority
  - Any pending warnings should be addressed before finalisation of the final output

- The information about the IUCLID version in which a rule became operational is now added in the VA file published on Zenodo

https://zenodo.org/doi/10.5281/zenodo.5141356



POST-ADMISSIBILITY – SOME CLARIFICATIONS

- **AIR/MRL**
  - Confidentiality Request (CR) assessment (EFSA)
  - EFSA launches the public consultation (no dedicated email to RMS/EMS, who will be informed of any comments at the end of the process)
    - Comments to be taken into account in the AR/ER preparation and reported in Vol 1/ER
  - Dossier updates to be agreed between the applicant, EFSA & RMS/EMS during the CR assessment phase and between applicant and RMS/EMS at a later stage
  - No. of dossier updates to be limited if possible but a consolidated version of the dossier must be submitted at the time of the submission of the AR/ER
- **NAS** – same as above, with the exception of:
  - Confidentiality Request assessment (RMS)
  - Dossier updates to be agreed between the applicant and the RMS

FILTERING RULES – NEXT STEPS [1/3]

- Working Party on Filtering Rules still on hold but will resume in 2024
- Document J scheduled for removal in **April 2025** and a "DAR Volume 4" report will be generated in support of the RMS
  - The field will be removed from the dossier so all existing Doc Js will also be removed → applicants have 18 months to fill in the dossier with the relevant data
- For **April 2024**:
  - Literature Reference Entity: Test Laboratory & Report number will always be removed for unpublished studies
  - UNLESS_CONF reduction to be applied to new & existing documents (as per the outcome of the stakeholder consultation held 17/08 – 27/09/2023)
  - Auxiliary rules to be switched OFF (as per the consultation above)
    - This implies that the information included in the sections "Other" or "Remarks" in association with picklists will be PUBLISHED
  - Possible change to the filtering rules for legal entities other than the applicant (from PUBLISHED → UNLESS_CONF)

FILTERING RULES – NEXT STEPS [2/3]

- New rule on publication of Analytical Methods to be implemented (based on Option 1 previously proposed by the Filtering WP)
  - The rule will impact the "Materials and Methods" and "Results and Discussion" sections of the documents
  - We will implement a high-level categorisation of the analytical methods in order to identify those **relevant for risk assessment/enforcement** → we will apply the standard "reduced UNLESS_CONF" approach
  - The Endpoints listed in the next slide will be subject to the new rule whereby if a CBI flag is set in the relevant Endpoint Study Record and a justification is provided, the data from certain fields will be redacted *(see slide 10 – extract from the public consultation file)*

FILTERING RULES – NEXT STEPS [3/3]

- Analytical methods subject to the new rule:
  - analysis of the micro-organism as manufactured (QC)
  - analytical profile of batches
  - methods for providing information on possible variability of seed stock/active micro-organism
  - methods for providing information on purity of seed stock/active micro-organism
  - methods for the analysis of the (formulated) product
  - methods for the analysis of the active substance as manufactured (QC)
  - methods to differentiate a mutant of the micro-organism from the parent wild strain
  - methods to identify and quantify contaminating micro-organisms
  - methods, procedures and criteria used to establish the presence and identity of the micro-organism, analysis of the micro-organism as manufactured
  - methods for relevant impurities, format change (ADD) April 2024

FIELDS SUBJECT TO THE ANALYTICAL METHODS RULE

IUC v6.7 Path	Current rule	Proposed rule
ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData.AttachedJustification.ReasonPurpose	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData.DataWaivingJustification	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource.DataAccess	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.ExtractionAndCleanUp	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.SuitabilityOfTheMethodForConfirmation	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.ExtractionAndCleanUp	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.IndependentLaboratoryValidationILVIfApplicable.ExtractionAndCleanUp	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.IndependentLaboratoryValidationILVIfApplicable.InstrumentDetector	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.ExtractionAndCleanUp	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.Calibration.Standards	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.LOQLOD.LimitOfDetection	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.LOQLOD.LimitOfQuantification	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.Recovery.FortificationLevel	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.Calibration.Standards	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.LOQLOD.LimitOfDetection	UNLESS_CONF	AN_METHODS
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ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.LOQLOD.LimitOfQuantification	UNLESS_CONF	AN_METHODS
ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.Recovery.FortificationLevel	UNLESS_CONF	AN_METHODS

DIFFERENT IUCLID INSTALLATIONS

- System requirements for the different installations are described here: https://iuclid6.echa.europa.eu/system-requirements
  - For larger installations ECHA recommends the use of PostgreSQL or Oracle rather than Derby
- Data transfer tool available: https://iuclid6.echa.europa.eu/data-transfer-tool
  - In case you wish to transfer existing databases from Derby to Oracle or PostgreSQL

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