

**Final report:
Proof of concept pesticides dossier for micro-organism in
IUCLID format**

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List of Abbreviations

Term	Definition
a.s.	Active substance
BPR	Biocidal Products Regulation (EU) No 528/2012
CA	Chemical active substance
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
CFU	colony forming units
CLH	Harmonised classification and labelling
cMS	Concerned Member State
CP	Chemical plant protection product (EU-revised format)
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPS	Endpoint summary
IUCLID	International Uniform Chemical Information Database
IBMA	International Biocontrol Manufacturers Association
MS	Member State
OECD	Organization for Economic Co-operation and Development
OHT	OECD harmonized template
PDPM	Pesticides dossier preparation manual
PM	Project manager
PMBOK	Project Management Body of Knowledge
PMP	Project management plan
PPP	Plant Protection Product
PTM	Project team member
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
RMS	Rapporteur Member State
RSS	Robust study summary
TOC	Table of content
WBS	Work breakdown structure
zRMS	Zonal Rapporteur Member State

List of Reference Documents

- SANCO/10181/2013–rev. 5, 12 June 2019: Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to the Regulation (EU) No 283/2013 and Regulation EU) No 284/2013
- Pesticides Submission Manual (ECHA, November 2019) “How to prepare a pesticides dossier”
- ECHA Guide: Functionalities of IUCLID in the web interface, October 2019 https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395
- knoell Germany GmbH, 9 July 2020, Proof of concept pesticides dossier in IUCLID format <https://zenodo.org/record/3937381#.XxFb3igzbD4>
- European Food Safety Authority (EFSA), 27th March 2019, Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances, doi: 10.2903/sp.efsa.2019.EN-1612

1 Executive summary

The current project is an extension of the pilot project: “Proof of concept pesticides dossier in IUCLID format”¹ performed according to the amendment to the contract NP/EFSA/DATA/TS/2019/01 and its aim is to investigate the applicability of IUCLID for the preparation of an active micro-organism² pesticide dossier. knoell’s aims were to test IUCLID, based on the same principles of the original pilot study, with regards the creation and applicability for a micro-organism plant protection product dossier, and provide feedback of the overall process, issues and time needed.

Upon commencement of the project, and to enable the initiation of the evaluation of the software according to the project aims and objectives, the following steps were performed;

- Creation of a new active micro-organism pesticide dossier with completed OHTs (this dossier covers preparation of the active micro-organism and microbial representative product datasets in IUCLID).
- Report on key findings of the pilot.

For testing of active micro-organism pesticide dossier (both active micro-organism and microbial representative product) in IUCLID the dossier for *Beauveria bassiana* 147 was chosen and the associated data was provided by EFSA to knoell at project initiation.

Constraints of the project:

- The data on composition and metabolites were not available to knoell, due to confidentiality reasons.

¹ The project (NP/EFSA/DATA/TS/2019/01) and its results are described in the report knoell, 2020 and are also valid for the current extension for micro-organism dossier. In this phase of pilot the industry association IBMA was involved in addition. The overall objective of this pilot project was to assess whether IUCLID and related technologies can manage a pesticide dossier and the data contained within. To achieve this objective knoell tested the creation and processing of an active substance clodinafop under Article 7 of Regulation (EC) No 1107/2009 and a renewal pesticides dossier under Article 15 of Regulation (EC) No 1107/2009 within IUCLID 6.

² Based on the guidance of ECHA (Guidance on the Biocidal Products Regulation. Volume V, Guidance on Active Micro-organisms and Biocidal Products. Version 2.1, March 2017, we have used the terminology “active micro-organism” and “microbial product”. We suggest also to use the according naming in IUCLID. The current IUCLID version uses the word “microorganism” and when the sections names or submission types in IUCLID were cited, we used the names used in IUCLID (e.g. EU PPP Microorganism).

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- For each study record, only one study report was inserted (one study record, one study report).
- An appropriate submission type for microbial representative product was not available in IUCLID.

Overall the evaluation of the software by knoell was positive. The entry of most of the active micro-organism related data into IUCLID did not cause any problems and was straightforward. The extensive amount of literature data citing information on the active micro-organism could be summarised easily within the IUCLID database thanks to its many fields and flexibility. It was also possible to test the validation assistant and prepare an example DAR with the use of the DAR report generator. These tools are still under development.

The main issues and recommendations for the future development identified during the testing of IUCLID are listed in Table 1 below:

Table 1 Summary of main issues identified and knoell's recommended response

Issue identified	Recommendation for the future
Missing submission type for microbial (representative) product	As a workaround, the submission type for the representative product with chemical active substance was selected. This new submission type is under preparation by the ECHA, and should be available soon
Entry of data for Biological properties.	In Section 2.1. provide an option which enables the user to present short text summaries and properly attach studies/literature (readable by report generator)
IUCLIDs use of multiple cross-references to link and guide the user to another location made data entry somewhat burdensome	Keep the cross references to minimum and where possible only cross-reference within the same main section.
Missing values, appropriate units CFU (colony forming units) and appropriate guidelines for active micro-organisms within specific fields such as pick lists.	Update of pick-lists and specific fields with necessary values/units to enable full functionality. ECHA is going to update the IUCLID templates accordingly
Linking of data between various datasets is not possible	Add an option to IUCLID, allowing the user to link several datasets (that currently is only available only within one dataset).
Missing functionality for the presentation of the results of the risk assessment in IUCLID	Ideally, the software should enable the user to extract key values for the risk assessment or generate reference lists with all needed values directly from IUCLID via report generator.

2 Project scope

2.1 Project goal

The current project is an extension of the pilot project: “Proof of concept pesticides dossier in IUCLID format”³ performed according to the amendment to the contract NP/EFSA/DATA/TS/2019/01 and its aim is to investigate the applicability of IUCLID for the preparation of the active micro-organism pesticide dossier⁴. This extension of the pilot study to include an additional case was initiated since the data requirements and thus also the way of presentation of the information in IUCLID for the microbial plant protection products differs from those containing chemical active substances.

The thorough check of available IUCLID templates, identification of missing IUCLID elements and recommendation of solutions to improve IUCLID, were main goals of the project. Table 2 lists the key tasks, deliverables and deadlines of this phase of the pilot project.

Table 2: Project tasks and deliverables

Tasks and deliverable	Deadline
Task: Creation of a new micro-organism pesticide dossier with completed OHTs. Deliverable: Proof of concept new micro-organism pesticide dossier as an IUCLID I6Z transferrable package file including the related datasets.	01.07.2020
Task: Continued participation in the pesticides dossier technical group. Deliverable: Report on key findings of the pilot. The report shall contain 1) a gap analysis detailing the refinements needed to the micro-organism submission type (in the same format as the TOC to IUCLID excel file) - list of OHTs to be mandatorily included; - list of other optional applicable OHTs;	26.07.2020

³ The project and its results are described in the report knoell, 2020 and are also valid for the current extension for micro-organism dossier. In this phase of pilot the industry association IBMA was involved in addition. The overall objective of this pilot project was to assess whether IUCLID and related technologies can manage a pesticide dossier and the data contained within. To achieve this objective knoell tested the creation and processing of an active substance clodinafop under Article 7 of Regulation (EC) No 1107/2009 and a renewal pesticides dossier under Article 15 of Regulation (EC) No 1107/2009 within IUCLID 6.

⁴ Based on the guidance of ECHA (Guidance on the Biocidal Products Regulation. Volume V, Guidance on Active Micro-organisms and Biocidal Products. Version 2.1, March 2017, we have used the terminology “active micro-organism” and “microbial product”

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Tasks and deliverable	Deadline
- list of missing IUCLID templates that could be useful for processing pesticides dossiers during the assessment process 3) list of issues encountered during the pilot and solution implemented or proposed (beyond those already identified for active substances). 4) detailed record of the time taken for each of the dossier preparation tasks/phases. A comprehensive report on key findings of the pilot project (.docx format)	

2.2 Set up of the case study for micro-organism

2.2.1 Available data

Testing of an active micro-organism pesticide dossier in IUCLID was done with *Beauveria bassiana* 147. All non-confidential data for this micro-organism was provided to knoell by EFSA at project initiation. The *Beauveria bassiana* 147 dossier was originally submitted to the authorities in 2013, and further updated in 2014. The 2014 version of this dossier was primarily used by knoell for the preparation of IUCLID dossier.

The dossier contained the active micro-organism and representative microbial plant protection product study reports (Document K) and the dossier in OECD format (Document A-I, L, M, N and O).

Due to confidentiality reasons, only the non-confidential sections were provided and the data on composition and metabolites were not available to knoell and could not be presented and tested fully in IUCLID.

2.2.2 Manual testing of IUCLID – dossier preparation

For the purpose of this project, it was agreed with EFSA that each study record will only contain one study report. This agreed approach enabled knoell to obtain the unique study register within IUCLID (one study record – one report). One robust study summary and endpoint summary, per data point, were entered into IUCLID. If sufficient data were not available for the adequate testing of the IUCLID templates, another summary per data point was summarised in addition.

Only the study reports that were summarised in IUCLID were attached to IUCLID. This is different to main pilot study - the proof of concept for the chemical active substance clodinafop, in which all study reports were transferred from CADDY to IUCLID (to check the capacity of IUCLID).

Since some data (e.g. compositional data, Document J) were considered to be confidential, these data were not available to knoell and could not be entered into IUCLID, hence exemplary IUCLID summaries were created and empty reports (dummy files) were attached to IUCLID.

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The work was performed with IUCLID 6.4.14.1 on a knoell IUCLID server. Specific testing of IUCLID, e.g. report generator and Validation Assistant were done in the ECHA IUCLID cloud instance, IUCLID 6 version 4.19.2.

Figure 1: Submission types in IUCLID used for the active micro-organism and microbial representative product dossier preparation

EU PPP Microorganisms	
1. Identity of the microorganism	4
2. Biological properties of the microorganism	5
3. Further information on the microorganism	3
4. Analytical methods	15
5. Effects on human health	20
6. Residues in or on treated articles, food and feed	6
7. Fate and behaviour in the environment	10
8. Effects on non-target organisms	21
10. Summary and evaluation	5

EU PPP Active substance application (representative product)	
1. Identity of the representative plant protection product	5
2. Physical and chemical properties of the representative plant protection product	38
3. Data on application	4
4. Further information on the representative plant protection product	2
5. Analytical methods	10
6. Efficacy data	2
7. Toxicological studies	10
8. Residues in or on treated products, food and feed	1
9. Fate and behaviour in the environment	1
10. Ecotoxicological studies	17
12. Classification and labelling	2
13. Summary and evaluation	2

The data reports for the micro-organism were transferred into the IUCLID submission type: *EU PPP Microorganism* specifically prepared for the active micro-organism. Since the IUCLID version 6.4.14.1 does not contain the submission type for the representative product containing an active micro-organism, the data for the representative product were entered into the submission type: *EU PPP Active substance application (representative product)* designed for products containing chemical active substances. In order to maintain a clear overview and reference between the required data points, the study record and endpoint summaries descriptions consist of the following elements:

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- Data point according to Regulation (EU) No. 283/2013 or 284/2013
- Short description of study type/data point
- „Old“ OECD data point as given in the dossier for *Beauveria bassiana* 147
- Year for study records

This naming of the study records with the true numbering (different to the numbering within the submission type for chemical active substance) should support a better navigation in the IUCLID.

This issue is illustrated by example in the Figure 2. One can see that pH is the data point 2.5. according to the Regulation (EU) 284/2013 but within the available chemical product submission type it is the point 2.4.

Figure 2: Study summary and endpoint summary naming

✓ 2.4 Acidity / alkalinity and pH value

	2.5 pH Last Modified:30/06/2020 20:09
	2.5 pH_IILM 2 (2012) Last Modified:01/07/2020 13:28

This naming convention was chosen to ease the evaluation of the submission types available in IUCLID for micro-organism (results of this evaluation is available in Sections 3.1 and 3.2). The name of the record is rather supporting information for visualisation of the data availability in IUCLID for the applicant and the authority. Based on knoell's experience with IUCLID applications under REACH and BPR, it is assumed and expected that the names of the study records will also not be disseminated also for PPP applications.

Please note that the proposal for the new submission type for microbial representative product is currently under preparation by the ECHA and with support of the pilot working group with the goal of the implementation of this new submission type in the next version update of IUCLID (see Section 3.2).

3 Results and observations of the pilot project

The results of the observations and issues encountered during the project are presented in the following sections in detail, including illustrations so that the recommended solutions can be easily understood and implemented.

The overall objective of this project was successfully achieved: the active micro-organism pesticide dossier was efficiently prepared within a short time frame within IUCLID.

To achieve better navigation of the technical description presented in the next sections, we organised the current section in the following way:

- Section 3.1 and Section 3.2 detail a gap analysis concerning the templates (including OHTs) available for the entry of the data for the active micro-organism and the representative microbial plant protection product.
- Section 3.3 lists the issues identified with IUCLID connected with the reporting of biological properties that are characteristic for the micro-organism.
- Section 3.4 deals with usability issues including those not specifically connected with the micro-organism properties.
- Section 3.5 reports on the first experiences with the DAR report generator, validation assistant and about some aspects of use of printing option.
- Section 3.6 indicates some open points for the future IUCLID development.
- Section 3.7 details the time needed for the completion of an active micro-organism pesticide dossier in IUCLID.

3.1 A gap analysis detailing the refinements needed to the micro-organism submission type

knoell evaluated the available IUCLID submission type EU PPP Microorganism based on the data requirements according to Regulation (EU) No. 283/2013 and with support of the micro-organism pesticide dossier created in IUCLID for the case study. The results of this evaluation were detailed within a gap analysis, which is provided in a tabular form in the Annex I, Table 6: A gap analysis of the available in IUCLID submission type EU PPP Microorganism. This analysis was conducted for all dossier sections for the micro-organism (also for the microbial representative plant protection product, but this was reported in different form as described in Section **Fehler! Verweisquelle konnte nicht gefunden werden.**).

The main results are the following:

- The available submission type in IUCLID can be used for the entry of most of the data presented in the dossier.
- The IUCLID templates available for biological properties require improvements (see Section 3.3.4)
- The submission type EU PPP Microorganism contains some IUCLID templates that are not considered as official data requirement point according to Regulation No. (EU)

283/2013. We recommend removing these data points from this submission type. If it is not possible, another option would be to keep the templates but mark them in IUCLID as non obligatory information (or mark e.g. by * the data points that are obligatory. Only obligatory data points would be checked by the validation assistant).

- Cross-references: There are cases in which the appropriate OHT template in IUCLID is available but not under the expected endpoint, for example: in the IUCLID Section 3.8. “Procedures for destruction or decontamination” the study summary cannot be entered but is cross referenced as “Cf. 3.7.” i.e. to section 3.7. “Recommended methods and precautions concerning handling, storage, transport or fire”. In this case such a cross-reference is justified and reasonable. There are however many examples as listed in the Table 6: A gap analysis of the available in IUCLID submission type EU PPP Microorganism, where in knoell’s view, such cross-references are not suitable. Some study summaries should be entered within a different section which seems to bring disorder to the dossier structure. As in the previous report, knoell recommends to remove the use of cross-references, where possible.
- Key values in endpoint summaries are related to chemical assessment (applicable for ecotoxicology and environmental fate) and in some cases require modification to include the micro-organism information.
- Workaround solutions and recommendations for IUCLID are provided in detail in Table 6 concerning each endpoint in this submission type.

In addition, further points noticed during the gap analysis are detailed within Section 3.3 and 3.4.

3.2 New submission type for the representative microbial plant protection product

The submission type for a microbial representative plant protection product was not available in the tested IUCLID version. In fact this submission type was under preparation by one of the working groups during the pilot project. The representatives of EFSA, MS, IBMA, ECHA and knoell created the draft new submission type that is going to be implemented into IUCLID by the ECHA and IUCLID software developers. As a base for the creation of this submission type the available submission type: EU PPP Active substance application (Representative product) was taken and many modifications were proposed to adjust this IUCLID submission type to meet the requirements for a microbial plant protection product dossier.

Modifications were connected with removal of unnecessary data points, creating more general study record and endpoint summary templates, moving of available templates (to avoid cross-references) and adjustment of numbering according to the Regulation No. (EU) 284/2013.

Dossier sections: “Residues in or on treated product, food and feed” and “Fate and behaviour in the environment” have the same data provisions as for active micro-organism (according to the Regulation No. (EU) 283/2013). Only if the data from active micro-organism are not sufficient, the new information should be generated on the microbial plant protection products. In fact in most of the cases, new data are not generated for the product and the data submitted for active micro-organism are considered as sufficient. To implement this

situation in IUCLID, the working group decided to introduce in these sections the possibility of entry of a data waiving at the main section level. This was also applied in the dossier prepared within this pilot project as it is illustrated in the Figure 3: Illustration of the data waiving for the Residues section. The data waiving statement was entered provisionally in the endpoint study summary. Knoell recommended addition of the study summary for the entire section to include such data waiving statement. No further study summaries would be needed (and were also not included in the pilot dossier).

Figure 3: Illustration of the data waiving for the Residues section

▼ 8 Residues in or on treated products, food and feed

8 Residues in or on treated product, food and feed (Rationale to waive residue studies on MPCP)
Last Modified: 01/07/2020 09:55

The overall new submission type is not presented within this report since this work is performed within the working group and submission type is currently being created by the ECHA. Knoell detailed comments were presented separately within this working group meetings.

3.3 Completeness of IUCLID fields for specific micro-organism data

3.3.1 Literature data in IUCLID

Micro-organism dossiers contain large amounts of literature data, much more than active substance dossiers. The entry of such data did not cause any problems when compared to the presentation of the data from the study reports. IUCLID is a very universal logical software that allows applicants to summarise various data sources within the same OECD template.

Below Figures illustrate how to use different IUCLID fields to report the literature as a data source.

Figure 4: Data source filed in IUCLID for literature data

The screenshot shows the 'Data source' field in IUCLID. It contains a reference to a publication: 'publication | Human Deep Tissue Infection with a'. Below the reference is a red plus icon and the word 'Select'. Underneath the reference field, there are two other fields: 'Data access' with the value 'data published', and 'Data protection claimed' with the value 'None'.

Figure 5: Reliability field in IUCLID for literature data

Study period Not reported	
Reliability 2 (reliable with restrictions)	Not reported
Rationale for reliability incl. deficiencies study well documented, meets generally accepted scientific principles, acceptable for assessment	

Figure 6: Reference filed in IUCLID for literature data

Reference Type publication
Title* Human Deep Tissue Infection with an Entomopathogenic Beauveria Species
Author Henke M.O., de Hoog G.S., Gross U., Zimmerman G., Kraemer D. and Weig M.
Year 2002
Bibliographic source Journal of clinical microbiology, Jul. 2002
Testing facility None
Report no. None
Study sponsor None
Study no. None
Report Date 2002-04-26
Remarks None

The reliability assessment according to Klimisch is currently not performed in any pesticide dossier (chemical nor micro-organism). In case this assessment is also going to be used for plant protection products, specific guidance would need to be established for the applicants.

3.3.2 Units

The accurate reporting of test results for studies performed with an active micro-organism requires that specific and appropriate units i.e. CFU (colony forming units) are available within the template. Currently, these units are not available in IUCLID, except for the Section 1.4.1. Content of the microorganism. The additional units should be included in IUCLID study records and endpoints summaries in the results fields in pick lists. As a workaround for this pilot project the units were entered manually under “other” and not by choosing an available

option in the drop down list. This is illustrated in Figure 7 by screenshot from IUCLID study summary for acute oral toxicity of micro-organism.

Figure 7: Illustration of missing units in a pick list

Dose descriptor
LD50

Effect level ? ▾

> ▾ 1800000000 ▾

other: ▾ CFU/kg bw
press Esc to close

Based on
test mat.

95% CL
None

Remarks on result
--

Missing units for the **active micro-organism** are presented according to EU PPP Microorganism submission type in IUCLID and listed below.

CFU/kg bw is missing in the following data points in IUCLID:

- 5.2.2.1 acute oral toxicity
- 5.2.2.2 acute inhalation toxicity
- 5.2.2.3 intraperitoneal/subcutaneous dose
- 5.2.5.1 health effects after repeated inhalation exposure
- 5.2.5.2 health effects after repeated oral exposure
- 5.4. In vivo studies in somatic cells

CFU/L or CFU/g is missing in the following data points in IUCLID

- 6.2.2. Viable residues
- 7. Environmental Fate (for all data points)
- 8.1. Effects on birds
- 8.2.1. Effects on fish
- 8.2.2. Effects on freshwater invertebrates
- 8.2.3. Effects on algae growth
- 8.2.4. Effects on plants other than algae
- 8.3. Effects on bees
- 8.4. Effects on arthropods other than bees
- 8.5. Effects on earthworms
- 8.6. Effects on non-target soil micro-organisms
- 8.7. Additional studies

Missing units for the **microbial product** are presented for the data points according to Regulation (EU) No. 284/2013, since current IUCLID submission type for the microbial product is not available in IUCLID.

CFU/kg bw

- 7.1.1 oral toxicity
- 7.1.2. Acute inhalation toxicity
- 7.1.3. Acute percutaneous toxicity

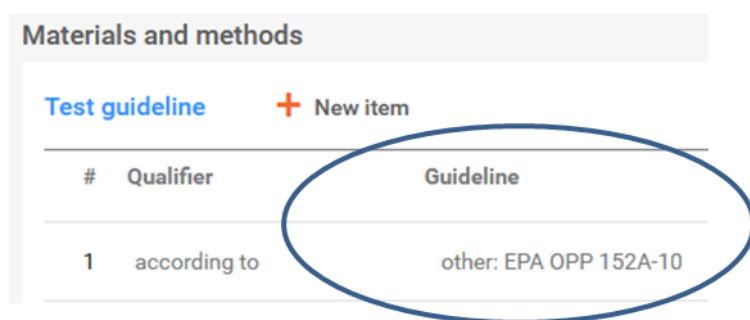
CFU/L or CFU/g:

- 10.1 Effects on birds
- 10.2. Effects on aquatic organisms
- 10.3 Effects on bees
- 10.4. Effects on arthropods other than bees
- 10.5. Effects on earthworms
- 10.6. Effects on soil micro-organisms
- 10.7. Additional studies

3.3.3 Guidelines

Similar to the issue concerning units, relevant guidelines specific for the testing of micro-organism are missing and need to be added to picklists, within study summary records, part “Material and methods”, “Test guideline” as shown in Figure 8.

Figure 8: Illustration of missing guidelines in a pick list



The missing guidelines were listed during the work of the technical group (in which participated EFSA, IMBA, ECHA, MS and knoell) and they are provided in a Table 3.

Table 3: List of missing guidelines

EPA Guidelines for micro-organisms	OHT template in IUCLID or EU data point
885.3050 Acute Oral Toxicity/Pathogenicity (February 1996) OPP: 152A-10	OHT 60 Acute toxicity: oral
885.3100 Acute Dermal Toxicity/Pathology (February 1996) OPP: 152A-11	OHT 62 Acute toxicity: dermal
885.3150 Acute Pulmonary Toxicity/Pathogenicity (February 1996) OPP: 152A-12	OHT 61 Acute toxicity: inhalation

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EPA Guidelines for micro-organisms	OHT template in IUCLID or EU data point
885.3200 Acute Injection Toxicity/Pathogenicity (February 1996) OPP: 152A-13	5.2.2.3 Intraperitoneal administration
885.3500 Cell Culture (February 1996) OPP: 152A-16	5.2.4 Cell Culture
885.4000 - Background for Nontarget Organism Testing of Microbial Pest Control Agents (February 1996) OPP: 154A-1, 154A-2, 154A-3, 154A-4, 154A-5	Header section 8 for active and 10 for product
885.4050 - Avian Oral, Tier I (February 1996) OPP: 154A-16	OHT 53 Toxicity to birds
885.4100 - Avian Inhalation Test, Tier I (February 1996) OPP: 154A-17	OHT 53 Toxicity to birds
885.4200 - Freshwater Fish Testing, Tier I (February 1996) OPP: 154A-19	OHT 41 Short-term toxicity to fish
885.4240 - Freshwater Aquatic Invertebrate Testing, Tier I (February 1996) OPP: 154A-20	OHT 43 Short-term toxicity to aquatic invertebrates
885.4280 - Estuarine and Marine Animal Testing, Tier I (February 1996) OPP: 154A-21	for aquatic toxicity point 8.2 for active substance and point 10.2 for products
885.4300 - Nontarget Plant Studies, Tier I (February 1996) OPP: 154A-22	OHT 51 Toxicity to terrestrial plants
885.4340 - Nontarget Insect Testing, Tier I (February 1996) OPP: 154A-23	OHT 50-2 Toxicity to terrestrial arthropods
885.4380 - Honey Bee Testing, Tier I (February 1996) OPP: 154A-24	OHT 50-2 Toxicity to terrestrial arthropods
885.4600 - Avian Chronic Pathogenicity and Reproduction Test, Tier III (February 1996) OPP: 154A-26	OHT 53 Toxicity to birds
885.4650 - Aquatic Invertebrate Range Testing, Tier III (February 1996) OPP: 154A-27	OHT 43 Short-term toxicity to aquatic invertebrates

EPA Guidelines for micro-organisms	OHT template in IUCLID or EU data point
885.4700 - Fish Life Cycle Studies, Tier III (February 1996) OPP: 154A-28	OHT 41 Short-term toxicity to fish
885.4750 - Aquatic Ecosystem Test (February 1996) OPP: 154A-29	for aquatic toxicity point 8.2 for active substance and point 10.2 for products
885.5000 - Background for Microbial Pesticides Testing (February 1996) OPP: 155A-1,2	header section 7 and section 9 for active and product
885.5200 - Expression in a Terrestrial Environment (February 1996) OPP: 155A-10	OHT 30 Biodegradation in soil
885.5300 - Expression in a Freshwater Environment (February 1996) OPP: 155A-11	OHT 29 Biodegradation in water and sediment: simulation tests
885.5400 - Expression in a Marine or Estuarine Environment (February 1996) OPP: 155A-12	OHT 29 Biodegradation in water and sediment: simulation tests

3.3.4 Biological properties

One of the essential chapters of an active micro-organism dossier is Chapter 2 on “Biological properties of the micro-organism”. Generally, a large quantity of literature references needs to be included in order to describe data on the micro-organism. Normally the biological properties are presented in such a manner that a general summary over several publications is prepared and not a summary (i.e. study record) per publication. In most cases each part of the section ends up with cited references presented as follows:

- Report: Data point (e.g. MA 2.1/01), Year
- Authors:
- Title:
- Source:
- Abstract:

In the available IUCLID submission type “EU PPP Microorganism” the data can be entered at 2.1 History of the micro-organism and its uses. Natural occurrence and geographical distribution, 2.2 Information on target organism(s) and 2.3 Host specificity range and effects on species other than the target harmful organism. All other data points (i.e. 2.1.1, 2.1.2, 2.2.1, 2.2.2, 2.4, 2.5, 2.6, 2.7, 2.8 and 2.9) refer to the editable data points (see Figure 9).

Figure 9: IUCLID Table of Content – Biological properties (Extract)

▼ 2 Biological properties of the microorganism	
▼ 2.1 History of the microorganism and its uses. Natural occurrence and geographical distribution	+ New ▼
<div>● 2.1, 2.4, 2.6, 2.7, 2.8, 2.9, 2.5 Biological properties (History, Development stages, Relationship to pathogens, genetic stability, metabo Last Modified:16/06/2020 10:32</div>	
<div>📄 2.1.1 (Cf. 2.1) Historical background</div> <div>📄 2.1.2 (Cf. 2.1) Origin and natural occurrence</div>	
▼ 2.2 Information on target organism(s)	+ New ▼
<div>📄 2.2 Information on target organism(s) IIM 2.3 Last Modified:16/06/2020 10:35</div> <div>● 2.2 Red Palm Weevil KII 3.4.2/01 (2011) Last Modified:29/06/2020 12:47</div>	
<div>📄 2.2.1 (Cf. 2.2) Description of the target organism(s)</div> <div>📄 2.2.2 (Cf. 2.2) Mode of action</div>	
▼ 2.3 Host specificity range and effects on species other than the target harmful organism	+ New ▼
<div>📄 2.3 Host specificity range and effects on species other than the target harmful organism Last Modified:16/06/2020 11:22</div> <div>● 2.3 Alligator KII 2.4/01 (1979) Last Modified:01/07/2020 12:45</div>	

Most of the data should be entered in the study record template available in 2.1. This template allows for the possibility to report data on each data point in simple Rich Text Fields (RTF) fields (see Figure 10).

Figure 10: Content of 2.1 Template (partly)

Biological properties of the microorganism	
General information on the microorganism	None
Historical background	None
Historical uses	None
Origin, natural occurrence and geographical distribution	None
Development stages / life cycle of the microorganism	None
Relationships to known plant or animal or human pathogens	None
Genetic stability and factors affecting it	None
Information on the production of metabolites (especially toxins)	None
Production and resistance to antibiotics and other antimicrobial agents	None

While entering the data from the available dossier in word format, as the order of points in IUCLID is not in line with the order given in Regulation (EU) No. 283/2013, finding the appropriate place in IUCLID was difficult. The order, as given in the study record description details the order of data points in the study record, i.e. “2.1, 2.4, 2.6, 2.7, 2.8, 2.9, 2.5”. Additionally the data points 2.2. and 2.3 needed to be reported separately.

Some points from the study record template 2.1, as “Monitoring plan to be used for the active micro-organism including handling, storage, transport and use” are detailed in chapter 3.7 and are repetitive. Whereas in other cases the requested information is biocide related (e.g. “Biological properties of the micro-organism in the biocidal product”).

All references within 2.1 study record can only be reported in the appendix. These references are not legible to the report generator tool (see Section 3.4.2 for more details).

Generally RTF fields are acceptable to report the data per data point (similar to how it is currently done in micro-organism dossiers).

knoell recommend to create separate templates for **separate data points** to match the data requirements as given in Regulation (EU) No. 283/2013 and **avoid cross-references** from one data point to another.

It would be ideal, if IUCLID is provided with an option to present short text summaries and properly attach studies/literature (readable by report generator). As aforementioned, the biological properties are presented in a general summary over several publications rather

than individual study records per publication. For these publications it is then not necessary to complete a full study record.

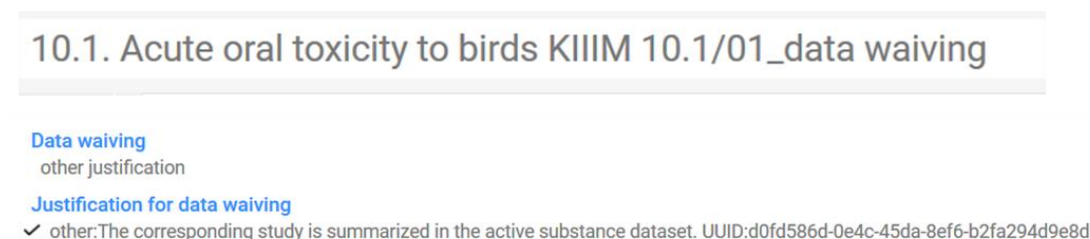
If the possibility of additional study records for the separate data points is chosen, a simple study record with reduced information is preferred, e.g. just bibliographic information. This summary should then not contain non-relevant text fields.

3.4 Usability issues

3.4.1 Linking of data between various datasets

In the dossier for the active micro-organism, there were many cases when the study performed on the active micro-organism covered also the data requirements for the microbial representative product. In such cases, in order to avoid the duplication of study summaries in two datasets - one in the active micro-organism and second in the representative product - the study summary was entered just once in the active micro-organism dataset. In the microbial representative product dataset a simple data waiving statement was entered with the UUID of the active substance dataset, in which the study was summarised, as it is shown in Figure 11.

Figure 11: Data waiving in the representative product dataset with the link to the active micro-organism dataset



The entry of UUID is a workaround used to unambiguously indicate the study record. The ideal option would be to set the reference link, which would directly lead to the dataset in which the summary was entered. This option is currently not available between different kinds of datasets, such as this case: it is not possible to link the study summary in the product dataset with the study summary within the active substance dataset (neither within study summary nor within the endpoint summary).

Linking is possible in IUCLID within one dataset by using the option “reference to the same study” shown in Figure 12.

Figure 12: Linking of study records using the same study report within one dataset

Cross-reference + New item

#	Reason / purpose	Related information	Remarks
1	reference to same study	Partition coefficient a.s.-copy	None

Knoell highly recommends inclusion of adding the possibility of linking different datasets (e.g. between the active micro-organism and the microbial representative product data set).

3.4.2 Attachments

IUCLID enables multiple attachments in each study record. Fields are designated for certain attachments like the full study report or background material (screenshots below in Figure 13).

Figure 13: Placing of full study report or background material in a study record

Overall remarks, attachments

Overall remarks
None

Attached background material + New item

#	Attached document	Remarks
	Attached full study report KIL_5.1_01.pdf	
	Illustration (picture/graph) None	

Unfortunately not all study records contain such an option, for example within the study summary for Biological Properties Section 2.1. There is no possibility to enter the reference and attach the report as presented above. Instead the study has to be attached by using an option of adding any attachment as shown in Figure 14.

Figure 14: Placing an attachment to the study summary in IUCLID Section 2.1. Biological properties

Attachments

Upload file

KIL_2.8.pdf
466.35 KB / Uploaded: 16/06/2020 10:21

Belonging to Reg. 283/2013 2.6
Relationship to known pathogens

If the study is attached in this way, it is not directly visible within the study summary itself, and to check if attachments are included, one has to click on the paper clip icon. Here a better visualisation would be helpful.

There are two further aspects that should be considered when the report cannot be attached to specially designed fields:

- They cannot be flagged as confidential (this would be relevant for the attachments in section 1.4)
- The report generator cannot include the appropriate reference in the reference list.

3.4.3 Toxicology

For certain studies (e.g. 5.2.2.1 Acute oral toxicity) the field “other findings”, could only be used for the entry of clearance and Infectivity/persistence. These results are specific for micro-organisms and IUCLID does not have specific fields for this information.

Figure 15: Entry of Clearance and Infectivity/persistence in IUCLID

Other findings

Clearance:

The test organism was detected in the faeces of two of six treated animals at approximately 24 h post-dose. The number of CFU found was 3.3E+04 for and 1.2E+05 for two animals. The test organism was not detected in the faeces of any animal at subsequent collection intervals.

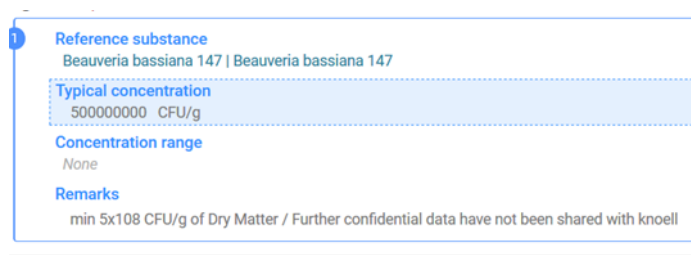
Infectivity/Persistence:

The test organism was not detected in the blood, organs or caecum contents of any animal at any collection interval.

Recommendation: to add separate fields to IUCLID templates.

3.4.4 Content of the micro-organism

The typical content of micro-organisms is in the level of hundreds of millions. In IUCLID this value has to be entered by typing all “0” (zeros) manually. It is recommended to allow notation as e.g. 1e8 also to avoid a mistake when entering this value.



Reference substance Beauveria bassiana 147 Beauveria bassiana 147
Typical concentration 500000000 CFU/g
Concentration range None
Remarks min 5x10 ⁸ CFU/g of Dry Matter / Further confidential data have not been shared with knoell

3.5 New features tested

3.5.1 IUCLID plug-ins: Validation assistant and DAR Report generator

The first versions of IUCLID plug-ins designed for the PPP application were tested in the IUCLID cloud instance with the IUCLID 6 version 4.19.2.

Validation assistant is a very practical tool allowing automatic check of the dossier completeness. The current tool contains a simple set of rules, partly applied from the REACH validation assistant, for example it checks whether IUCLID fields such as a description of materials, results, references, are completed as required. It also checks if the data waiving statements are presented in the correct way (this is certainly only a simple completeness check; the correctness and compliance of the data waiving cannot be checked by this tool). In the future it would be very useful if the Validation assistant could ensure that the correct fields in IUCLID have been filled with content and check if the required document (e.g. report) has been attached. For example one could apply the rule that all robust study summary records have to have an attachment.

The new version of validation assistant has a practical option to export of the validation assistant report in .xls format.

DAR Report generator is one of the tools (also confidentiality claims, notified studies), that will be available for the PPP applications. The newest version of IUCLID has already a prototype for the DAR report generator and a report could be created for the dossier for *Beauveria bassiana* 147. This report generator is still under development, therefore was not tested in detail by Knoell during this pilot project. It was however noticed that currently the report could only be created only for the dossier product file and not product dataset – However we note that during our previous testing phase of the chemical active substance this functionality was available.

3.5.2 Printing of files

IUCLID version 6.4.14.1. has an option to print IUCLID documents: selected study records or the selected dataset. This is very useful functionality which allows persons not having access to IUCLID software to view the information entered into IUCLID.

Knoell checked the print option from several datasets, and came to the following conclusions:

- Product dossier (dossier file in non-editable format): Print file could be created from the product dossier, but does not contain summaries for the micro-organism.
Recommendation: to include the summaries for micro-organism in the print file (or in general active substances or other datasets linked to the product).
- Product dataset (editable dataset with chosen submission type: EU PPP Active substance application (representative product): Print file can be created but does not follow the structure of the chosen submission type. This means that the content is not organised, as it would be expected when the submission type is chosen for printing.
- Micro-organism dataset: printing is possible but similarly as for the product dataset; the print file does not inherit the structure of the chosen submission type.
Recommendation: to organise the data in the print according to the chosen submission type.
- The selection of content available in the web interface of IUCLID does not fully function: e.g. option “Select documents to be included” does not work

3.6 Proposed future features

In respect to introduction of IUCLID as a tool for handling of pesticide dossiers, there is a need for some additional features or fields in IUCLID that could ease the work of applicants and authorities. New potential features are proposed below.

3.6.1 Details about the studies in the reference list

The reference list according to the format as given in SANCO/12580/2012– rev. 4 requires the indication of vertebrate studies (Y/N), data point and whether the studies were previously used, as shown in Figure 16.

Figure 16: Reference list according to SANCO/12580/2012– rev. 4

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities ^{2,3} Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used ¹ Y/N If yes, for which data point?

Current IUCLID version does not have any special fields to indicate it. If this reference list format should be created, based on the IUCLID entries, which would be a desired option, one could implement the additional tick boxes to make such indication possible in the IUCLID. When the report generator for the reference list would be used, all information could be pulled from the IUCLID and would not need to be added manually in the reference lists.

3.6.2 Further tick boxes

There is additional essential information concerning the studies and dossier that, in knoell's opinion, should be included in additional fields, such as information whether:

- Study is used for risk assessment
- The endpoint is an EU agreed endpoint in the context of PPP authorisation
- Outcome of previous evaluation as requested in Appendix E of the EFSA administrative guidance i.e.
 - o Yes, evaluated and accepted + mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006)*.
 - o Yes, evaluated and classified as supplemental + mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006)*.
 - o Yes, evaluated and not accepted+ mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006)*.
 - o No, submitted after the legal deadline and hence, not evaluated
 - o No, not previously submitted

On the level of the studies this could be handled by addition of fields or tick-boxes, making possible the additional selection.

3.7 Record of the time taken for the dossier preparation tasks/phases

In Table 4 below, it shows the time required for preparation of the dossier for the active micro-organism based on the number of RSS entered. For the interpretation of the numbers provided in Table 4, it is necessary to mention that, for the purpose of this project, only one RSS per endpoint was prepared in IUCLID, And this was done in a basic copy paste from the word format (which may not mirror a real case scenario).

Thus, the preparation of the active micro-organism dataset took approx. 156 hours. Within this time the new IUCLID records were created (one IUCLID study record per one study report in the relevant IUCLID section) and the respective study reports attached. In addition the data waiving statements were entered and the endpoint summaries were prepared. The main findings per data point were presented in the endpoint summaries. The time taken for the preparation of the microbial representative product dossier was, as expected, faster than that of the active micro-organism and took approx. 106 hours.

Two tables, Table 4 and Table 5, provide details on the number of robust study summaries and data waivers prepared within the project and the overall time needed for the preparation of selected IUCLID sections.

Table 4: Time spent on the preparation of the IUCLID sections of the *micro-organism dataset*

IUCLID section	Number of RSS summaries	Time spent per section
1. Identity of the microorganism	3 study summaries	20 h
2. Biological properties of the microorganism	3 study summaries	13 h
3. Further information on the microorganism	3 study summaries	14 h
4. Analytical methods	8 study summaries, 4 data waivers	15 h
5. Effects on human health	11 study summaries, 3 data waivers	50 h
6. Residues in or on treated products, food and feed	1 study summaries, 2 data waivers	15 h
7. Fate and behaviour in the environment	5 study summaries	12 h
8. Effects on non-target organisms	9 study summaries, 1 data waiving	17 h
Overall time	43 study summaries, 10 data waivers: 156 h	

* The time covered the preparation of the IUCLID robust study summaries (RSS), endpoint summaries (EPS) and IUCLID handling in these sections

Table 5: Time spent on the preparation of the IUCLID sections of the microbial representative product dataset

IUCLID section	Number of RSS summaries	Time spent per section*
1. Identity of the plant protection product	5 study summaries	9 h
2. Physical, chemical and technical properties of the plant protection product	9 study summaries, 19 data waivers	19 h
3. Data on application	4 study summaries	14 h
4. Further information on the plant protection product	2 study summaries	
5. Analytical methods	1 study summary, 7 data waivers	9 h
6. Efficacy data	1 study summary	12 h
7. Effects on human health	5 study summaries, 1 data waiver	13 h
8. Residues in or on treated products, food and feed	1 data waiver	11 h
9. Fate and behaviour in the environment	1 data waiver	7 h
10. Effects on non-target organisms	8 data waivers	12 h
Overall time	27 study summaries, 37 data waivers: 106 h	

* The time covered the preparation of the IUCLID robust study summaries (RSS), endpoint summaries (EPS) and IUCLID handling in these sections

This overall time and related costs of the dossier preparation as presented above do not fully refer to the true situation for two reasons:

- the time recorded covered preparation of just one robust study summary per endpoint, whereas usually the dossiers contain more studies per endpoint that would also normally need to be summarised in the dossier
- the time recorded refers only to the inclusion into IUCLID of the available summaries and do not cover the scientific evaluation of the study reports. The available summaries were just transferred into IUCLID.

We consider however that this information might be helpful as a rough approximation of the future possible costs of the manual dossier transfer from the current word format to the IUCLID format.

4 Overall conclusions

The manual testing of IUCLID proved that the preparation of the micro-organism pesticide dossier with IUCLID software is feasible; nonetheless currently there are still some restrictions, if one considers the tested version of IUCLID 6.4.14.1. These restrictions are connected with lack of an appropriate submission type for the microbial product and not fully satisfying IUCLID section for the presentation of biological properties. One should however note that the new submission type is under preparation by the ECHA and it is planned to be released in one of the next versions of IUCLID, so that it should be available for the applicants although it was not available for the pilot project. knoell provided comments on how to improve the section for biological properties which should help in the better and more efficient presentation of the data.

Further improvements of IUCLID are connected with the reporting of results for studies performed with microbial agent requires in appropriate units CFU (colony forming units) and according to appropriate guidelines. Within the pilot project the specific fields were identified to which new values in pick-lists should be entered. ECHA is going to update the IUCLID templates accordingly.

knoell was able also to make first tests of the validation assistant and prepare an example draft DAR with the use of the DAR report generator plug-in tool. These tools are still under development but their first versions are promising for the IUCLID users.

We conclude that the entry of most of the data into IUCLID did not cause any problems and was straightforward. The literature data often reported in the active micro-organism dossier could be summarised satisfactorily thanks to the IUCLID database flexibility. IUCLID as a database fulfils well the needed requirements for the summarising of data in structured format. For the completeness of reporting it is worth to mention that the recommendations provided in previous knoell report are also valid for the micro-organism (such as missing endpoints or study records) but were not listed as separate issues in this report. Additional aspects worth further improvements are connected with the presentation of the risk assessment as well as status of evaluation as described in the Section 3.6.

knoell also finally recommends to support applicants with a more detailed guide on how to present the data in IUCLID. Whenever workaround solutions are required, it must be expected that applicants may come to different solutions and harmonization will be more challenging in the future.

Annex I. Proof of concept pesticides dossier for micro-organism in IUCLID format – final report

Table 6: A gap analysis of the available in IUCLID submission type EU PPP Microorganism

IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
1 Identity of the microorganism	1. IDENTITY OF THE MICRO-ORGANISM	In Section 1 there is no possibility to add any endpoint study summary. The addition of an endpoint summary for all sub points would be required, if the list of endpoints would be generated from study summaries by the report generator (and if this information cannot be extracted from the current IUCLID summaries).	
<i>1.1 (Cf. 1.3) Applicant</i>	1.1. Applicant	no comments	no comments
1.2 Microorganism manufacturer	1.2. Producer	no comments	no comments
1.2.1 Location of manufacturing plant(s)		no comments	no comments

Proof of concept pesticides dossier for micro-organism in IUCLID format – final report

IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
1.3 Name and species description, strain characterisation	1.3. Name and species description, strain characterisation	no comments	<p>Current IUCLID template gives the possibility to choose:</p> <ul style="list-style-type: none"> - type of substance- where the option micro-organisms or toxin produced by a micro-organism from the picklist can be chosen - origin of the substance <p>In the "origin of the substance" picklist under option "other", there is no possibility to summarize all information, which is required under point 1.3 of Reg. 283/2013.</p> <p>The improvement of the picklist should be considered with regards to the following points:</p> <ul style="list-style-type: none"> - is indigenous or non-indigenous at the species level to the intended area of application - is a wild type - is a spontaneous or induced mutant - has been modified using techniques described in Part 2 of Annex IA and in Annex IB to Directive 2001/18/EC (*) of the European Parliament and of the Council <p>Potential attachments can be attached, but it is not visible when something is included. These attachments cannot be read by report generator. Any attached document cannot be flagged as confidential.</p>
1.4 Specification of the material used for manufacturing of formulated products	1.4. Specification of the material used for manufacturing of formulated products	Header / no comments	
1.4.1 Content of the microorganism	1.4.1. Content of the micro-organism	no comments	Content of micro-organisms has to be expressed by entering all "0" manually. It is preferred to allow notation as e.g. 1e8, 10 ⁸
1.4.2 (Cf. 1.4.1) Identity and content of impurities, additives, contaminating microorganisms	1.4.2. Identity and content of impurities, additives, contaminating micro-organisms	Cf. Not OK	Recommendation: not to use Cf. and create new study record to enter the data separately in the point 1.4.2. Additionally: Content of micro-organisms has to be expressed by entering all "0" manually. It is preferred to allow notation as e.g. 1e8, 10 ⁸

Proof of concept pesticides dossier for micro-organism in IUCLID format – final report

IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
1.4.3 (Cf. 4) <i>Analytical profile of batches</i>	1.4.3. Analytical profile of batches	Cf. Not OK	Recommendation: not to use Cf. and create new study record to enter the data separately in the point 1.4.2. Additionally: Content of micro-organisms has to be expressed by entering all "0" manually. It is preferred to allow notation as e.g. 1e8, 10 ⁸
2 Biological properties of the microorganism	2. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM	General problem: many data points in section 2 (2.1.1., 2.2, etc.) should be entered in the overall documents (e.g. under 2.1). The information entered in such a way is not in a correct order and don't exactly fit Regulation (EU) No. 283/2013.	Recommendation: to create separate IUCLID templates for each data points to match Reg 283/2013 and avoid cross-references (Cf.)
2.1 History of the microorganism and its uses. Natural occurrence and geographical distribution	2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution	Document does not match data points as given in Reg 283/2013.	All references could only be reported in the appendix (no possibility for report generator to read data). Recommendations: to attach the (several) publications to each respective field (e.g. 2.1.1, 2.1.2) in the available study record template or to include the current study record as an endpoint summary and give the possibility to report the data (mainly literature) in rather general study records.
2.1.1 (Cf. 2.1) <i>Historical background</i>	2.1.1. Historical background	Cf. Not OK	Recommendation: Provide an option in IUCLID to present short text summaries and properly attach studies/literature. Reduce the requested information, e.g. just bibliographic information and remove all non-relevant text fields.
2.1.2 (Cf. 2.1) <i>Origin and natural occurrence</i>	2.1.2. Origin and natural occurrence	Cf. Not OK	Recommendation: Provide an option in IUCLID to present short text summaries and properly attach studies/literature. Reduce the requested information, e.g. just bibliographic information and remove all non-relevant text fields.
2.2 Information on target organism(s)	2.2. Information on target organism(s)	Endpoint summary should reflect subchapters as in Reg. (EU) 283/2013 or separate templates for each subchapter.	Study records contain much unnecessary information, e.g. info about resistance.
2.2.1 (Cf. 2.2) <i>Description of the target organism(s)</i>	2.2.1. Description of the target organism(s)	Cf. not OK. Proposal to remove it.	Recommendation: to provide a template to include a short free text summary and attach the references with bibliographic information

Proof of concept pesticides dossier for micro-organism in IUCLID format – final report

IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
2.2.2 (Cf. 2.2) <i>Mode of action</i>	2.2.2. Mode of action	Cf. not OK	An endpoint summary point to describe the Mode of Action (MoA) would be more sufficient than describing the MoA for every study record. Not every study record has/needs a MoA description.
2.3 Host specificity range and effects on species other than the target harmful organism	2.3. Host specificity range and effects on species other than the target harmful organism	OHT OK but complex	Endpoint summary with inappropriate text fields (info about "Key value for chemical safety assessment") Study Record template contains many fields that cannot be filled. In most cases a summary (one RTF field) incl. publications as attachment would be sufficient. But the applicant might want to include GEP studies in certain cases and then the appropriate OHT needs to be added.
2.4 (Cf. 2.1) <i>Development stages/life cycle of the microorganism</i>	2.4. Development stages/life cycle of the micro-organism		No possibility to include pictures or graphs to describe the life cycle.
2.5 (Cf. 2.1) <i>Infectiveness, dispersal and colonisation ability</i>	2.5. Infectiveness, dispersal and colonisation ability	Cf. not OK	Recommendation: Provide separate data point and not just references to 2.1 to ensure the proper presentation (and order according to Reg. (EU) 283/2013) of summaries and corresponding studies/literature for each data point
2.6 (Cf. 2.1) <i>Relationships to known plant or animal or human pathogens</i>	2.6. Relationships to known plant or animal or human pathogens	Cf. not OK	Recommendation: Provide separate data point and not just references to 2.1 to ensure the proper presentation (and order according to Reg. (EU) 283/2013) of summaries and corresponding studies/literature for each data point
2.7 (Cf. 2.1) <i>Genetic stability and factors affecting it</i>	2.7. Genetic stability and factors affecting it	Cf. not OK	Recommendation: Provide separate data point and not just references to 2.1 to ensure the proper presentation (and order according to Reg. (EU) 283/2013) of summaries and corresponding studies/literature for each data point
2.8 (Cf. 2.1) <i>Information on the production of metabolites (especially toxins)</i>	2.8. Information on the production of metabolites (especially toxins)	Cf. not OK	Recommendation: Provide separate data point and not just references to 2.1 to ensure the proper presentation (and order according to Reg. (EU) 283/2013) of summaries and corresponding studies/literature for each data point

Proof of concept pesticides dossier for micro-organism in IUCLID format – final report

IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
<i>2.9 (Cf. 2.1) Antibiotics and other anti-microbial agents</i>	2.9. Antibiotics and other anti-microbial agents	Cf. not OK	Recommendation: Provide separate data point and not just references to 2.1 to ensure the proper presentation (and order according to Reg. (EU) 283/2013) of summaries and corresponding studies/literature for each data point
3 Further information on the microorganism	3. FURTHER INFORMATION ON THE MICRO-ORGANISM		
<i>3.1 (Cf. 2.2) Function</i>	3.1. Function	Cf. not OK	Suggestion: provide drop down menu with the following options — control of bacteria, — control of fungi, — control of insects, — control of mites, — control of molluscs, — control of nematodes, — control of weeds, — other (must be specified).
3.2 Field of use envisaged	3.2. Field of use envisaged	Possible entries in mask not in line with Reg. (EU) 283/2013.	Suggestion: provide drop down menu with the following options — field use, such as agriculture, horticulture, forestry, and viticulture, — protected crops (e.g. in greenhouses), — amenity, — weed control on non-cultivated areas, — home gardening, — house plants, — stored products, — other (specify).
<i>3.3 (Cf. 3.2) Crops or products protected or treated</i>	3.3. Crops or products protected or treated	Cf. not OK.	A separate data point to include information according to Reg. 283/2013 would be helpful. Free-text option

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
3.4 (Cf. 1.4.1) <i>Method of production and Quality Control</i>	3.4. Method of production and quality control	Cf. not OK. According to 283/2013, neither method of production nor info according to quality control available under 1.4. Since this info belongs to the production process it is normally presented in Document J and just a reference note is included under 3.4 ("Confidential information. Please refer to Doc J Point MA 3.4.")	Suggestion: 1. Free text box to provide full information on how the micro-organism is produced in bulk 2. Free text box to provide the quality assurance criteria for the production 3. Free text box to describe and specify the techniques used to ensure a uniform product, and the assay methods for its standardisation, maintenance and purity of the micro-organism
3.5 (Cf. 2.2) <i>Information on the occurrence or possible occurrence of the development of resistance of the target organism</i>	3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)	Cf. not OK.	In IUCLID, no field to provide information on resistance is available.
3.6 (Cf. 2.1) Methods to prevent loss of virulence of seed stock of the microorganism	3.6. Methods to prevent loss of virulence of seed stock of the micro- organism	Cf. not OK. Since this info belongs to the production process it is normally presented in Document J and just a reference note is included under 3.6 ("Confidential information. Please refer to Doc J Point MA 3.6.")	Suggestion: 1. Free text field to provide methods to prevent loss of virulence of starting cultures 2. Free text box where to describe any method, if available, that could prevent the micro-organism from losing its effects on the target species
3.7 Recommended methods and precautions concerning handling, storage, transport or fire	3.7. Recommended methods and precautions concerning handling, storage, transport or fire	no comments	The template includes references to biocidal products, which are proposed to be deleted (e.g. Procedures, if any, for cleaning application equipment (relevant for biocidal products only) The following parts are biocide related and could be completely deleted from the template: - Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only) - Possibility of reuse and recycling According to the data requirements (Reg. (EU) 283/2013) only deconstruction in soil and water needs to be addressed for micro-organism and also chemicals. The release to air is normally not relevant.
3.8 (Cf. 3.7) <i>Procedures for destruction or decontamination</i>	3.8. Procedures for destruction or decontamination	Cf. OK	

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
3.9 (Cf. 3.7) Measures in case of an accident	3.9. Measures in case of an accident	Cf. OK	
4 Analytical methods	4. ANALYTICAL METHODS	Header	The list of methods to be listed in the picklist of the analytical endpoint was previously discussed with ECHA and EFSA and is the following: analytical methods analytical profile of batches Methods for the analysis of the active substance as manufactured Methods for the analysis of the plant protection product Methods for the analysis of the preparation Methods for the analysis of the micro-organism as manufactured Methods for risk assessment Methods for post-approval control and monitoring purposes Methods for the determination of residues Methods to determine and quantify residues (viable or non-viable)
4.1 (Cf. 4) Methods for the analysis of the microorganism as manufactured	4.1. Methods for the analysis of the micro-organism as manufactured	no comments	See comment to the point 4 Analytical methods.
4.2 (Cf. 4) Methods to determine and quantify residues (viable or non-viable)	4.2. Methods to determine and quantify residues (viable or non-viable)	no comments	See comment to the point 4 Analytical methods.
5 Effects on human health	5. EFFECTS ON HUMAN HEALTH		The guidelines for microorganisms (885.xxx) cannot be chosen in IUCLID.
5.1 Basic information	5.1. Basic information	Not able to insert an endpoint summary under point 5.2 - 5.5 in IUCLID; only here in point 5.1	
5.1.1 (Cf. 5.1.2) Medical data	5.1.1. Medical data	Cf. OK	
5.1.2 Medical surveillance on manufacturing plant personnel	5.1.2. Medical surveillance on manufacturing plant personnel	no comments	

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
5.1.3 Sensitisation/allergenicity observations, if appropriate	5.1.3. Sensitisation/allergenicity observations, if appropriate	no comments	Mortality/dermal scoring could only be filled in the 'other effects' field; many fields could not be filled (Publication instead of guideline study). Data points in this example dossier were repetitive. Template for sensitisation in 5.2.1 is more suitable for reporting the data of a sensitisation study than template 5.1.3.
5.1.4 Direct observation, e.g. clinical cases	5.1.4. Direct observation, e.g. clinical cases	no comments	
5.2 Basic studies	5.2. Basic studies	Not able to insert an endpoint summary under point 5.2 - 5.5 in IUCLID; only in point 5.1	
5.2.1 Skin sensitisation	5.2.1. Sensitisation	no comments	Mortality/dermal scoring could only be filled in the 'other effects' field; many fields could not be filled (Publication instead of guideline study). Data points in this example dossier were repetitive. Template for sensitisation in 5.2.1 is more suitable for reporting the data of a sensitisation study than template 5.1.3.
5.2.2 Acute toxicity, pathogenicity, and infectiveness	5.2.2. Acute toxicity, pathogenicity and infectiveness	no comments	
5.2.2.1 Acute oral toxicity, pathogenicity and infectiveness	5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness	no comments	Results on clearance and infectivity/persistence could only be filled in the 'other findings' field
5.2.2.2 Acute inhalation toxicity, pathogenicity and infectiveness	5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness	OHT available but needs adaption for micro- organism	Intertracheal route of administration is not an option; MMAD and GSD; duration of exposure could not be filled. clinical sings could not be filled properly; results on clearance and infectivity/persistence could only be filled in the 'other findings' field (Wrong guideline in the study summary (S3 All Tier2 Doc MII, Feb 2014))
5.2.2.3 Intraperitoneal/subcutaneous single dose	5.2.2.3. Intraperitoneal/subcutaneous single dose	OHT available but some adaptations are recommendable	IUCLID template is for dermal administration -> some fields don't make sense (Type of coverage; Details on dermal exposure)

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
5.2.2.5 Skin irritation	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism. Skin irritation is only requested for the PPP. In POC MO dossier Mortality/dermal scoring could only be filled in the 'other effects' field
5.2.2.6 Eye irritation	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point). Eye irritation is only requested for the PPP.
5.2.3 Genotoxicity testing	5.2.3. Genotoxicity testing		
5.2.3.1 (Cf. 5.2.3) <i>In vitro studies</i>	5.2.3.1. In vitro studies	Cf. OK	
5.2.4 (Cf. 5.2.2.3) <i>Cell culture study</i>	5.2.4. Cell culture study	Cf. not OK	To create new IUCLID template for this endpoint correctly in IUCLID.
5.2.5 Information on short-term toxicity and pathogenicity	5.2.5. Information on short-term toxicity and pathogenicity	no comments	
5.2.5.1 Health effects after repeated inhalatory exposure	5.2.5.1. Health effects after repeated inhalatory exposure	no comments	No specific field in IUCLID for data on infectivity, persistence and clearance. Suggestion to add separate fields to report it.
5.2.5.2 Health effects after repeated oral exposure	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
5.2.5.3 Health effects after repeated dermal exposure	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
5.2.6 (Cf. 3.7) <i>Proposed treatment: first aid measures, medical treatment</i>	5.2.6. Proposed treatment: first aid measures, medical treatment	Cf. OK	
5.3 (Cf. 5.2.2.2) <i>Specific toxicity, pathogenicity and infectiveness studies</i>	5.3. Specific toxicity, pathogenicity and infectiveness studies	Cf. OK	
5.4 In vivo studies in somatic cells	5.4. In vivo studies in somatic cells	no comments	No space for an endpoint summary in IUCLID under point 5.4 -> the endpoint summary could be added to point 5.4.
5.5 (Cf. 5.4) <i>Genotoxicity — in vivo studies in germ cells</i>	5.5. Genotoxicity — In vivo studies in germ cells	Cf. OK	

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
5.6 (Cf. 5) Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation	5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation	Cf. OK	No space for an endpoint summary in IUCLID under point 5.6 -> added the endpoint summary 5.6 under point 5; alternatively the endpoint summary could be added to point 5.6.
6 Residues in or on treated articles, food and feed	6. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED	no comments	
6.1 Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs	6.1. Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs	no comments	Germination, Infection, Invasion, Virulence could only be reported in "Any other information on results incl. Tables".
6.2 Further information required	6.2. Further information required	no comments	Not able to insert an endpoint summary under point 6.2 in IUCLID. Recommendation: to add the endpoint summary to section 6.2.
6.2.1 Magnitude of residues in processed commodities	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
6.2.1.1 (Cf. 6.2.1) Non-viable residues	6.2.1. Non-viable residues	Cf. Not OK. Not able to insert a study summary or waiver for non-viable residues. The summary regarding this point was included under IUCLID point 6.2.3. It is proposed to allow entering study records directly at this point. Template for chemicals could be used in order to report data on metabolites.	
6.2.1.2 (Cf. 6.2.1) Viable residues	6.2.2. Viable residues	Cf. Not OK. Not able to insert a study summary or waiver for viable residues. The summary regarding this point was included under IUCLID point 6.2.3. It is proposed to allow entering study records directly at this point. The current template is not suitable to report the data on viable residues.	
6.2.2 Magnitude of residue trials in plants	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
6.2.3 Exposure to consumer	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
6.3 Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 and 6.2	6.3. Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 and 6.2	no comments	
7 Fate and behaviour in the environment	7. FATE AND BEHAVIOUR IN THE ENVIRONMENT	It's not possible to create a new endpoint study record. It is proposed to add the endpoint study record.	
7.1 Persistence and multiplication	7.1. Persistence and multiplication	It's not possible to create a new endpoint summary or endpoint study record. It is proposed to add them.	
7.1.1 Soil	7.1.1. Soil	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
7.1.2 Water	7.1.2. Water	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
7.1.3 Air	7.1.3. Air	no comments	The key values for chemical safety assessment are not suitable for microorganism. It is proposed to only include a rather general endpoint summary with link to relevant study records, key information and additional information.
7.2 Mobility	7.2. Mobility	It's not possible to create a new endpoint summary or endpoint study record. It is proposed to add them.	
7.2.1 Adsorption and desorption	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
7.2.2 Other distribution data	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for Micro-organism dossier)

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
8 Effects on non-target organisms	8. EFFECTS ON NON-TARGET ORGANISMS	no comments	There is no endpoint summary that is specifically suitable for a general summary. Key values cannot be reported in the endpoint summaries because it is not possible to choose a suitable unit from the picklist. Unit "CFU/L" should be added to picklist in field "Effect concentrations" in all endpoint study records.
8.1 Effects on birds	8.1. Effects on birds	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general endpoint summary with the link to relevant study records, key information and additional information.
8.2 Effects on aquatic organisms	8.2. Effects on aquatic organisms	no comments	
8.2.1 Effects on fish	8.2.1. Effects on fish	Not possible to create a general endpoint summary "Effects on fish".	
8.2.1.1 Short-term toxicity testing on fish	-	No official data requirement point according to Reg. (EU) 283/2013. All templates for robust study summaries (for all types of tests) should be available under endpoint 8.2.1.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
8.2.1.2 Long-term toxicity testing on fish	-	<ul style="list-style-type: none"> - No official data requirement point according to Reg. (EU) 283/2013. - All templates for robust study summaries (for all types of tests) should be available under endpoint 8.2.1. - The key values for chemical safety assessment are not suitable for microorganism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information. 	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
8.2.2 Effects on fresh water invertebrates	8.2.2. Effects on freshwater invertebrates	Not possible to create a general endpoint summary "effects on aquatic invertebrates"	
8.2.2.1 Short-term toxicity testing on aquatic invertebrates	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
8.2.2.2 Long-term toxicity testing on aquatic invertebrates	-	- No official data requirement point according to Reg. (EU) 283/2013 - The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
8.2.3 Effects on algae growth	8.2.3. Effects on algae growth	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
8.2.4 Effects on plants other than algae	8.2.4. Effects on plants other than algae	no comments	Waiving based on method of application and available data on algae and terrestrial plants. The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
8.2.5 Inhibition of microbial activity	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
8.3 Effects on bees	8.3. Effects on bees	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
<i>8.4 (Cf. 8.3) Effects on arthropods other than bees</i>	8.4. Effects on arthropods other than bees	Cf. OK	In order to clearly distinguish between bee and other arthropods it is proposed to allow entering the other arthropod data in 8.3.
8.5 Effects on earthworms	8.5. Effects on earthworms	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.

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IUCLID TOC (EU PPP Microorganisms)	TOC for micro-organism (Reg. 283/2013 Part B)	Availability of OHTs or other templates in IUCLID	Additional comments and recommendations
8.6 Effects on non-target soil microorganisms	8.6. Effects on non-target soil micro-organisms	no comments	The key values for chemical safety assessment are not suitable for micro-organism. It is proposed to only include a rather general EPS with link to relevant study records, key information and additional information.
8.7 Further studies	8.7. Additional studies	Proposal to rename the template: Further studies to Additional studies if possible	A general template would be suitable to report the data accordingly.
8.7.1 Terrestrial plants	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (or at least not to indicate as not required for micro-organism dossier)
8.7.2 Mammals	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
8.7.2.1 (Cf. 5.2.2) Acute toxicity	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
8.7.2.2 (Cf. 5.2.5) Short-term toxicity	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
8.7.2.3 (Cf. 5.2.5.1-5.2.5.3) Long-term toxicity	-	OHT not needed: No official data requirement point according to Reg. (EU) 283/2013.	To remove the data point from the TOC IUCLID EU PPP Microorganism (the link does not make sense since there is no such data point)
10 Summary and evaluation	9. SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT	The data point for the summary should be renamed to 9. "Active substance related information" and "Biocidal product related information" would need to be adapted.	