IUCLID for microbial active substances

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IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION



Agenda

General points

- Report generator
- Biological properties
- Data points
- Endpoint study record copying
- Confidentiality WGS
- Justification for confidentiality claims
- Data protection field
- Copyrights
- Non-conventional active substances in IUCLID

Detailed observations to IUCLID data points

General points

Report Generator

- Applicants are still asked for the preparation of DAR documents, instead of authorities generating DAR from IUCLID, due to poor quality of the reports.*
- In the Microorganisms, the most challenging section is the section of Biological properties (Substance section 2).

* This means double costs for applicants, preparing several dossier formats.

Biological properties

- The structure in Substance section 2 (Biological Properties) should follow the structure from the data requirements (Commission Regulation EU 2022/1439).
- Ideally the subpoints under Substance point 2 should be separated.
- The report generated for Substance section 2 does not reflect the structure of Data entry in IUCLID and even text fields from Substance section 6 (Effects on terrestrial vertebrates) appear in this report.

Data points

- Data points in IUCLID should reflect data requirements as per Commission Regulations EU 2022/1439 and EU 2022/1439
- Some examples where it is not the case:

  Substance 2 – subsections do not follow DR

  Substance 8.2.2.3 – not a data requirement

  Substance 8.5.2, Mixture 10.5.2 – do not follow DR

  Mixture 10.1 – do not follow DR

Endpoint study record copying

- There is no possibility to copy/paste a study summary from substance to mixture and the other way around, or between different data points of the same section, for example acute oral toxicity study in Substance dataset and Mixture dataset

Whole Genome Sequence data and confidentiality

- Providing WGS data is not a data requirement, but the information is often used for addressing data requirements (secondary metabolites, antimicobial resistance, strain identification).
- In many cases WGS is not published and shall be treated as confidential.
- Applicants are willing to submit analysis reports derived from WGS data, but not always the underlying WGS data itself.
- Large file, IUCLID space issues.

Justifications for confidentiality claims

- Would there be a possibility of entering justifications per study report (not per data point)?

Data protection field

- In study records, under ‘Data source’ you can indicate data access and data protection claimed. For data protection claimed there is no option ‘no’ or ‘not applicable’.
- It is needed for example for non-GLP studies or data that has already been protected once at MS level (i.e. previously submitted and relied upon).

Copyrights

- If a third party (Foreign user) is working under the Applicant Legal Entity, an additional copyright issue arises.
- If a third-party user includes a publication in the Applicant's IUCLID account, the user must hold (or obtain) the necessary copyrights or permissions to that publication; the Applicant must also ensure that such rights or permissions are in place before using it.

Non-conventional substances challenges (Chemical template)

- No fit of data to chemical dossier structure

dsRNA

Natural substances

Detailed points

- In the following slides, the up to date IUCLID experience with microbial active substances dossier is presented, given by IUCLID data point
- Some comments are common to the chemical and microbial templates

Detailed points

Substance dataset 1 and 2

- For information on the identification of the substance, only a reference substance can be entered (linked). However, the link alone does not fit for a microbial active substance. Key Information field could be added to enter information on the strain (e.g. taxonomy). It should be possible to add literature references.
- The input field “Historical background” seems to be redundant, as this is an input field “History of use” below.
- Under “Phylogenetic tree” it is possible to upload only one picture. This is very inconvenient.

Detailed points

Substance dataset 1.4

- Making batch composition records is very tedious and time consuming. This could be simplified by allowing simple copying of records, and to allow copying of the contents of a record to another record, rather than having to copy the entire record via “copy data from”.
- Ideally, several records should be creatable from a single entry. For example, in case of a 5-batch study, one batch with all variables should be created first, which then can be copied into four additional records. With the ‘copy data from’ function you first create a single entry, which you then copy to obtain two, then copy again those two to obtain four, and then you need to copy again to get the fifth.
- In addition, what is the added value of a ‘legal entity composition’. A reference specification for one or multiple manufacturing sources is required, and the composition of individual batches. Not having a legal entity composition.
- No space is available within the records to include or explain calculations (e.g. dry weight calculations in case of TKs, statistics, etc.) The remarks fields are much too small and do not allow text formatting.

Detailed points

Substance 5.3

- Test types under Material & Methods for studies under 5.3.1.2 not applicable to microorganisms (Microbial Pesticide Test Guidelines).
- Input for administration/exposure for an intratracheal/ intranasal infectivity and pathogenicity studies (5.3.1.2) not suitable, as the fields focuses on inhalation exposure only. Inhalation exposure is however not applicable for microorganisms.
- The field “Interpretation of results” (Applicant summary and conclusions) allows to choose for GHS criteria, however, these do not apply to biological agents such as fungi, bacteria or viruses.
- Field addressing clearance in infectivity and pathogenicity studies summaries would be very useful.

Detailed points

Substance 1.4 - Batch analysis - CBI flagging

- The results of batch analyses should be defaulted as CBI. This can be fed with information from the User guide regarding confidentiality.

- Bulk flagging of entries would also be highly useful, although it may not be technically feasible in all cases. When a new entry is created for a batch composition with, for example, 20 impurities or components that all need to be flagged individually, the process is tedious and prone to error. It might therefore be preferable to add a flag at the impurities-section level, so that all impurities are flagged by default and the user only needs to unflag those considered relevant (or alternatively, a separate field could be created for relevant impurities).

Detailed points

Mixture dataset 1.4.3

- Discussion of impurity type and origin is outside the scope of a mixture dataset and should instead be addressed in the substance's manufacturing process. Impurities are process-specific rather than product-specific, and their profiles can vary between manufacturing sources.
- However, relevant impurities, metabolites of concern, additives, safeners, or synergists may be included in the mixture dataset where they are necessary for risk assessment.

Detailed points

Mixture dataset 2.4

- In the block pH value (Results and discussion), for the concentration the unit % w/v and % w/w should be added as default choices. Together with % v/v, these would be the most common options.

Detailed points

Mixture dataset 2.5.2

- In the surface tension summary record, only a single value for the surface tension can be added (under key value for chemical safety assessment), while often, there are more. The same for viscosity.
- For the surface tension, the concentration has to be indicated, but you can only pick µg/L, mg/L or g/L, which is far too limited. Percentages, either % w/w, % w/v or % v/v should be allowed.

Detailed points

Mixture dataset 2.6.2 and 2.6.3

- The shelf-life is expected to go under 2.6.2, but in the ‘endpoint’ dropdown list in the study record, no appropriate endpoint type is available. The endpoint type ‘storage stability and reactivity towards container material’ is put under 2.6.3 but should have been put under 2.6.2.
- Under 2.6.3, a low temperature stability option is not available (thermal stability is put under 2.6.2). These entries should probably be fixed.
- Judging regulation 2022/1440, all these studies belong under 2.6.2.
- 2.6.3 appears to be reserved for other data like effects of air, light and moisture.

Detailed points

Substance dataset 4/Mixture dataset 5

The analytical method template contains several mistakes:

- In the recovery field, it is unclear why the mean recovery allows a range to be included
- In the repeatability field, which should be named precision instead, it is not possible to fill in the actual %RSD. The RSD_R and RSD_r are the only parameters that can be filled in, and both of them have the R and r in superscript, where this should be subscript.
- In the same field, there is no possibility to pick a unit for the mean content, which should be fixed (it should allow % w/w, mg/kg, but also CFUs etc). In addition, if it is important to indicate the mass transition for the recoveries, why not do this for the precision as well? Methods within the scope of SANCO/3030/99 can also be based on LC-MS/MS.
- The ILV entry is meaningless, considering an ILV must always be a separate study which cannot be put in the same study record as the primary validation study. Selecting the appropriate study scope under the 'endpoint' field should be sufficient. Linking primary validation and ILV could potentially be done by using the cross-reference function.
- For methods validated to SANTE/2020/12830, it is required to fill in the repeatability (precision) which is not required for these methods. When picking a method in support of risk assessment or monitoring, this quality check should automatically be disabled.
- The calibration should contain a field for the range of the standards, but also a field for the range in the test item/matrix.
- The numeric field for matrix effects (%) should allow ranges, or multiple entries (one per matrix). A matrix effect can differ quite a lot between matrices.
- As there is an entry for each validation parameter (repeatability, precision, accuracy, calibration), except for the specificity, it is recommended to add a specificity field to allow reporting interference.

Thank you!



