

Pesticide Steering Network
IUCLID Subgroup

12 June 2025

Feedback from EACL



European Association of Regulatory
Consultants and Contract Research
Laboratories

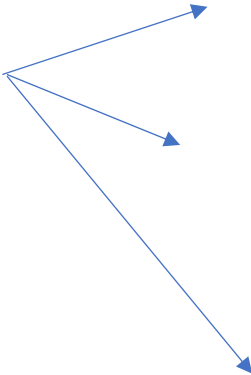
Format changes: Microorganisms



- Major format change for the biological properties (Section 2) **is necessary**.
- The current structure does not allow correct data insertion:
 - study summaries only inserted as unformatted text
 - data protection only possible in groups of references
 - one confidentiality box for all documents attached
 - validation rules are not applied
- This structure prevent from the correct generation of reports, including reference lists.

▼	2 Biological properties of the microorganism	1
>	● Biological properties of the microorganism	
>	2.1 (Cf. 2) Origin, occurrence and history of use	
	2.2 (Cf. 2) Ecology and life cycle of the microorganism	
	2.3 (Cf. 3.1) Mode of action on the target organism and host range	
	2.4 (Cf. 2) Growth requirements	
	2.5 (Cf. 2) Infectivity to the target organism	
	2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms	
	2.7 (Cf. 2) Genetic stability and factors affecting it	
	2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern	
	2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes	

Format changes: Microorganisms

- Since entry is shared with other regulatory fields, solutions are limited. Several possibilities...
- To use the current flexible record and summary record, and to “unblock” the points 2.1-2.9 to allow the entry of endpoint study records (ESR).
- Such ESR should be simple and contain as a minimum: standard blocks for administrative data, Data source, Materials and methods, Results and summary



2 Biological properties of the microorganism	1
>   Biological properties of the microorganism	
> 2.1 (Cf. 2) Origin, occurrence and history of use	
2.2 (Cf. 2) Ecology and life cycle of the microorganism	
2.3 (Cf. 3.1) Mode of action on the target organism and host range	
2.4 (Cf. 2) Growth requirements	
2.5 (Cf. 2) Infectivity to the target organism	
2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms	
2.7 (Cf. 2) Genetic stability and factors affecting it	
2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern	
2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes	

Format changes: Microorganisms

- Another possibility is to create a “fake” point to allow the ESR, i.e. 2.10
- This approach is similar to the available solution at the environmental occurrence section (IUCLID 7.3: Additional information on environmental fate and behaviour), where a “fake” requirement has been included.

Endpoint summary

Simple level of information, enough for list of endpoints.

NEW Endpoint study record

- Selection of endpoint – list of all from 2.1 - 2.9

2 Biological properties of the microorganism	1
2.1 (Cf. 2) Origin, occurrence and history of use	
2.2 (Cf. 2) Ecology and life cycle of the microorganism	
2.3 (Cf. 3.1) Mode of action on the target organism and host range	
2.4 (Cf. 2) Growth requirements	
2.5 (Cf. 2) Infectivity to the target organism	
2.6 (Cf. 2) Relationship to known human pathogens and to pathogens to non-target organisms	
2.7 (Cf. 2) Genetic stability and factors affecting it	
2.8 (Cf. 2 and product dataset 1.4.1) Information on metabolites of concern	
2.9 (Cf. 2) Presence of transferable antimicrobial resistance genes	
2.10 Additional information biological properties	

In case that the format change will take still several months, are there any interim solutions proposed by EFSA?

IUCLID version 9.01

Report generator

- Using the new IUCLID version 9.01, the report generator does not work
(failure messages, e.g. exception occurred during background job execution ...)

e.g.

- MRL report
- 3 - Active Substance B-7 (Residues)
- 3 - Active Substance B-9 (Ecotox)

Data points

- For methods, the fragment ion data have been eliminated, so we have to repopulate it.
- In fate, a persistent flaw in recent releases (not specific to this release) is that for route and rate in degradation endpoint summaries, only one DT50/DT90 value can be included in the key value for assessment when in reality there are usually multiple values.