IUCLID for microbial active substances

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Microorganisms and IUCLID

➢Validation rules for micro's

- Not always appropriate IUCLID entrance level checked
  - **BR_PPP_015** Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement. - To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint. Other types of study summaries (e.g., Supporting studies) should be filled in as much as possible. - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.

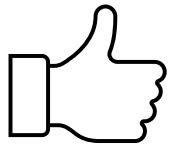
Business rules for less relevant input

- E.g endpoint summary required for data requirement (DR) with only waivers **BR_PPP_016**

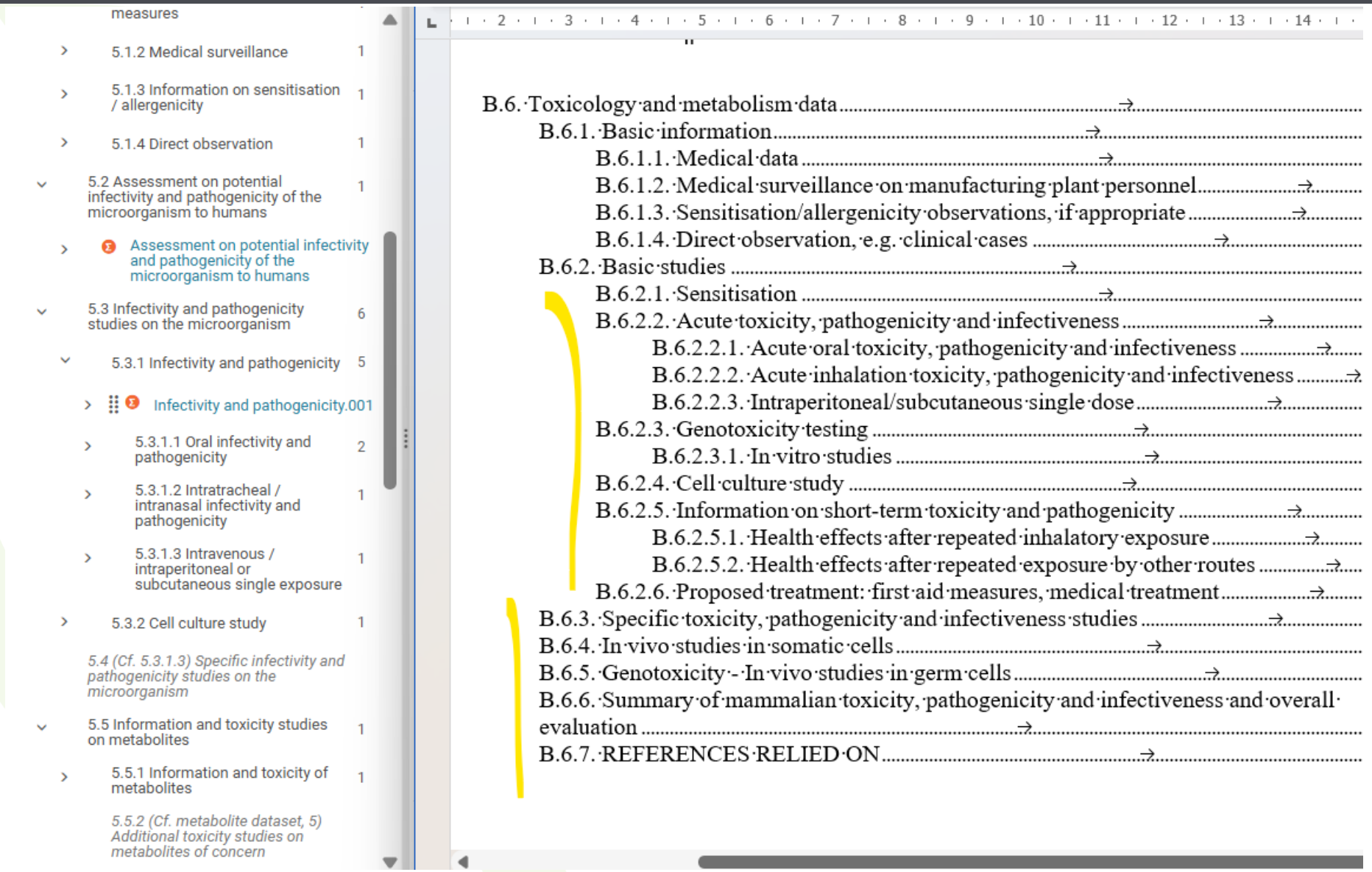
Microorganisms and IUCLID

Need for update of report generator for microbial dossiers

- Section toxicology has different numbering and content than data requirements
- Section residues: the IUCLID entrance is not reflected in report
- Related to slide above; OHT format for publications
- With rtf output report can be edited in Word



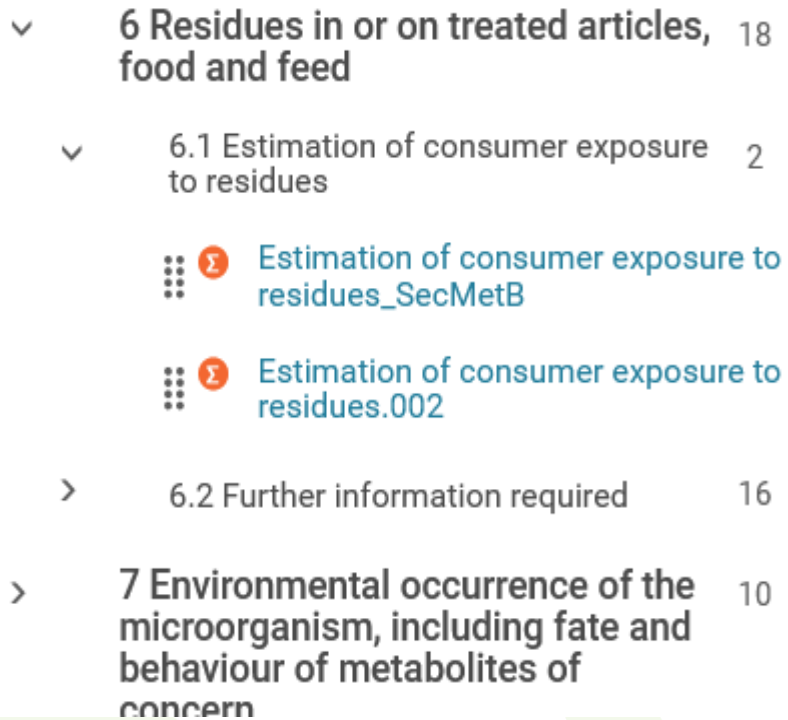
Report generator



Report generator

- In line with the current data requirements some points are no longer in IUCLID but still in report generator (genotoxicity)
- Point 5.2 on infectivity and pathogenicity to humans is missing in the report!

Report generator



B.7. RESIDUE DATA

B.7.1. PERSISTENCE AND LIKELIHOOD OF MULTIPLICATION IN OR ON CROPS, FEEDINGSTUFFS OR FOODSTUFFS

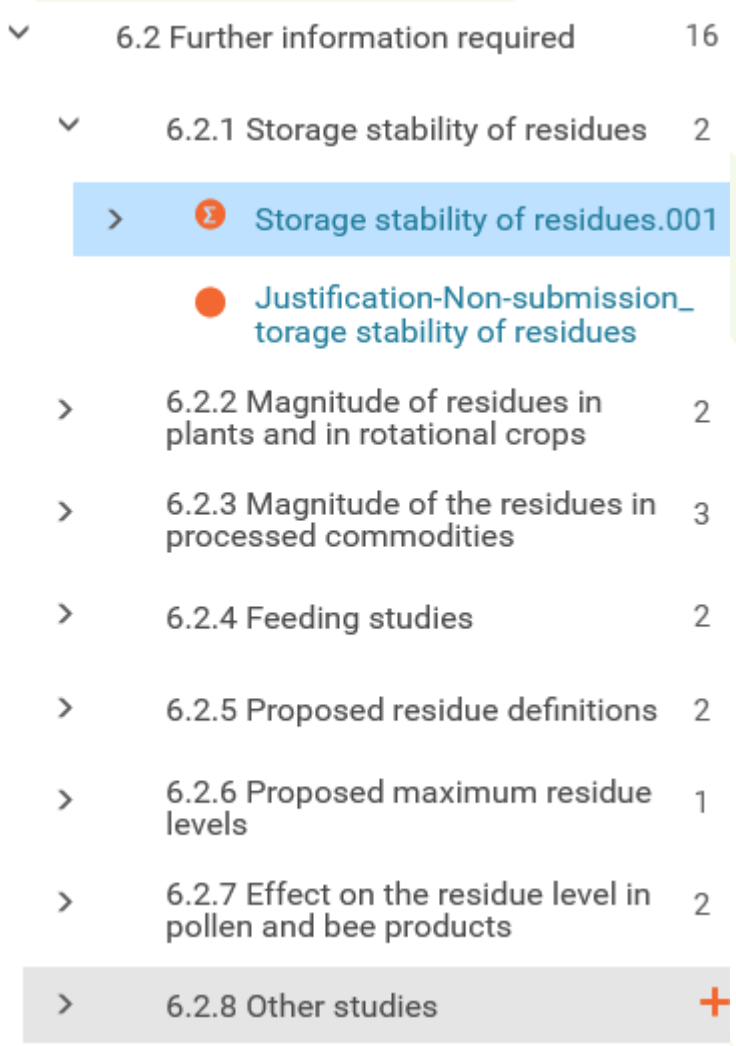
Summary

Studies

No individual studies available for migration of residues.

- The entrance is not reflected

Report generator



DR 2023: **6.2 Data generation on residues**

B.7.2. FURTHER INFORMATION REQUIRED
B.7.2.1. Viable and non-viable residues
B.7.2.1.1. Magnitude of residues in plants

Old DR

Summary

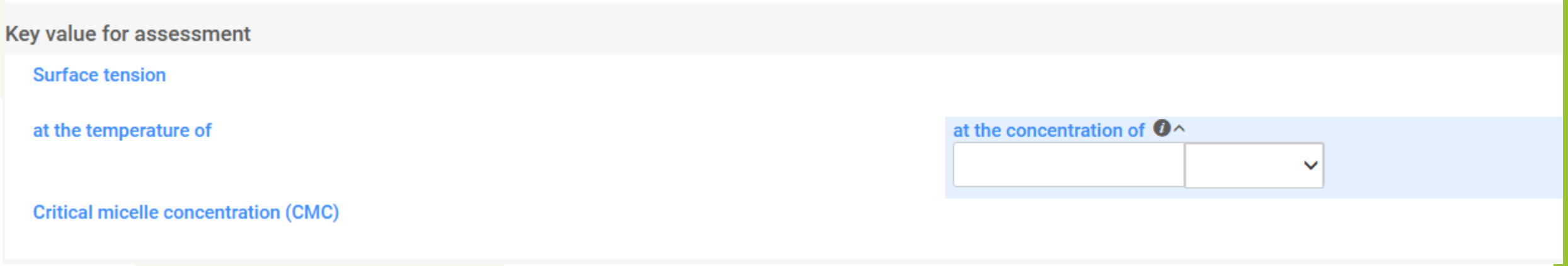
B.7.2.1.2. Magnitude of residues in processed commodities

B.7.2.2. Additional information on residues in food and feedingstuffs
Summary

Phys. Chem. issues

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.



Study input

Non-GLP studies:

- 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 non-GLP studies.

Thank you!

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