

**Final report:
Proof of concept pesticides dossier 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)
CLH	Harmonised classification and labelling
cMS	Concerned Member State
CP	Chemical plant protection product (EU-revised format)
EPS	Endpoint summary
IUCLID	International Uniform Chemical Information Database
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
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
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

1 Executive summary

IUCLID (International Uniform Chemical Information Database) is perhaps one of the most utilized software applications for the electronic submission (e-submission) of chemical data in Europe. It enables organizations or individuals to record, store, submit, and exchange data on intrinsic and hazard properties of chemical substances in the format of the OECD Harmonized Templates (OHT) (<https://iucid6.echa.europa.eu/project-iucid-6>), accessed 15.09.2019). This report provides an overview of the pilot project that was commissioned by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) to explore and examine the feasibility of preparing a pesticide dossier in IUCLID format with the aim to improve transparency and maximize access to data on chemicals and their use.

At present, the current pesticide tool, CADDY (Computer Aided Dossier and Data Supply) organizes and archives complex pesticides dossiers for submission to the relevant authorities. The relevant data are uploaded to CADDY as separate data files, however unlike IUCLID the OHT's cannot be directly recorded within the CADDY format itself and hence data cannot be stored and extracted in a structured way. IUCLID currently facilitates the e-submission of biocidal active substance and product dossiers under BPR (Biocidal Products Regulation), industrial chemicals dossiers under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), CLH dossiers and much more.

knoell employed their extensive IUCLID knowledge and technical expertise of each of the technical areas required to deliver the new active and renewal pesticide dossier in IUCLID. These dossiers were created based on the available templates within IUCLID 6 and the submission types already available for pesticides, identifying key similarities and the best fields for use.

knoell's aims were to test, as part of a pilot study, the creation and use of a plant protection product dossier in IUCLID format, and provide feedback of the overall process, issues, time taken and make future recommendations for the application. Further aims and objectives include the critical assessment of the feasibility, intuitiveness, effort and benefit to all stakeholders for pesticide dossier creation using IUCLID. The use of IUCLID should ease the submission and evaluation process for applicants and the relevant authorities.

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

- A new active substance (a.s.) pesticide dossier was created and evaluated using OHTs in IUCLID (i6z) format as a transferrable package file including the related dataset.
- A renewal of an active substance pesticide dossier was created and evaluated with completed OHTs in IUCLID (i6z) format as a transferrable package file including the related dataset.
- A comprehensive report on key findings of the pilot project was generated, along with a reviewed Pesticide Dossier Preparation Manual (PDPM).

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Overall the evaluation of the software by knoell was a positive one.

Strengths of IUCLID:

- The manual testing of IUCLID proved that the preparation of the applications for pesticides with IUCLID software is feasible and after some improvements also considered to be suitable for an efficient collation of data in dossier format.
- Two submission types were uploaded into IUCLID.
- These IUCLID dossiers were placed in an EFSA IUCLID cloud-based storage location, providing a central setting for all of the regulatory bodies involved in the project to enter comments. This facilitated simultaneous work between the participants as the cloud-based system enables a number of IUCLID users' access to the one dossier – be that the IUCLID cloud or server version.
- The annotation function can be used during the commenting phase of the dossier evaluation. The comments from the regulatory bodies to the dossiers prepared within the project were collected in the IUCLID format and answers from the applicant (knoell) could be provided also with use of annotations.
- It was possible to use a large number of existing OHTs templates within IUCLID for the purpose of the pesticide dossier.
- New tables compiling information have been developed and inserted to enhance clarity on the information provided and avoid duplication (e.g. the list of test information and batches).
- It is possible to generate tables automatically based on the information summarized in IUCLID, facilitating the information submission.

Weaknesses of IUCLID:

- Some necessary OHT templates are missing within IUCLID. These missing templates may lead to inconsistency (e.g. non-harmonised data structure) in data entry by applicants and ultimately to additional work for the regulatory bodies (see section 4.1).
- Cross-references used in IUCLID to link and guide the user to another location were somewhat burdensome. For example, documents to be completed/checked were not always in the expected place in the submission type section tree. Reviewing of the information e.g. during completeness check is cumbersome and requires use of workarounds (see section 4.4.3).
- One of the major issues encountered during the preparation of the pesticide dossier was the presentation of the studies performed on metabolites and impurities. Although IUCLID allows separate datasets to be created for 'Other substances', which was not possible in CADDY dossiers, the linking of these data sets requires further optimization. For example, metabolites could not be sufficiently linked when needed as in certain sections of the dossier there was no provided functionality facilitating this purpose. Additionally, metabolites in general could not be treated (or listed) as components of the composition (in contrast to solvents, impurities or additives). Although the datasets can be linked to the composition of the plant protection product, the true relation between active substance and metabolites datasets could not be displayed correctly (see section 4.6.2).
- The current IUCLID 6 (i6z) software does not always give the possibility to flag certain information as confidential business information (CBI). Additionally, there is a clear need for

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guidance to advise the applicant that certain fields within IUCLID do not need to be flagged as CBI as they will never be disseminated to the public. (See section 4.5.1).

- A template for the Good Agricultural Practices (GAP) table is not available (see section 4.7.2).
- There is currently no possibility to report the extensive risk assessments properly within the IUCLID system. Much of the existing information could only be copied in Rich text format (RTF) fields.
- No template is available for the literature data. knoell propose that a template should be set up in accordance to EFSA guidance (EFSA Journal 2011; 9(2):2092. 49 pp.) (see section 4.7.3).
- The current web IUCLID interface does not include many useful functionalities of the classic interface (see section 4.2.2).

Constraints of the project:

- No efficacy data was available in the dossier selected for the pilot testing.
- For each study record, only one study report was inserted (one study record, one study report).
- Due to the limited data availability for some studies in the original (old) dossier the summaries/data from the renewal dossier were used to complete the study summaries.
- Several workarounds were developed to overcome the absence of some OHTs as per pesticide legislation.
- Current IUCLID **web interface** does not include many functionalities of the classic IUCLID interface.

Main recommendations for improvement are summarised below.

Based on the manual testing of IUCLID for pesticide dossiers, knoell would like to recommend performing the following changes as listed below. Such recommendations focus on overcoming technical issues and lack of applicability of certain templates / filters for pesticide dossiers within the IUCLID system.

- Allow the applicant to enter 1:1 the crop dossier from SANCO templates to IUCLID summaries and ensure the endpoint summaries are named in the same consistent way. If some sub-endpoints are still missing – we recommend adding them to the IUCLID structure (see sections 4.2.1 and 4.3.1).
- Remove cross-references so that the content is located appropriately and logically within IUCLID (see section 4.4.3). In particular, the cross-references within sections 1.8 - 1.10 should be removed so that each section 1.8 - 1.10 could be presented in separate sub-points.
- Include the confidentiality flags option (not available for endpoint in sections 1.8 - 1.10 in the current version) or clear rules on which IUCLID content will never be disseminated (see section 4.5.1).
- In order to solve the issue with the presentation of the data for the active substance and metabolites, the recommendation for the future is to present all the data (for the active

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substance and its metabolites) within one endpoint of the active substance and show the tested material within the test material information (see section 4.6.2).

- Handling of annotations could be improved: currently the answers from the applicants cannot be directly referenced to the request. This could be solved in the future by including additional fields for the applicant (see section 4.10).
- An option to import the annotations from a dossier containing comments made by the authorities into a separate report (e.g. .docx or .xlsx formats) and dataset (i6z) should be considered.
- The current web interface does not include many functionalities of classic interface. Some are named below: limited import, export, dossier creation option, lack of the inventory overviews (e.g. annotation inventories), missing linking of some IUCLID elements. We recommend to improve web interface and implement the useful options of the classic interface.
- It is difficult to find the appropriate place in IUCLID for the administrative templates. In many cases, IUCLID software does not contain a unique location to attach a given endpoint, so that only the option left for the applicant is within the information panel within the classic interface, which could be used to attach the template (see section 4.8). One should think about defining one prominent place to include all administrative templates, such as “Summary and evaluation” or simply include the obligatory field within the relevant endpoint, which would be well described and more visible.
- knoell also recommend to perform a second test phase, after implementation of all suggested improvements from phase one of testing (also cases not covered by the pilot).
- Before IUCLID is implemented for pesticide dossiers and trainings are provided to future users, it is advisable to plan adequate/realistic timeframes for applicants and authorities to get confident and proficient in working within IUCLID.

Moreover, it is advisable that EFSA designate time to the definition of issues associated with data ownership/confidentiality in order to provide to ECHA with a clear illustration and indication of how IUCLID must be improved to address possible concerns from applicants.

2 Project scope

2.1 Project objectives

The overall objective of this pilot project is 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 under Article 7 of Regulation (EC) No 1107/2009 and a renewal pesticides dossier under Article 15 of Regulation (EC) No 1107/2009 within IUCLID6. Furthermore, knoell analysed the possibility of further IT software developments for the software application to facilitate the greater applicability of IUCLID6 for pesticide dossiers. However, only the recommendation on automation of some steps, and not development of new tools, was within the scope of the pilot project.

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The EFSA have furthermore outlined three key objectives for this pilot project in order to meet the overall objective

Objective 1: Participation in the pesticide dossier pilot project with the ultimate goal of preparing a findings report of the software test for its applicability as a pesticide dossier management tool. This objective also included a review of the pesticides dossier preparation manual developed prior to the pilot project.

Particularly this objective includes:

- attendance at the pilot kick-off meeting and the pilot closure meeting
- joining web conferences during the pilot
- performing the role of an applicant by creating a dossier for a new active substance and a dossier for the renewal of an active substance from existing scientific data
- responding to clarification requests by EFSA and Rapporteur Member State (RMS) during the pilot
- preparing a report, tracking the issues encountered during the pilot, record of the time taken for each of the dossier preparation tasks/phases, the solutions applied and recommendations for the future activities/ next phase of work
- a review of the pesticides dossier preparation manual developed during the pilot

Objective 2: Adaptation of a current active substance pesticide dossier under Article 7 of Regulation (EC) No 1107/2009, into an IUCLID format, using available draft pesticide submission types provided by ECHA.

In particular, the tasks within this objective required to:

- link the dossier to a reference substance in IUCLID
- complete the administrative dossier header information
- upload all files/documents from the original new active substance dossier into the appropriate sections of the pesticide dossier table of contents. Where the file/document was not confidential or has been sanitised, it could be uploaded without modification. Where the file/document contained confidential information it had to be replaced with a 'dummy' file of the same file type (in these cases with a justification statement entered into IUCLID). In general, attention had to be paid to the way confidential information was reported in IUCLID, e.g. by using confidentiality flags and justifications
- when available, the appropriate OHT or other IUCLID templates had to be completed in addition to uploading the original file
- information had to be also extracted from the dossier and added to the templates included in the pesticides administrative guidance annex and uploaded into IUCLID
- in cases where studies were reported but no OHT exists or where parts of the dossier could be transformed into data entry forms this information had to be recorded and included in the final project report
- additional dossier management tasks using IUCLID agreed during the pilot planning (e.g. testing the validation assistant, the reporting and the filtering tools on the dossier elements)

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Objective 3: Adaptation of a renewal application of an active substance pesticide dossier according to Article 15 of Regulation (EC) No 1107/2009, into an IUCLID format, using the dossier created in objective 2.

In particular, the tasks within this objective required to:

- add additional formulations for the chemical products included in the renewal application ensuring dossier content is consistent
- complete/update the relevant administrative dossier header information
- upload all new files/documents included in the renewal dossier into the appropriate sections of the pesticide dossier table of contents. Where the file/document was not confidential or has been sanitised, it could be uploaded without modification. Where the file/document contained confidential information, it had to be replaced with a 'dummy' file of the same file type (in these cases with a justification statement entered into IUCLID). In general, attention had to be paid to the way confidential information was reported in IUCLID, e.g. by using confidentiality flags and justifications
- when available, the appropriate OHT had to be completed in addition to uploading the original file
- information had to be extracted from the dossier and added to the templates included in the pesticides administrative guidance annex and uploaded into IUCLID
- in cases where studies were reported but no OHT exists or where parts of the dossier could be transformed into data entry forms this information had to be recorded and included in the final project report
- additional dossier management tasks using IUCLID agreed during the pilot planning (e.g. testing the validation assistant, the reporting and the filtering tools on the dossier elements)

3 Project activities and methodology

The pilot project was grouped into three main phases

1. Planning, initiation and verification
2. Execution – Manual testing in IUCLID
3. Final preparation phase – Pilot report and Pesticide Dossier Preparation Manual (PDPM)

which are detailed further within the following sections.

3.1 Planning, initiation and verification

This first phase of the project aimed to set the basis for the subsequent phases in terms of defining the approach to deliver successfully the requested key information and documents. The project started with a kick-off meeting on 26 November 2019, where knoell, EFSA and ECHA clarified the means for cooperation to achieve the goals of the project. Figure 1 below illustrates how the project stakeholders, for example EFSA as the contracting entity, knoell as a

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contractor, ECHA as the responsible for the IUCLID development and the six member states (PT, FI, PL, DE, FR, AT) who participated in the working group as well as industry representative, ECPA and ECCA cooperate together to achieve the ultimate project outcome and fulfil the project scope.

Figure 1 Workflow and stakeholders of the pilot project

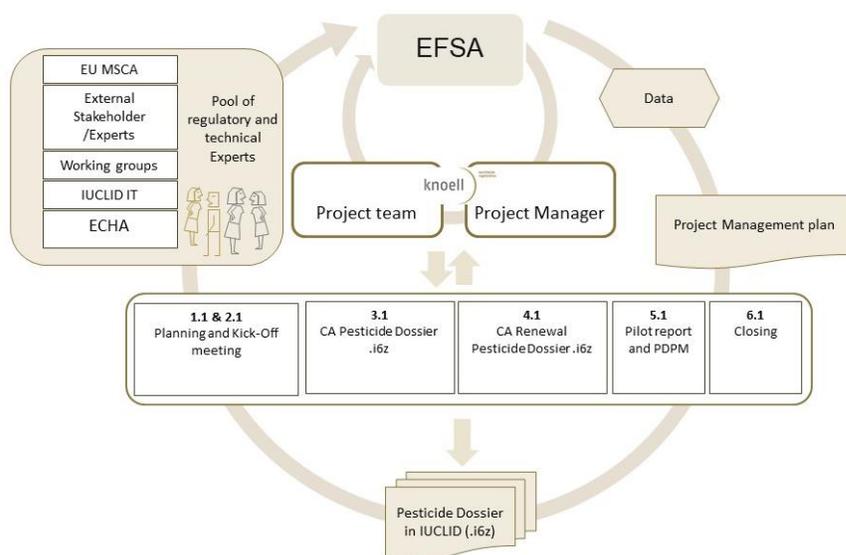


Table 1: Pilot project stakeholder list

Individual Name or Group, agency, company	Department / Area
EFSA	Project Sponsor
Knoell	Project contractor – service provider
ECHA	IUCLID IT team
EFSA legal	Legal department for all legal matter and contractual issues
COM	The EU Commission
Applicant	The a.s. applicant
Data owner	Data owners of studies within the a.s. Substance
ECHA	European Chemical Agency and IT development team
RMS	Rapporteur Member State of a.s. submission
cMS	Concerned Member State
knoell legal	for all contractual issues

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Individual Name or Group, agency, company	Department / Area
knoell Project sponsor	
Project core team	PTM
Project manager	
Project team –Expert council	PTM
Technical advisor	An external technical advisory boards
IUCLID developers	IT software development

The timeline of key deliverables was agreed:

Table 2: Project deliverables

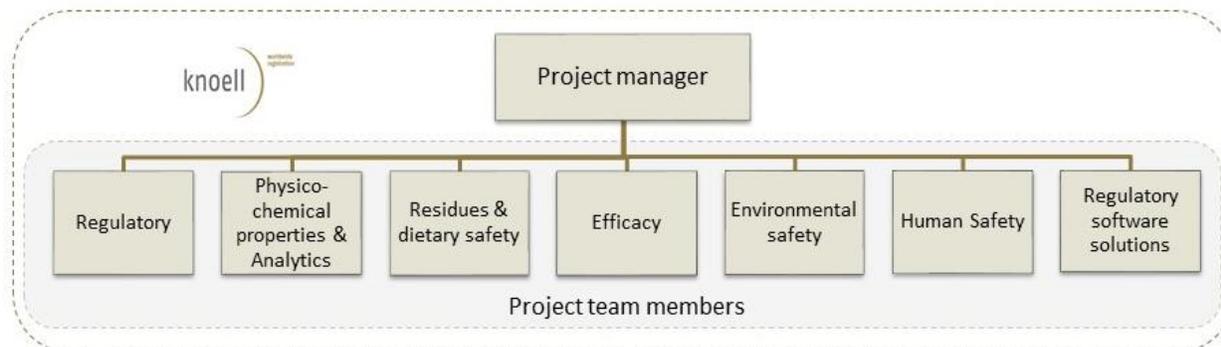
Deliverable	Deadline
A new active substance (a.s.) pesticide dossier with completed OHTs in IUCLID (i6z) format as a transferrable package file including the related dataset	26.01.2020
A renewal of the active substance pesticide dossier with completed OHTs in IUCLID (i6z) format as a transferrable package file including the related dataset	26.02.2020
A comprehensive report on key findings of the pilot project (.docx format)	31.03.2020
A reviewed Pesticide Dossier Preparation Manual (PDPM),	17.04.2020

For more information on the exact deliverables, please refer to the work breakdown structure (WBS) illustrated in Figure 9.

In the first step knoell received access to the active substance pesticides dossier and renewal dossier for which the IUCLID pesticides dossier should be created, as well as access to ECHA IUCLID cloud instance (IUCLID version starting from 6.4.2 to 6.4.9), in which the newest versions of IUCLID were tested. Both dossiers were prepared for the active substance: clodinafop.

knoell's IUCLID test team consisted of crop protection experts, who were very experienced with the preparation of the pesticide dossiers across various technical sections, and IUCLID experts, who have years of experience working with this software for the preparation of dossiers for REACH and BPR applications. In addition the team was supported by an internal IT support group – regulatory software solutions. knoell's IUCLID “matrix” team of experts from different regulatory and scientific field enabled and eased the swift distribution the tasks easily, exchange the knowledge and responsibilities in the project.

Figure 2: knoell project team set-up



Before the knoell team started with the manual testing and dossier creation in IUCLID, the knoell team initially reviewed the ECHA Draft Pesticides Submission Manual (ECHA, November 2019) “How to prepare a pesticides dossier” that gives the guidance on how the pesticide dossier should be created in IUCLID. Based on this manual and the experienced gained from BPR and REACH IUCLID projects, knoell prepared the internal IUCLID maintenance rules that specified in more detail aspects such as:

- naming of study records and study summaries
- naming of test material information,
- dealing with confidential data in IUCLID (use of confidentiality flags and inclusion of dummy files instead of confidential information)
- handling of analytical methods in IUCLID
- editing rules

These rules enabled the knoell experts to present the data content in IUCLID in a consistent manner. An excellent example for the need for consistency and harmonization of data entry is the test material information – the correct and harmonized method for entry of this information is advantageous when one considers the availability of the inventory of the batches tested in various (eco)toxicological study reports.

knoell’s recommendation for dealing with the variance of test material information:

Prior to the initiation of data entry in IUCLID, particularly before the test item information for all scientific sections is summarized in IUCLID, a separate document listing information on all batches of the test item with a link to which type of studies the batches were applied (physico-chemical, toxicological, ecotoxicological, etc.) should be compiled and completed by all the project team. An example of a summary of such document is shown in Figure 3 below

Figure 3: Example of a document listing test information and batches

D	E	F	G	H	I	J
Chemical Name (common name, company, trade name or name used in the report)	Purity	Batch number	Date of expiry	Description of the test substance	Name of test material in IUCLID inventory	UUID of test material created in IUCLID inventory
other name provided in the report	as in the report	as in the report	as in the report	as in the report	a.s. or r.p.name	number of the test material created for the project

The purpose of this list is to prevent a duplication of test material information, whilst also at the same time obtaining a complete register of the tested samples/batches.

Finally, before initiating the actual manual testing in IUCLID, knoell ensured that all project team members, particularly those less familiar with IUCLID (i.e. team members who have mainly only worked with MS Word and CADDY for pesticide dossiers), were trained sufficiently to adequately use and test the IUCLID software. This training focused mostly on the use of the web interface, but also introduced navigation in the classic interface of IUCLID. The training material, available on the ECHA IUCLID webpage, was used, especially concerning the web IUCLID interface¹.

3.2 Execution – Manual testing in IUCLID

Objective 2 and 3 of EFSA were executed in the second phase of the project. knoell implemented proposed methodology to test the functionality of IUCLID. knoell entered all pesticide data manually for both the active substance pesticide dossier and the renewal active substance dossier for the creation of two complete dossiers. The goal of this phase was to document each step of the data entry, tracking any issues that occurred along the way and identifying the potential of the software for such an application. knoell paid special attention to document any limitations of the system, missing templates and devise workarounds to mediate the issues and complete the project. The ways to improve features of the software application for the handling of confidential and third party data were particularly important. Test documentation logs stored all knoell recommendations, further optimizations and customizations during the testing period.

Throughout the duration of the project, and in accordance with the project communication plan, the knoell project team met on a weekly basis, to report the status of the project. These meetings were essential to discuss not only the project specifics but also to alert the project lead and members to any issues which required attention and resolution, often also in the cooperation with EFSA and ECHA.

Timeline: December 2019 - February 2020

¹ <https://iuclid6.echa.europa.eu/documentation>

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Key deliverables

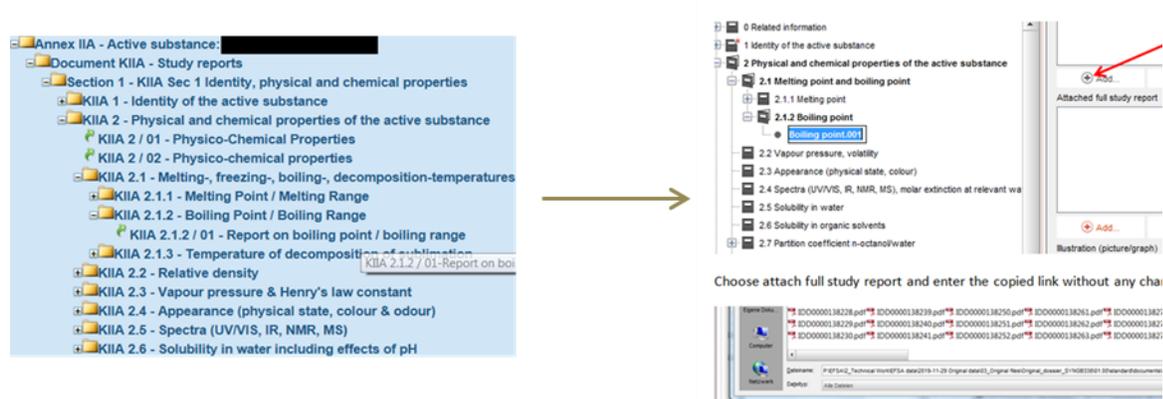
1. A new active substance (a.s.) pesticide dossier with completed OHTs (OECD harmonized template) in IUCLID (i6z) format as a transferrable package file including the related dataset
2. A renewal of the a.s. pesticide dossier with completed OHTs (OECD harmonized template) in IUCLID (i6z) format as a transferrable package file including the related dataset.

For more information on the exact deliverables, please refer to the Work Breakdown Structure illustrated in Figure 9.

3.2.1 Deliverable 1: Preparation of a new active substance (a.s.) pesticide dossier (original dossier)

The execution phase began with the manual migration of all study reports (except reports containing confidential information) available in CADDY to relevant IUCLID endpoints corresponding to the data points as given in Regulation (EU) No. 283/2013 and Regulation (EU) No. 284/2013.

Figure 4: CADDY table of contents in comparison to IUCLID endpoints



For the purpose of this project, it was agreed with EFSA that each study record will only contain one study report so as to obtain the unique study register within IUCLID (one study record – one report). Nonetheless, additional available study reports for a specific data point were migrated to IUCLID, but no robust study summaries were prepared (see next step below) for these additional reports.

In the next step the robust study summaries were prepared for each study as endpoint study records in IUCLID based on OECD summaries contained within the documents M-II/M-III (old dossier format in which the active substance pesticide dossier was provided to knoell). Although more than one study was submitted for several endpoints, only one robust study summary per endpoint was prepared for the purpose of the pilot phase, as agreed with EFSA. Separate datasets were created for the metabolites/impurities. Due to the limited data for some studies in the original (old) dossier the summaries/data from the renewal dossier were used to complete the study summaries.

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Figure 5: M-Doc endpoint study header in comparison to an IUCLID study record

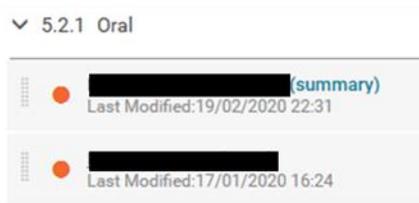
5.2.1 Oral

Report: [redacted] - A unpublished report [redacted] 198
 Dates of experimental work: 02.03. - 08.04

Guidelines: OECD 401, Deviations from 92/69/EEC m used as highest dose

GLP: Yes (laboratory certified [redacted] (Federal Department of Home Affairs), Be

Material and methods: Test material: [redacted] [redacted] technical was administered in [redacted]



The screenshot shows the IUCLID interface for the '5.2.1 Oral' endpoint. It displays a summary record with a red status indicator, the text '(summary)', and the last modified date '19/02/2020 22:31'. Below it, another record is visible with the last modified date '17/01/2020 16:24'.

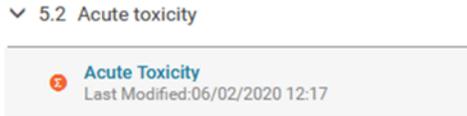
The endpoints study summaries (i.e. the summary record that summarises the information available in all the endpoint study records of a given endpoint section) were based on the information contained within the study summary tables of the M-II/M-III and N documents.

Figure 6: M Doc study summary tables entered as endpoint summaries in IUCLID

5.2 Acute toxicity

Table 5.2-1: Acute toxicity data obtained with [redacted]

Study	Species Strain	mg/kg bw, mg/m ³ , effe
Acute oral LD ₅₀	Rat Tif: RAI, Sprague-Dawley	1829 mg/kg bw (males 1392 mg/kg, females 2271 mg/kg)
Acute oral LD ₅₀	Mouse	> 2000 mg/kg bw

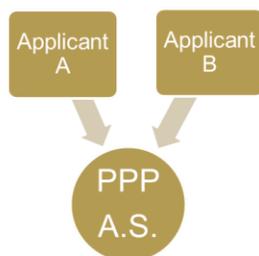


The screenshot shows the IUCLID interface for the '5.2 Acute toxicity' endpoint. It displays a summary record with a red status indicator, the text 'Acute Toxicity', and the last modified date '06/02/2020 12:17'.

3.2.2 Deliverable 2: Preparation of a renewal of the active substance (a.s.) pesticide dossier

The renewal dossier prepared within this pilot served as an example of a task force (registration group or consortium) application (i.e. the participation of two applicants (A & B) using the same active substance (a.s.) and plant protection product (PPP)).

Figure 7: Illustration of a Task Force application



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The pilot project renewal dossier was based on an original dossier submitted previously by the applicant A which was used to establish the new active substance (a.s.) pesticide dossier. Now, for the purpose of the renewal dossier submitted by applicant A, the dossier contained the newly available non-confidential data of both applicants and the confidential data of the applicant A. This dossier therefore contained all data required for the renewal dossier according to EU Regulation 1107/2009. For this dossier the data from MCA/MCP document and Document N were transferred to IUCLID. Data not submitted for renewal were not deleted from the data set, but identified with “NOT SUBMITTED FOR RENEWAL”. New studies were marked with “NEW” and IUCLID templates were used.

In this case, applicant B submitted their confidential information as listed directly to the authority:

1. Validation of a chromatographic analytical method for a significant impurity
2. A Quantitative Structure-Activity Relationship (QSAR) study - Evaluation of the impurities in the active substance for possible toxicological relevance for mutagenicity using QSAR
3. Comparison of toxicological and ecotoxicological endpoints for reference source a.s. technical (Applicant A) and a.s. technical manufactured by Applicant B
4. Components of Vol 4 Document J
 - a. Method of manufacture
 - b. Specification of purity – including the impurity with the analytical method validation study
 - c. Analytical profile of batches
 - d. A GC method of analysis for the a.s.
 - e. Summary of the methods for determination of the active substance and impurities

Due to the confidentiality of these data, they were not available to knoell and could not be entered into IUCLID hence only exemplary IUCLID summaries were created and empty reports (dummy files) were attached to IUCLID. This was considered by EFSA to be sufficient for the purpose of testing the submission of confidential data from two different applicants A and B.

To facilitate transparency all data rights and ownership were recorded within the reference and data access fields. This enabled the sponsor (data owner) and data access to be set up as shown in Figure 8 below.

Figure 8: Data access fields in IUCLID



The screenshot displays the 'Data source' section of an IUCLID record. It contains three main entries:

- Reference**: study report | [REDACTED] | 871012
- Data access**: data submitter is data owner
- Data protection claimed**: None

Proof of concept pesticides dossier in IUCLID format – final report

The image shows a list of data access options on the left and a dropdown menu on the right. The list includes: "data submitter is data owner", "data submitter has Letter of Access", "data no longer protected", "data published", "not applicable", and "data submitter has permission to refer". The dropdown menu is titled "Data access" and has a question mark icon. It shows "other:" as the selected option, with "task force data" entered in the text field below it.

One could consider adding another option of data access, currently not available in IUCLID (see Figure above): “registration group data” to display explicitly a Task Force situation. In order to specify further details about the ownership, the remarks fields can be used.

In addition IUCLID enabled the entry of information on whether the Applicant A or B was owner of the study in each of the study records.

In the execution of this phase of the project, testing of selected administrative templates in accordance to EFSA administrative guidance was also performed (this is reported in section 4.8. of the current report).

3.3 Final preparation phase – Pilot report and PDPM

This final phase of the project (objective 1) was to draft a final report (current document) of all issues encountered and documented during the testing of IUCLID.

Timeline: March –April 2020

Key Deliverables

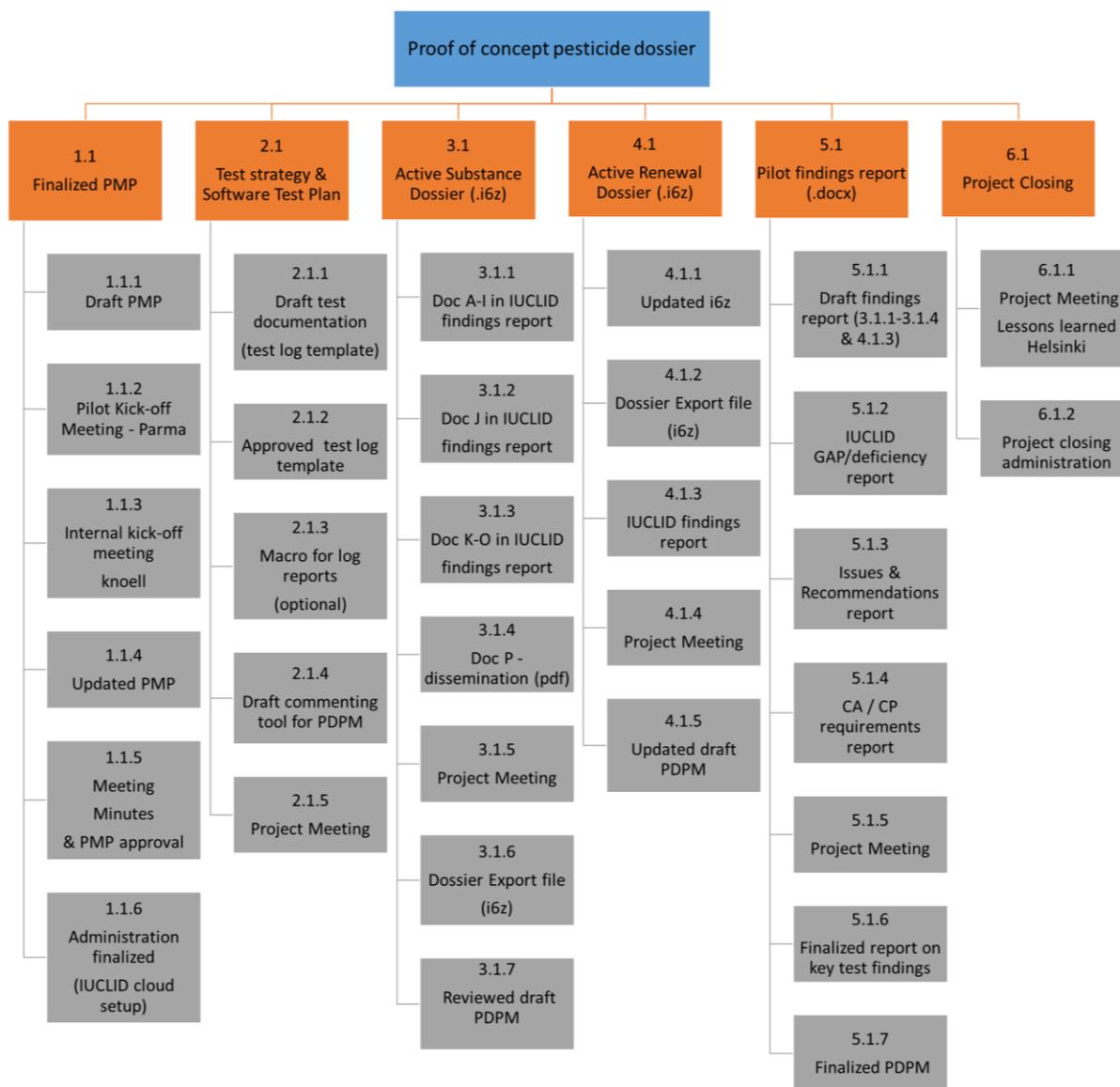
1. A comprehensive report on key findings of the pilot project
2. A reviewed Pesticide Dossier Preparation Manual (PDPM).

For more information on the exact deliverables, please refer to the work breakdown structure (WBS) of the project illustrated in Figure 9.

The WBS illustrates hierarchically structures and organizes the pilot project elements and defines the total scope of the pilot project in terms of deliverables. Each descending level is an increasingly detailed definition of a pilot project component. The lowest level of the WBS, the work packages, are not illustrated here however were defined and elaborated within the project schedule, and during the project realisation the work packages followed management plan. Each project team member received a defined work package, with budget estimations conditions and schedule. This enables the project manager to monitor and control all activities.

Proof of concept pesticides dossier in IUCLID format – final report

Figure 9: Work breakdown structure (WBS) of the pilot project



4 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 followed.

The overall objective of this project was successfully achieved: two pesticide dossiers were efficiently prepared within a short time frame within IUCLID. The goal of the project team was to provide an error-free and high quality dossier, both in terms of content and formal requirements.

Taking knoell's past experience with the implementation of IUCLID in Biocidal Products Regulation (BPR) into account, it is worth mentioning that the entire pilot project and the preparatory phase are evaluated very positively by the knoell team: good planning is key in the implementation of a new IT system.

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

1. A gap analysis concerning the templates (including OHTs) available for the entry of the data required for pesticide submission (section 4.1),
2. Report of issues encountered during the pilot project and the solutions implemented or proposed in the following subsections: 4.2 Technical completeness, 4.3 Issues with missing documents, 4.4 Usability issues, 4.5 Issues with administrative features, 4.6 New features proposed, 4.7 Aspects requiring further developments.
3. Section 4.8 deals specifically with the Appendixes provided within the pesticides technical guidance and the possibility of automatic generation of their content from IUCLID summaries as well as location of the Appendixes in the IUCLID sections.
4. We present the time needed for the completion of two IUCLID pesticides dossiers in section 4.9.
5. Finally, 4.10 describes the possibility of the use of IUCLID annotation function for the commenting phase of the dossier.

4.1 A gap analysis concerning availability of OHT in IUCLID

knoell evaluated the available IUCLID templates based on the data requirements according to Regulation (EU) No. 283/2013 and Regulation (EU) No. 284/2013, in addition to the information available in the example active substance pesticide dossier chosen for this project. The results of this evaluation were detailed within a gap analysis, which is provided in a tabular form in the Annex I "Evaluation of available OHT templates and issues encountered" of this report. This analysis was conducted for all dossier sections, both for the active substance and the representative product, respectively.

The gap analysis covered the following aspects:

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- *Missing information within tested dossier*; i.e. whether the information (study reports and study summaries provided to knoell in an original dossier format submitted to the authorities) in the example active substance dossier is available for a given endpoint.
- *Missing OHT templates*; i.e. whether the OHT template is available in IUCLID for each required information / endpoint in IUCLID.
- *Cross-reference of OHT templates*; i.e. if the appropriate OHT template in IUCLID was available, in the second step it was reported if the template is correctly placed or entered in another endpoint to which reference was provided.
- *Workaround solutions and recommendations for IUCLID*; i.e. improvements are included in the tables as well.

In addition, the team members focused their attention on the reporting of issues connected with the use of IUCLID, finding “out of box” solutions that could be implemented into IUCLID, to assist and optimize the software’s capability and feasibility for pesticide dossier preparation. During the project, notably for the manual testing of IUCLID for the preparation of the new active substance pesticide dossier and the renewal dossier, all issues relating to these tasks were logged. Where the straightforward transfer of the data was not possible or proved difficult, knoell analysed the cause and proposed an interim solution, and where possible a further recommendation for the IUCLID or process improvement.

The tables provided in the Appendix II list the difficulties encountered during the pilot project with the current IUCLID version and its direct use by the applicant (knoell), solutions implemented and the recommendation for the future implementation. These issues were regularly reported during the pilot project to EFSA, who further prioritised them and identified actions to solve the problem.

Some issues could not be solved in a satisfactory manner within the pilot project as they required further consideration, discussion between various stakeholders to achieve a final way forward. These issues are presented in the following subsections.

4.2 Technical completeness

4.2.1 *Missing information within tested dossier*

The example active substance dossier for a new active substance was originally submitted in 2002 when the data requirements were clearly different to the data requirements of today, hence some endpoints were not covered. In addition, the active substance original dossier as well as renewal dossier did not contain efficacy data, since these data are also not required within the active substance approval process at that time, and therefore the entry of data in IUCLID for these endpoints was not tested in detail within the current project. Although these sections on efficacy could not be sufficiently tested due to the lack of available data for testing, knoell nonetheless has extensive experience within the framework of BPR submissions, and can conclude that the efficacy fields in IUCLID lack applicability as often a lot of tables and text need to be reported for efficacy.

Moreover, for the purpose of this project, it was agreed with EFSA that each study record will only contain one study report so as to obtain the unique study register within IUCLID (one

study record – one report). Additional study reports included per data point were migrated to IUCLID, but no robust study summaries were prepared.

4.2.2 Web versus classic interface

The current web interface does not include many of the functionalities of the classic interface. Some of these include: limited import, export, dossier creation option, lack of the inventory overviews (e.g. test material information or annotation inventories), missing linking of some IUCLID elements. This means that currently the web interface does not allow the user to fully understand all possibilities and functionalities of IUCLID. Within the pilot both web and classic interfaces were used. The web interface is constantly being updated by the ECHA and already within the pilot scope many new functions were successfully implemented. The overview of the currently available IUCLID web interface functions are summarised by the ECHA.

4.3 Issues with missing documents

4.3.1 Missing OHT templates

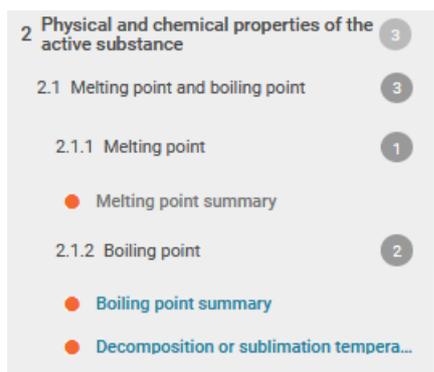
Some OHT templates were missing in IUCLID and required a workaround. An example of such cases is given below. An analysis of the availability of the OHT templates in IUCLID illustrated that within the section “Physical and chemical properties of the active substance”, the endpoint CA 2.1. Melting point and boiling point (purified a.s.) contains 3 sub -endpoints (see Table 3: below):

Table 3: MCA section endpoints

CA 2.1.1	Melting point for solid Freezing/ solidification point for liquid
CA 2.1.2	Boiling point (measurement up to 360° C)
CA 2.1.3	Decomposition or sublimation temperature

Within the IUCLID submission type “EU PPP Active substance information” the endpoints “Melting point” and “Boiling point” are listed with the OHT templates correctly linked; however the “Decomposition or sublimation temperature” is not listed as a separate endpoint, as can be seen below.

Figure 10 IUCLID endpoint study records for Physical and chemical properties of the active substance



In the current project the information about the decomposition or sublimation temperature was entered in IUCLID in section 2.1.2 (under the boiling point), as a separate study record, which was named as such to indicate the entered content. This missing OHT template was therefore also listed in the data gap analysis table, Annex I, together with the workaround applied and the recommendation for the future optimizations of this IUCLID section.

Problems connected with missing OHT templates:

Missing OHT templates in IUCLID or just the IUCLID template that reflects the data requirements according to EU Regulation 1107/2009, Regulation (EC) No. 283/2013 and Regulation (EC) No. 284/2013 might lead to random individual solutions chosen by the applicants on how and where they enter the data in IUCLID, which in turn may lead to a lack of a harmonized approach in data entry. This may further cause additional work and follow up requests of the regulatory bodies evaluating such documents.

Based on knoell's evaluation, most of the OECD Harmonised Templates², necessary for a plant protection product active substance approval are available in IUCLID format. However, for some data requirements under the Regulation (EC) No. 1107/2009 the OHT templates do not exist and consequently they are also not yet implemented in IUCLID.

4.3.2 Missing subchapters according to the SANCO templates

The IUCLID structure currently does not include all subchapters according to the SANCO templates. Some sections contained only the general section and further subdivision into subsections. Two examples of this issue are illustrated below.

Example 1: Analytical methods / PPP mixture / product dataset

Under section 2.8 of IUCLID, which concerns the technical properties of the substance, all single technical properties had to be added manually as there are no separate IUCLID

² <http://www.oecd.org/ehs/templates/harmonised-templates-physico-chemical-properties.htm>, accessed on 11.03.2020

subsections with clear naming and reference to the data requirements for this section. knoell implemented the use of transparent record naming rules to indicate the summarized endpoint, which also included correct indicative numbering. Nevertheless, this approach if not standardized, allows each and every applicant to apply their individual approach and summarize the data as they see fit in IUCLID. Consequently, if there is differentiation of data entry, the extraction of these data with report generator could be problematic. To avoid any unambiguity, knoell propose that IUCLID revise the structure to include the relevant sub section points 2.8.1 – 2.8.7 in IUCLID.

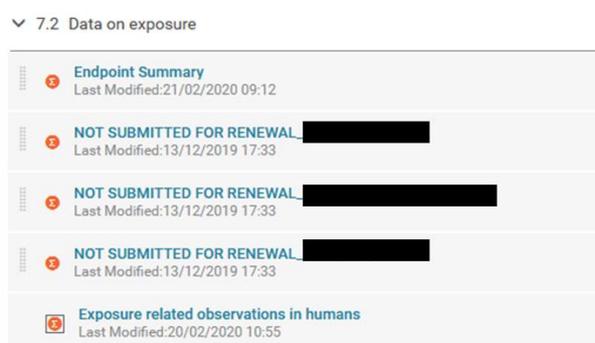
Figure 11: Missing subsections under technical characteristics



Example 2: Toxicological studies / PPP mixture / product dataset

Another example of a similar issue encountered was under section 7.2 data on exposure in IUCLID, where it should also include some subsection points for operator exposure, resident exposure, worker exposure etc. knoell's recommendation for such issues would be to add the relevant and necessary subsections in IUCLID. It should be considered to create different summary documents for operator, bystander/resident and worker. This approach would enable the applicant to focus on the relevant numbers and mitigation measures/personal protection equipment (PPE), which are partly specific for the different exposure groups.

Figure 12: Missing subsection under toxicology



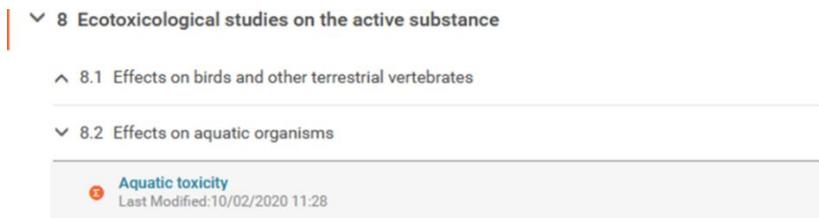
4.3.3 Missing overall endpoint summaries

During the testing of IUCLID, it became evident that overall endpoint summaries could not be created or entered for all endpoints. For example, although this functionality is possible for section 8.2, it is not possible for section 8.1 in active substance dataset.

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knoell recommends that this functionality should be improved so an overall endpoint summary information can be entered (and later extracted via a plug in report generator tool) for all endpoints of the dossier.

Figure 13: Missing overall endpoint summaries



4.3.4 Missing endpoint summaries and study summaries

Similar to the aforementioned issue, several endpoint summaries cannot be entered to specific endpoints. For example in section 5.8.3 an endpoint summary could not be created, and only a new study record can be created.

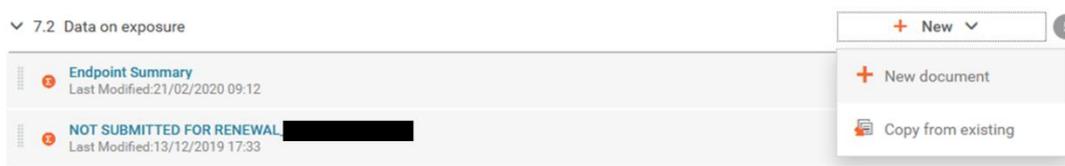
Figure 14: Missing endpoint summaries



As a workaround, in this case knoell created the new study summary record that was named endpoint summary (shortly EPS). Notwithstanding, it is recommended that this functionality and creation of endpoint summaries should be included (potentially in relation to the endocrine disruptors (ED) guidance document) in the future.

Concurrently, in other section endpoints whilst the creation of EPS is possible, new study summaries cannot be created. For example in the section 7.2 does not have this functionality. If operator exposure studies or DFR studies are available these cannot be currently included in IUCLID in the relevant section, but can only be included within an endpoint summary to this section.

Figure 15: Missing study summaries



Endpoint study records provide the applicant with the means to summarize the study test reports, in a robust study summary format and enter all the details of the study in predefined fields, describing in detail how a study was conducted. They also enable the user to attach the study report to the study record itself. Endpoint summary records allow applicants to

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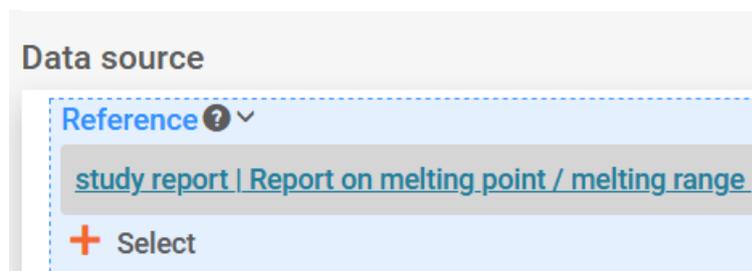
summarize and collate results of several endpoint study records thus providing further information on the endpoint as a whole. Knoell recommends to improve the functionality of IUCLID by including the option to create endpoint summaries and endpoint study records for all sections in IUCLID.

4.4 Usability issues

4.4.1 Data migration from CADDY to IUCLID and study record in IUCLID

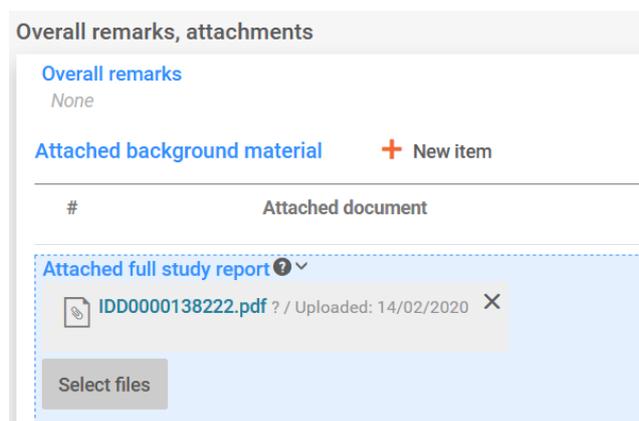
During the migration of the data from CADDY to IUCLID the agreed rule was applied that only one study record will contain only one study report. This is in alignment with the requirements of the notification of studies where the study notification identifier must be linked to the results of that study. Although this rule was implemented within the pilot, it is however technically possible to attach more than one study report or further documents to one study record in IUCLID. Certainly, this shows the flexibility of IUCLID and is a quite useful feature; none the less the current design does not allow the user to link one reference / study record unambiguously with one study report. If such a record of studies is required (i.e. requiring the attachment of multiple reports), one possible option would be to attach the study report within the data source filed:

Figure 16: Data source reference in IUCLID



This option is not available in IUCLID now. Currently the study reports are linked within the study summary, field “Attached full study report”:

Figure 17: Attachment of documents within a study record in IUCLID



As shown, one can link more full study reports within one study report.

4.4.2 Time considerations connected with data migration

The manual migration of data from CADDY to IUCLID is time consuming: It took approx. 40 hours to migrate the 335 study reports presented in the original dossier to IUCLID. This migration focused on the creation and naming of new study records in IUCLID and the attachment of the associated study report within the record itself. This time required for migration did not include the actual transfer of the content of the study summaries to IUCLID - this was much more time consuming.

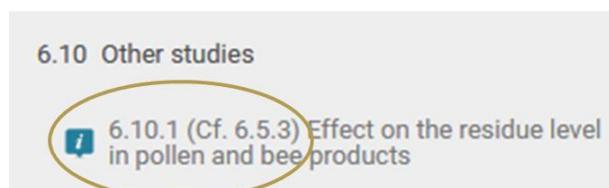
For future dossier preparation for the renewal of the active substances in IUCLID, we expect that the originally submitted dossier (in another IT format) needs to be completely transferred into the IUCLID. Our experience with the renewal process within the BPR shows that such renewal dossiers might need to include either only the new available information or all available information (also submitted in the original active substance approval). For the latter case, to limit the manual work and connected high costs, an IT data migration tool from another IT system (e.g. CADDY) to IUCLID as well as tool to transfer of text from M docs to IUCLID summaries would be very useful. Such a tool is currently not available.

4.4.3 Cross-reference of OHT templates (Cf. ...)

In some cases OHT templates exist in IUCLID but they are not located under the (sub)section listed in IUCLID according to the data requirements. Instead a cross-reference' is given to link to a different subsection (endpoint study record) which contains the data. This is referenced in IUCLID by the text (Cf...).

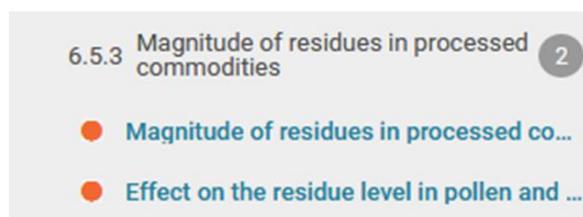
Two examples are provided below to illustrate an issue with such cross-referencing:

Figure 18: Example 1 Residues / active substance dataset



As shown above the entry of study or study summary in section 6.10.1 is not possible – according to IUCLID it should be entered into section 6.5.3

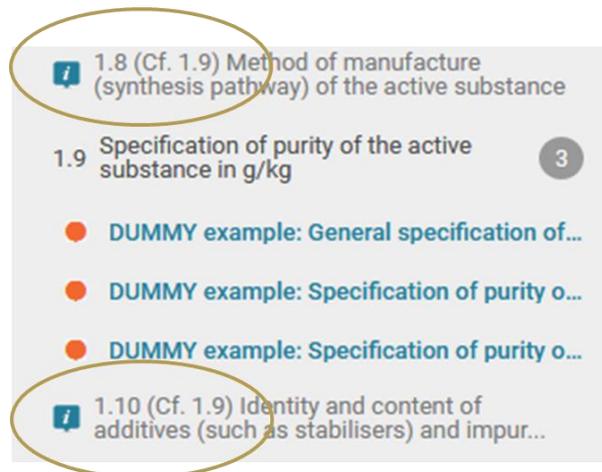
Figure 19: Example 1 Residues / active substance dataset – cross reference section



In this case the cross-reference from section 6.10.1 to section 6.5.3 makes little sense as pollen and bee products are not processed commodities of crops. A honey residue study

contains elements of a general residue study and a feeding study; therefore a new OHT template would need to be developed.

Figure 20: Example 2: Identity of active substance / active substance dataset



In the tested version of IUCLID the sections 1.8, 1.10, 1.11 are not editable and all summaries must be completed in section 1.9. There was no possibility to present this information on method of manufacture (CA 1.8), specification on purity (CA 1.9), information on significant and relevant impurities (1.10) and the analysis of 5 batches separately. More specifically, the rich text field (RTF) available for this information in IUCLID is generally sufficient to insert the information on method of manufacture and the reaction schemes, flowcharts can be attached in a separated document. In case however if all information referring to point 1.8, 1.9, 1.10 and 1.11 should be summarized within one rich text field, a valid way of the information entry for some of the applicants and projects seems to be problematic.

Problems connected with cross-references

Applying cross-references spreads the data over the IUCLID in non-expected places or various information is included in just one summary e.g. in illogical, non-dedicated places. Reviewing of the information e.g. during completeness check is cumbersome and requires use of workarounds.

Based on the systematic evaluation of all endpoints (presented in the Annex I) one can conclude that within all sections such cross-reference was applied. The following sections were mostly affected by cross referencing: section 1. Identity of active substance, section 3. Further information on the active substance, section 6. Residues.

This method of cross referencing for the PPP submission types (and also frequently used within BPR layout) was considered as a major disadvantage of the current version of IUCLID by the IUCLID testers. The cross referencing was a frustrating feature while using IUCLID and preparing the pesticide dossier as the user believes it distorted the content by neither locating it appropriately nor logically within IUCLID. It was perceived that a large diverse content of data were offloaded to one section rather than organizing them systematically.

knoell recommends to restructure the table of contents avoiding the need of such cross-references in IUCLID.

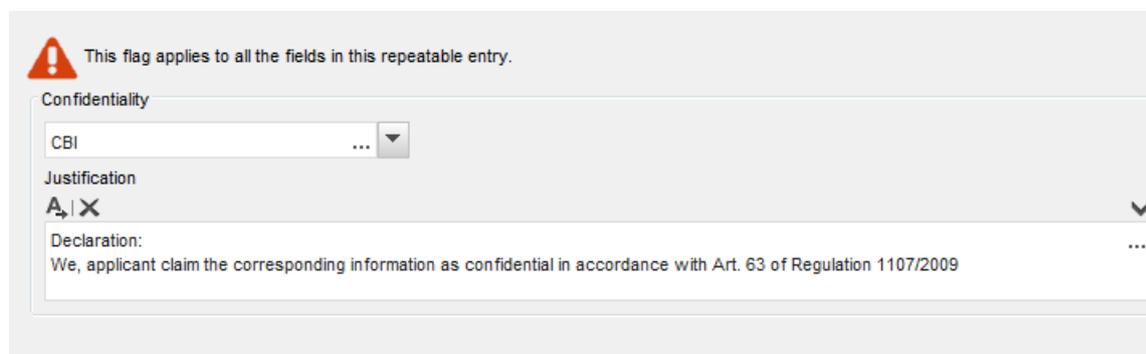
In knoell's opinion the use of cross-references in one of the most problematic IUCLID issues that requires improvements and adaptations of IUCLID, as the content and sequence of information in IUCLID is sometimes confusing and not as logical as it could be. This may fuel the resistance in the use of IUCLID.

4.5 Issues with administrative feature

4.5.1 Confidentiality issues

According to the Article 63 (2) of Regulation (EC) No. 1107/2009 the applicant has the opportunity to claim information as confidential within the dossier. In IUCLID, applicants can label information, items or documents as confidential using a CBI (Confidential Business Information) predefined flag. When this flag is set a justification of the confidentiality is required.

Figure 21: CBI flag in IUCLID

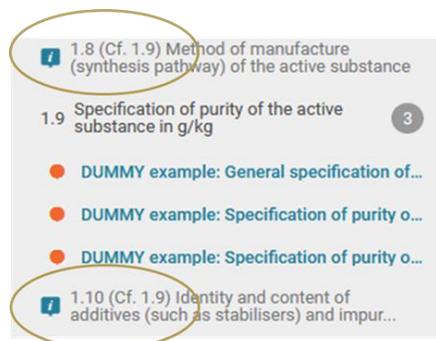


The screenshot shows a web-based form for setting confidentiality. At the top, a warning icon and text state: "This flag applies to all the fields in this repeatable entry." Below this, there is a section titled "Confidentiality" containing a dropdown menu with "CBI" selected. Underneath is a "Justification" section with a text area containing the text: "Declaration: We, applicant claim the corresponding information as confidential in accordance with Art. 63 of Regulation 1107/2009".

Additionally, there is a clear need for guidance to advise the applicant that certain fields within IUCLID do not need to be flagged as CBI as they will never be disclosed. For example such fields would never be disseminated and would always be treated as confidential information, even without setting any confidentiality flags. For the tested PPP submission types such clear rules on what will be disseminated and what will be kept confidential in IUCLID are missing and need to be implemented before IUCLID is rolled out for PPP dossier use. IUCLID should be programmed in such a way to implement it according to the PPP regulation, e.g. the points (a) to (g) of the Article 63 of the Regulation (EC) No 1107/2009 and currently mostly included in Document J (Confidential Information) should never be published. This means that the confidentiality claims would not be necessary but the dissemination tool would automatically recognise these dossier elements as confidential. Generally, the data points CA 1.8 (Method of Manufacture (synthesis pathway) of the active substance), CA 1.10 (Identity and Content of Additives (such as stabilisers) and impurities), CA 1.11 (Analytical Profile of Batches), CP 1.4.1 (Composition of the plant protection product), CP 1.4.3 (Information on safeners, synergists and co-formulants) and CP 7.4 (Available Toxicological Data Relating to Co-Formulants) always include confidential business information and could be generally disseminated.

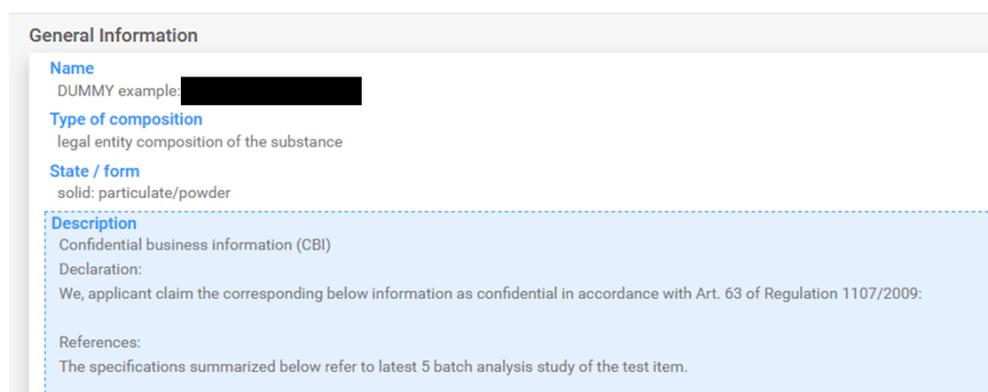
It was particularly difficult handling the confidentiality claims for the substance identity data within the pilot project since there was no predefined field to enter information and instead large amounts of information were entered in the free text fields.

Figure 22: Difficulty of setting CBI flags for substance identity data, section 1.9



As presented in the previous section, the method of manufacture (CA 1.8), specification on purity (CA 1.9), information on significant and relevant impurities (1.10) and the analysis of 5 batches (CA 1.11) had all to be included in IUCLID point 1.9 in which, however, not all the data can be provided in fields specially designed for this information. Instead, some of the information had to be included in the free text within the description filed as shown below.

Figure 23: CBI justification in free text field



In this section 1, data point 1.9 there was no possibility to label all relevant information with the confidentiality flag. The confidentiality flag was separately added to each constituent of the technical material and each listed impurity but the applicant cannot flag the manufacturing process description given in the general field „Description“. As shown in the “Declaration” would not be detected on the automatic selection of the data by any IT IUCLID rule or tool, since this is “hidden” in a free text field that could only be identified in the manual check of the IUCLID content.

Confidential data 1.8-1.10

knoell recommend to first separate information provided in section 1.8-1.10 into the separate sub points and further include the confidentiality flags option or clear rules on which IUCLID

content will never be disseminated.

4.5.2 Confidential data for the task force submissions

The example used for this pilot project for a task force / registration group case, was a rather simple example with only two applicants, the same active substance and a product. The main dossier of applicant A which included all the information apart from the confidential information of the applicant B, contained most of the data and data only had to be handled between two applicants.

Often, real cases are more complex and might include a larger number of task force members where more confidential data have to be handled and still common conclusions provided to the authorities. There are in general two options possible:

- 1) To use a trustee, who would handle all the confidential data and submit these on behalf of all applicants (which is certainly difficult for the applicants concerning the cooperation and exchange of the information), or
- 2) All the applicants would provide separate dossiers which then would be consolidated and conclusions submitted to each applicant separately.

Clear rules and process should be set up on how to handle such complex cases of third party confidential information within task force submissions in the future.

4.6 New features proposed

4.6.1 Renewal of the active substance pesticide dossier and presentation of new data vs old data

To reinforce a clear distinction between new data (i.e. new studies and their associated study summaries) and previously submitted data during the original application knoell used the “Template” function in IUCLID. All new studies were entered into a template, which in turn was attached to the substance or mixture data sets.

The template endpoints are clearly illustrated by the inclusion of a small square around the “normal” circle icon of the endpoint

Figure 24: Use of the templates in IUCLID for new study summaries.



Notwithstanding, this workaround solution is not optimal as any IUCLID content can be entered within these templates and the separation of the data is not a primary purpose of such IUCLID entities. If new study reports/summaries need to be clearly separated from the originally submitted data for a submission, another IT IUCLID solution is necessary. Also for further processing of the dossier and for transparency purposes, the introduction of the new option allowing recording all changes at any time would be recommendable. This applies especially for the RTF fields, where changes are not clearly visible in the report obtained from the current IUCLID dossier comparison tool.

Currently, the IUCLID format submitted to the authorities (e.g. within REACH or BPR process), must to be in the IUCLID dossier format. An IUCLID dossier is a write-protected version of the data stored in a raw data set of IUCLID, which means it cannot be further edited. The only changes that can be performed on the dossier are the attachment of annotations, which are designed to include comments of the regulatory bodies on the content of the dossier.

Possible future solution:

It would be advisable to consider whether IUCLID could be equipped with a tool to make new edits and add new content to the dossier file. This step would require a new programming of IUCLID and addition of such option.

4.6.2 Linking of metabolites

One of the major difficulties encountered during the preparation of the pesticide dossier was the adequate presentation of the studies, which were performed on metabolites and, if available, also studies performed on impurities. An advantage of creating different dataset for each metabolite is that one could also use the same dataset for the case when a metabolite in one application would be an active substance in another application. This might be the case for active substances belonging to the same chemical group.

The draft Pesticides Submission Manual (ECHA, November 2019) “How to prepare a pesticides dossier” advised users to create separate IUCLID datasets for each component of the product (including metabolites) and link it to the IUCLID section 1.4 ‘Detailed quantitative and qualitative information of the composition of the plant protection product’ or ‘Detailed quantitative and qualitative information on the composition of the representative plant protection product’. According to this recommendation, separate datasets were created for the metabolites of the active substance and then linked to the section 1.4. in a separate study record, in addition to the composition of the plant protection product as shown in Figure 25 below. The problem associated with this approach is that section 1.4. does not contain an option to actively link metabolites, and in general metabolites cannot be treated as components of the composition (in contrast to solvents, impurities or additives). Although the datasets are linked to the composition of the plant protection product, the real relation between active substance and metabolites cannot be correctly displayed. This presentation of data caused some confusion since the data on one endpoint e.g. partition coefficient or acute toxicity, although available for the active substance and metabolites, were spread over various datasets and difficult to find within IUCLID.

Figure 25: Linking study records of metabolites

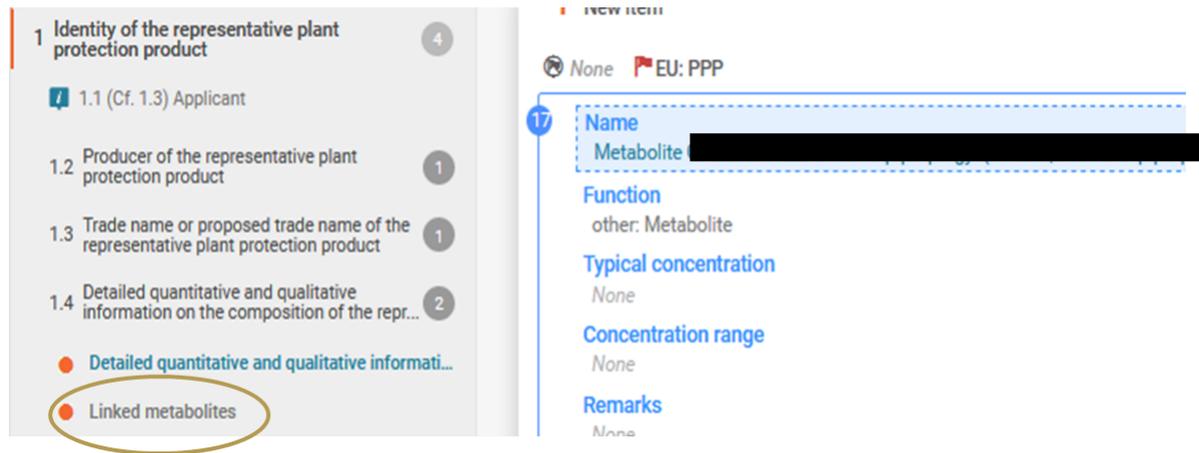


Figure 26: Schematic diagram of how metabolite data was presented within the pilot

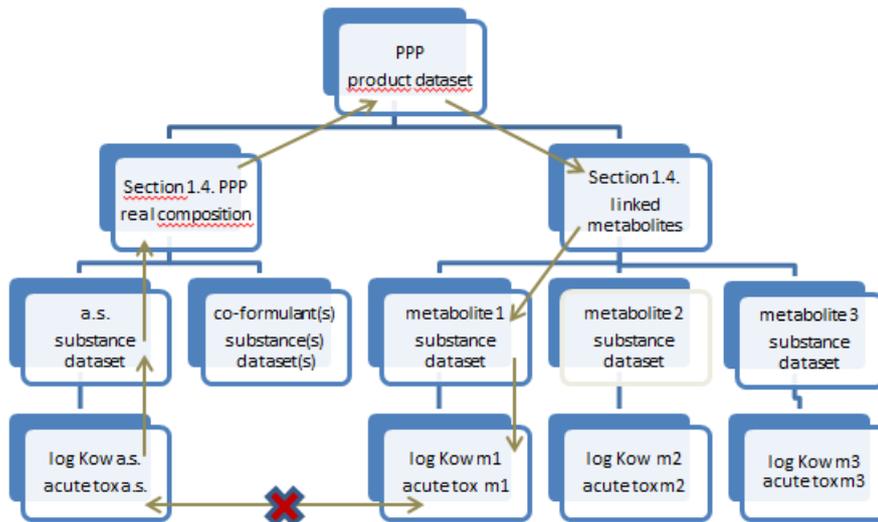


Figure 26 illustrates how each study is linked with different substance dataset. Such an overview data linkage as presented in the diagram above is not currently possible in IUCLID. Instead, in order to move from the active substance dataset (e.g. log Kow a.s. study record) one needs to go through each element of the IUCLID tree (6 moves) and cannot jump between the study record summarising the log Kow for active substance and the study records of the metabolites (i.e. in one step). The visualisation of the data in IUCLID and possible cross checking between different study record elements would be a very useful feature, if available, that could be used also for e.g. in the visualisation of composition elements and related safety datasheets.

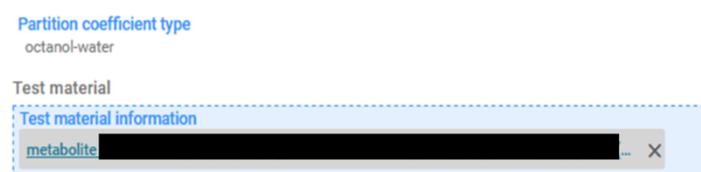
To achieve a similar approach to the current CA dossier layout and based on the testing of this problem within the pilot project, knoell proposes to include the summaries for metabolites within the active substance dataset instead of presenting them in separate datasets for each metabolite/impurity. This would be in line how it is presented in the current CA/CP dossier format according to the guidance document SANCO/10181/2013. The summaries would then be included in one place in IUCLID and the overall conclusion for the endpoint could be presented in the endpoint summary as illustrated in Figure 27 below. It is worth to mention that there might be cases when the same substance is an active substance and the metabolite of another active substance. Once the data are entered into IUCLID, they can be easily used for both cases/applications: for example by copying of the study summary or linking of the IUCLID template containing study summary. The exact handling of the data depends on the individual set up of IUCLID by the applicant.

Figure 27: Suggested layout for metabolites



In order to assure the correct linking between the study (summary) records and the tested material (active substance, metabolite, etc.) the test material information field within a study summary should be used.

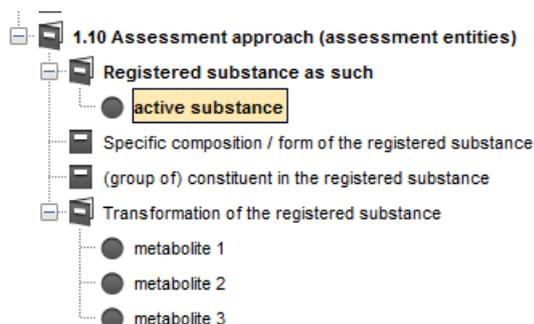
Figure 28: Test material information on metabolites in IUCLID



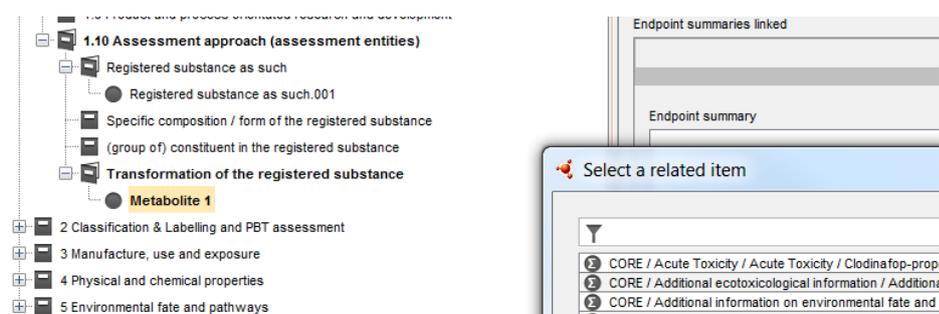
Furthermore, the assessment entities option seems to be a good solution for the future to show relation between the active substance and metabolites. This option is already commonly used within the REACH submission types in the current IUCLID version, to enable users to group a set of substance property data (across endpoints) that are relevant for the assessment. For instance assessment entities are used to present the data for the substances that easily hydrolyse for which some data are generated for the substance as such and some for the transformation products (water solubility or partition coefficient). Within the section 1.10 (REACH submission type) the assessment entity provides the relation between the datasets and endpoint summaries. When such an option is used, the report generator can correctly recognise the relationship between the datasets and summaries and pull the data into the Chemical Safety Report in a structured way. Another example is the use of the assessment entity to present the data generated on different nanoforms when such different nanoforms are covered by one REACH registration.

Figure 29 below shows how the assessment entity could be used also for the plant protection product in the future, however we wish to note that the tested IUCLID version did not yet include the assessment entity functionality for the PPP submission types.

Figure 29: Assessment entity functionality in IUCLID



Proof of concept pesticides dossier in IUCLID format – final report



In conclusion, independently on whether the availability of assessment entity in IUCLID is a given or not, the recommendation for the future is to present all the data (for the active substance and its metabolites) within one endpoint of the active substance and to show the tested material within the test material information. This would allow easy navigation between the data; nonetheless, the correct linking between active substance and metabolites would be possible with the assessment entities (or other specially designed location). For future developments and the implementation of plug-ins (report generator, validation assistant), etc. the provisionally linked content (as it is now in case of metabolites linked to the section 1.4) cannot be currently accessed for such tools. This means also that the studies for metabolites cannot be pulled from the dossier into the assessment reports or accessed by the validation assistant in a correct way.

4.6.3 Composition of the product/mixture

The composition of the mixture/product was also reviewed within the tested IUCLID version and the product composition contained, apart from the mixture components, also such elements as additives and impurities.

According to the ECHA proposal and as agreed within the working group all the impurities should be in the future stored under “Components”. Then, the phrase selected in the Function pick list would be a new phrase “no applicable”. All additional information could be inserted in the remarks field, if needed.

In accordance with Regulation (EC) No. 284/2013 for plant protection products the following information shall be reported with regards to the composition data:

- the content of the technical active substance (based on the specified minimum purity) and the declared content of pure active substance and, where relevant, the corresponding content of the variant (such as salts and esters) of the active substance ,
- the content of safeners, synergists and co-formulants,
- the maximum content of relevant impurities, where appropriate

Since information on relevant impurities (in case present in the technical active substance) is summarized in active substance dataset or basic substance dataset (in case present in the co-formulant) it is a possibility to use only components blocks.

The mixture (formulated product) consists of components (active substance, co-formulants, safeners or synergist) therefore it is comprehensibly that the blocks present in the section 1.4 in IUCLID then only refers to „components“.

It should be considered to add the phrases „safener“ and „synergist“ to the list of function currently available.

4.6.4 IUCLID plug-ins

The IUCLID plug-ins that could be used for the PPP submission types were limited to the DAR report generator, dissemination preview and print of the data. Whilst these tools are very beneficial they still require further improvement (see below) so that the correct data can be extracted into the output report and this output is presented in a user friendly and readable format. Other plug-ins such as the validation assistant (the completeness tool) and fee calculator are not available yet for pesticide dossiers.

The following improvements are proposed:

- Only DAR report creation on plant protection product is possible, but the data set also needs to be generated for the active substance including metabolites and impurities
- The applicant currently submits the dossier in a format in accordance to the guidance document SANCO/10181/2013– rev. 5, which would be a desirable report generator format as well.

The availability of these plug-ins with their full functionality (as it is under REACH submission types) would allow users to fully appreciate the application of IUCLID as a data submission IT system for pesticide dossiers. IUCLID is much more than a simple envelope or container of study reports. IUCLID is a powerful tool to enter data in organized fields, arrange as study summaries and analyse their content by the use of automated tools. Furthermore, information within IUCLID can be extracted by the report generator feature to create reference lists and summary documents e.g. Document N. The main prerequisite for efficient and effective output from the application of the developed plug-ins is that data is entered in the fields for which the plug-in tool was mapped to (i.e. users must enter the data in IUCLID in the relevant and defined fields, or pick-list in standardize format).

4.7 Aspects requiring further development

4.7.1 Risk assessment

In the tested version of IUCLID, there is no possibility to report the extensive risk assessments adequately. In such cases, much of the information can only be copied in free text fields within the robust study summaries and endpoint summaries. There are no specific sections especially available for the entry of exposure and modeling results.

4.7.2 GAP Table

In a pesticide dossier the GAP table is included in Doc D-1, Doc N2 (List of Endpoints) and MCP 3.3 and the information is repetitive. Only a specific template is given in the Document N2 template, which was attached to the IUCLID dossier, section 3.2. Generally as discussed within the pilot working group there is a need to align the different GAP table versions (e.g. also compared to dRR format in Part A). knoell recommends to allocate the GAP table at one

prominent point, for example under the “Summary and evaluation” (section 13 in the product/mixture dataset) and add, in this special case, a reference in 3.3 of the mixture set.

4.7.3 Literature data

Currently IUCLID does not contain an appropriate literature summary (although it is available in the as a short summary under REACH and BPR submission types). This new summary needs to be included in IUCLID for pesticide dossiers. The template of a literature review report as given in the Appendix to the EFSA guidance 2011;9(2):2092 was attached in the IUCLID section 11. Summary ad evaluation

4.8 Appendixes provided within the pesticides technical guidance

Within this chapter, we describe how different scientific information should be extracted from the IUCLID dossier and added as appendixes, according to the recommendation in the pesticides administrative guidance annex³. Documents tested within the pilot project are specifically described within the following table.

Table 4: List of appendixes tested within the pilot project

Annex point	Document	PPP IUCLID dossier
1.9 Specification of purity of the active substance in g/kg	Appendix J - Template for presentation of assessment for the equivalence of batches	Document attached to section 1, point 1.9 in a.s. dataset (study record / general specifications)
4 Analytical methods	Appendix D - Template for the overview table for analytical methods used for risk assessment	Document attached to section 4, endpoint summary Σ 4.1.2 in a.s. dataset
5.3 Short-term toxicity, 5.5 Long-term toxicity, 5.6 Reproductive toxicity, 5.7 Neurotoxicity studies, 5.8 Other toxicological studies	Appendix F - Template for presentation of results in tabular format for mammalian toxicology studies	Not included, but comments provided
5.8.3 Endocrine disrupting properties	Appendix I - Template for presentation of assessment of endocrine disrupting properties	Document attached to Point 5.8.3, in a.s. dataset
6.2 Metabolism, distribution and expression of residues	Appendix G - Template for presenting metabolism	Document attached to the Σ endpoint summary in section 6 in

³ EFSA Technical Report: Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances; approved 27 March 2019

	residues trials	a.s. dataset
7.1.2 Rate of degradation in soil	Appendix H – Template for presentation of kinetic fitting	Document attached to the Σ endpoint summary in Point 7.1.1. in a.s. dataset

4.8.1 Appendix J - Template for presentation of assessment for the equivalence of batches

This appendix provides a template on how the information for the assessment of the compliance of the batches used in the (eco)toxicological studies with the technical specification needs to be presented. Two tables C1 and C2 are given to harmonize and facilitate the assessment for the equivalence of batches.

Both tables were completed with the dummy information (due to the confidentiality of these data processed within the project) and attached as Appendix J to the point 1.9 in section 1 of the active substance dataset (study record referring to the description of the general specifications). The screenshot below shows the table C1.

Figure 30: Table C1 of Appendix J



Administrative guidance on peer-review of pesticide active substances – Appendix J

Appendix J – Template for presentation the assessment for the equivalence of batches

Table C1: Proposed template for the link between batch and study type

Batch	Study type	Author of the study and report number
Batch 1	Bird acute study / oral acute study	Author, A Report no.: 1000X
Batch 2	Fish acute study, aquatic invertebrate acute study / Ames test	Author, B Report no.: 1000Y
Batch 3	Earthworms chronic study	Author, C Report no.: 1000Z
Etc.	Etc.	

The corresponding table C1 could be automatically generated based on the information summarized in IUCLID, if all batches are appropriately described in test material entities within the respective study record, since Table C1 is a simple list for all endpoint studies with the test material, the study endpoint and the bibliographic reference. The test material inventory in IUCLID allows seeing all the study (records) that are linked with the same test material:

Figure 31: Linked references in IUCLID

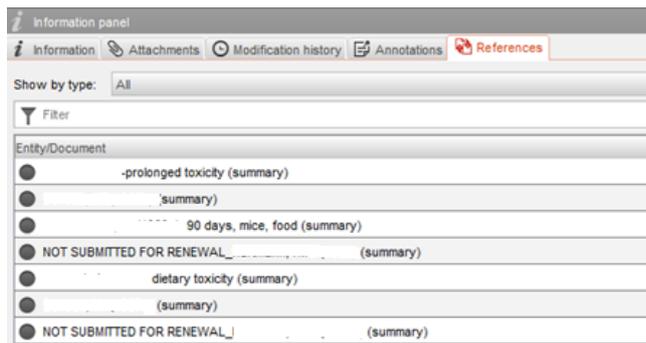


Table C2 contains the detailed composition of the batches used in the (eco)toxicological testing: the active substance, impurities and additive concentrations presented against the reference specification. The aim of the table is an easy check if the tested batches are within the reference specification.

Figure 32: Table C2 of Appendix J

Administrative guidance on peer-review of pesticide active substances – Appendix J efsa

Table C2: Proposed template on how the composition of batches used in the (eco)toxicological studies and the technical specification should be presented.

Short name or code of the substance	Content (g/kg) proposed by applicant / by RMS in the new specification	Content (g/kg) reference specification, if any	Batch X			Batch XX			etc			Tier I assessment	Remarks ²
			Content (g/kg)	Permitted max ²	% difference ³	Content (g/kg)	Permitted max ²	% difference ³					
Active substance	950	930	948	Not relevant	2.1x 10 ³	952	Not relevant	-2.1x 10 ³	-	-	-		Not relevant
Impurity A	2	2	1.8	3	xxx	1.5	3	xxx	-	-	-	e.g. Impurity A covered by batch XX	Tier 2 is not relevant

Also table C2 could be potentially automatically generated based on the information included in IUCLID. There are two options that can be considered where to provide the full compositional information on the tested batches.

Option 1:

First of all the section 1.9. is well designed to present the specification of purity of the active substance (including impurities and their concentrations). Within the separate study records the composition of each batch tested in (eco)toxicological studies could also be entered for all tested batches as shown below.

Figure 33: 1.9 Specification of purity in IUCLID

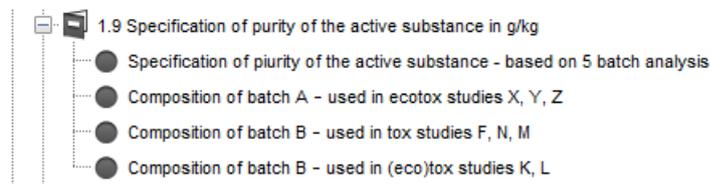


Table C2 would then be a summary of the information in all 1.9 documents. However the current version of IUCLID does not allow linking the information in section 1.9 with the study record summarising the (eco)toxicological information (no link between Section 1.9. and e.g. 5).

Generally speaking Section 1.9 should be re-designed to meet the requirements of the current regulation and all supporting documents (for example toxicological assessment for renewal purposes). It should be possible to generate the report from section 1.9 listing all batches described and the references to study linked. One would however also consider to add the ownership of the study within the study summary as these data are member specific and confidential. In the case of registration groups one may have numerous batches for different members and one would need to be able to filter of the data for the study owner.

Option 2:

One could also consider alternatively to complete the full composition of the test material in the test material information entity directly and link such test material entity specific to one batch with all the study summaries for this the same batch with the same purity was used.

The advantage of this option is an easy link between the test material information and batch tested. The report generator could extract the necessary information from IUCLID in an automated process. The disadvantage of this option is that there is no possibility to claim the entire composition as confidential – as the confidentiality flags cannot be currently set up within the test material entity. Notwithstanding, by setting confidentiality and dissemination rules in IUCLID, one could agree to always keep this information as confidential or simply include new confidentiality flags. The other point to consider is that the test item is linked to different studies (not only toxicological and ecotoxicological) and this corresponding information would be visible through the links in other studies, which not necessarily are confidential, e.g. physico-chemical information and tested batches. One could overcome this problem by setting two test material entities with the same content, but different confidentiality status.

Figure 34: Solving the issue with two test material entities

Name*

A.S. Batch A

Composition

Composition

Type	Reference substance	Concentration
Constituent	Active substance / Active substance	950 g/kg
Impurity	Impurity A / Impurity A	2 g/kg

⊕ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Composition / purity: other information

... Other

Other characteristics

Test material form

... Other

Details on test material

⊕ | ✕

- State of aggregation:
- Particle size distribution:
- Mass median aerodynamic diameter (MMAD):

Confidential details on test material ⚠

⊕ | ✕

4.8.2 Appendix D - Template for the overview table for analytical methods used for risk assessment

This appendix summarizes the analytical methods used for risk assessment in a tabular format as shown below.

Figure 35: Appendix D



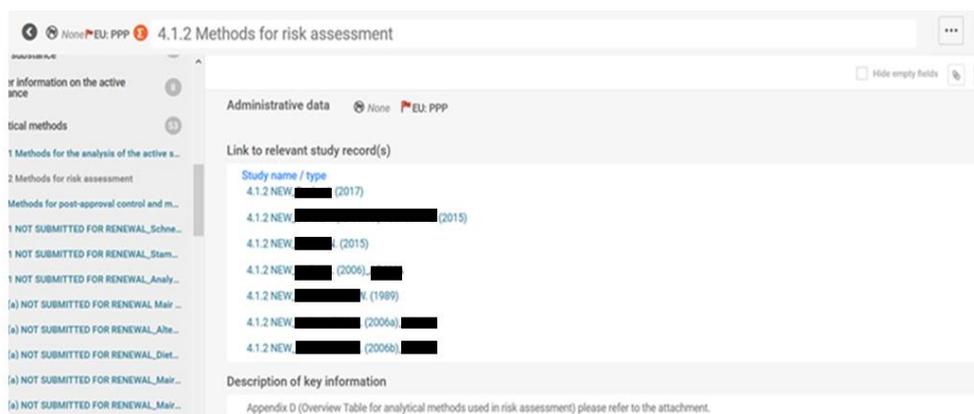
Administrative guidance on peer-review of pesticide active substances – Appendix D

Appendix D – Template for the overview table for analytical methods used for risk assessment

Annex point Reference within Assessment Report	Author, date	Study title	Analytical method Author, date, No.	Technique, LOQ of the method, validated working range	Method meets analytical validation criteria	Remarks (in case validation criteria are not met)	Acceptability of the method
1							

The corresponding template was completed and attached in section 4 / in the endpoint study summary (Σ): 4.1.2 of the dossier referring to Methods risk assessment as indicated below.

Figure 36: Attachment of Appendix D in IUCLID



The function to attach any document in endpoints study summary (Σ) is hidden in web interface of IUCLID. It is, to the best of our knowledge, not visible if a document has been attached to the endpoint study record or not. Knoell suggestion would be to improve the functionality of IUCLID by introducing a visual indication of documents attached there. A symbol could be added to indicate if documents have been uploaded.

The generation of Appendix D from IUCLID would be of advantage and seems to be possible based on the data included in the IUCLID: The information on techniques, LOQ, working ranges, etc. can be extracted directly from IUCLID. Nevertheless there is one potential problem to be considered. Let us consider the following example for acute toxicity to fish.

We can have 3 different possible types of reports provided by the applicant:

- A toxicological study report by Author A (study director) containing the analytical phase part by Author A (study director); here the reference to the report will be given in IUCLID two times: in the toxicological section and the analytical section (the same data source)
- A toxicological study report by Author A (study director) containing the analytical phase part by Author B (study director); here the reference to the report will be given in IUCLID two times: in the toxicological section and the analytical section (the same data source, however in the analytical phase the reference has to be done to the analytical phase report, author B)
- A separated study report by Author A (study director) and a separated analytical phase report by Author B (study director); in IUCLID two different reports will be assigned since two separated authors A and B. Via cross references the link to the original report will have to be given.

In order to generate the table with the content similar to Appendix D template, there would have to be a clear link in IUCLID between the analytical section and the respective toxicological section (and vice versa), in which the original study is described. In the example as described above,

Noteworthy, we can have (as listed above) the same data source which will be present in section 8 (toxicology) and section 4 (analytics). The IUCLID software would have to be improved accordingly.

4.8.3 Appendix I - Template for presentation of assessment of endocrine disrupting properties

This template is designed for presentation of the assessment of endocrine disrupting properties. The information included in the dossier was not sufficient to complete the appendix I and the endpoint 5.8.3.

The relevant data from the publications presented in IUCLID has been summarised and reviewed as part of the ED assessment in the respective Review Report within the dossier. As this document is confidential, no information could be presented directly in IUCLID dataset.

Moreover, by the time the Review Report was written, the current ED Guidance was not available. Hence, this report does not represent an ED assessment according to the current standards. From the experience gained with ED assessments under the BPR, where the same guidance applies, IUCLID does not have an adequate format to present such a complex assessment structure. In BPR submission cases up to now, the ED Assessment (i.e. Appendix E) was attached and not entered directly to an IUCLID record.

4.8.4 Appendix G - Template for presenting metabolism residues trials

This template is a very complex excel table summarising the metabolism studies in primary crops, rotational crops, livestock and supervised residue trials. The information included in this excel table could be extracted from IUCLID, if it were to be programmed to include the respective required elements..

4.8.5 Appendix F - Template for presentation of results in tabular format for mammalian toxicology studies

The Appendix F is one example template for presentation of results based on some reproductive toxicity endpoints. The format in general provides some basic required information however, is difficult to apply for other study types or endpoints without further adaptation. It should be clearly stated in the guidance what is exactly requested and to what extent the applicant is free to adapt this appendix. For example, if there is a repeated dose study with four groups per sex, the direct comparison between male/female may be need to be displayed as results in one row. This will be difficult applying the table structure provided in Appendix F with the historical control data in the same rows.

Currently, the data are provided by applicants are in a non-harmonized format: most often the data have to be extracted (often by hand) from pdf files (protected or non-protected). Sometimes the Word tables are provided, however the results are almost never presented in the Excel format.

Considering the possibility of retrieving the data from the IUCLID into the template F, one could try to automate this retrieval. A result field could be added to every result parameter block: Clinical chemistry, haematology, pathology, histopathology, etc.

Within the result field a number of table examples could be made available to choose from (e.g. applicable for 3 doses, 2 sexes, xy standard sampling time points) with the possibility of

individual adding of rows or columns if necessary. Thus, the general format would be ideally the same.

In summary, a result field within IUCLID that could be handled like a word document for table creation in combination with a variety of table examples, would be ideal. For most of the result tables, a set of about 3 templates per block (e.g. haematology) should cover a high percentage of templates actually needed.

4.8.6 Appendix H - Template for presentation of kinetic fitting

Appendix H is a template that can easily be applied for the presentation of kinetic fitting. The information can be extracted from IUCLID.

Figure 37: Appendix H

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Appendix H – Template for presentation of kinetic fitting

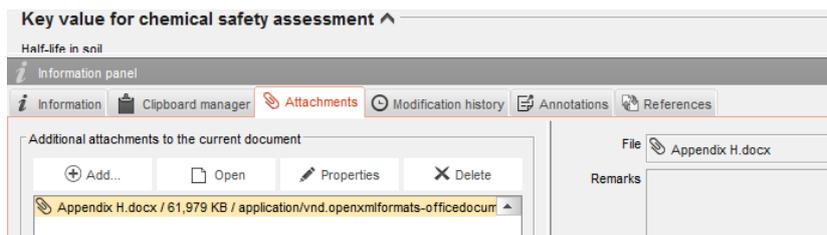
Substance	Soil	Kinetic model	Mo	Parameter (K, K1, k2, g, tb, α, β)	χ ² , % error	Prob >t	Lower CI	Upper CI	DT ₅₀ [days]	DT ₉₀ [days]
XXX	Soil I	SFO	89.79	k=0.003534	4.4	1.5E-06	0.003	0.004	196	652
		FOMC	94.21	α=0.2454 β=23.87	4.2	n.r. n.r.	0.05 -16	0.4 64	not reliable	not reliable

n.r. Not relevant.

In the pilot project this template was attached to the section 7.1.1. within the endpoint summary.

In conclusion, in most of the cases the information required in the administrative templates could be extracted directly from the IUCLID dataset, providing all of the required data are included in IUCLID. One point of concern is then to find the correct administrative templates. In many cases, IUCLID software does not contain a unique location to attach a given endpoint, so that only the option within the information panel within the classic interface could be used to attach the template, as illustrated below on the example of the Appendix H

Figure 38: Attachment of Appendix H in IUCLID



Certainly it is not the optimal way and one could think about the prominent place to include all administrative templates, such as Summary and evaluation or simply include the obligatory field within the relevant endpoint, which would be well described and more visible.

4.9 Record of the time taken for each of the dossier preparation tasks/phases

The table below shows the preparation of two dossiers in numbers. For the interpretation of the numbers provided in the table, it is necessary to mention that, for the purpose of this project, all the study reports available in the original submission and the renewal dossier were migrated from CADDY to IUCLID, but only one robust study summary per endpoint were prepared in IUCLID.

Thus the manual transfer of 335 study reports available in the original dossier for the active substance, metabolites and representative product, took approx. 40 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 study report attached. The migration of the additional 226 reports that were submitted in the renewal dossier took approx. 20 hours.

Table 5: Time spent on the preparation of the pesticide dossier in IUCLID

	Approximate time spent on the preparation of dossiers in IUCLID:				
	Overall	Migration of study reports from CADDY to IUCLID	Active substance & metabolites summaries	Representative product	Internal meetings, IUCLID handling
Initiation, verification	90 h				
Original dossier	~500h	~40h (for migration of 335 study reports)	~350h	~70h	~40h
Renewal dossier	~250h	~20h (for migration of new 226 study reports)	~130h	~50h	~50h
Overall	~840h	~60h	~480h	~120h	~90h

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Two tables below provide the details on the number of robust study summaries prepared within the project and time needed for the preparation of selected IUCLID sections. This time does not cover the time needed for the data migration, which is provided in the table above.

Table 6: Time spent on the preparation of selected IUCLID sections of the **active substance dataset** vs prepared robust study summaries (RSS) and endpoint summaries

IUCLID section	Active substance pesticide dossier the list of RSS & time needed*		Renewal of active substance pesticide dossier the list of new RSS & time needed*	
2. Physical and chemical properties of the active substance, incl. classification	<p>20 RSS (17 for a.s. & 3 for 3 metabolites)</p> <p>2.1.1. Melting point 2.1.2. Boiling point 2.1.3. Decomposition / sublimation summarised under 2.1.2 summary 2.2 Vapour pressure 2.3 Appearance 2.4 Spectra 2.5 Solubility in water 2.6 Solubility in organic solvents 2.7 Partition coefficient n-octanol/water+ 3 RSS for 3 metabolites 2.8 Dissociation in water 2.9.1 Flammability 2.9.2 Self-heating 2.10 Flash point: waiving 2.11 Explosive properties 2.12 Surface tension 2.13 Oxidising properties</p>	34h	<p>2 RSS</p> <p>2.1 Melting point 2.12 Surface tension</p>	24h
4. Analytical methods	<p>8 RSS (6 for a.s. & 2 for metabolites)</p> <p>4.1.1 Methods for the analysis of the active substance as manufactured 4.2 (a) post-monitoring method for plant matrices + 1 RSS for metabolite 4.2 (a) post-monitoring method for animal matrices + 1 RSS for metabolite 4.2 (b) post-monitoring method for soil 4.2 (b) post-monitoring method for water 4.2 (c) post-monitoring method for air</p>	8h	No new RSS	5h

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IUCLID section	Active substance pesticide dossier the list of RSS & time needed*		Renewal of active substance pesticide dossier the list of new RSS & time needed*	
5. Toxicological and metabolism studies on the active substance	<p>20 RSS (19 for a.s. & 1 for metabolite)</p> <p>5.1 Toxicokinetic 5.2.1 Acute toxicity. Oral 5.2.2 Acute toxicity. Dermal 5.2.3 Acute toxicity. Inhalation 5.2.4 Skin Irritation 5.2.5 Eye Irritation 2.5.6 Skin Sensitisation 5.3.1 Oral 28-day study 5.3.2 Oral 90-day stud 5.3.3 Other routes, 5.3.3.2 Dermal 5.4.1 Genotoxicity testing – Ames 5.4.1 Genotoxicity testing - Gene mutation study in mammalian cells 5.4.1 Genotoxicity testing – Cytogenicity 5.4.1 Genotoxicity testing – UDS DNA sythesis 5.4.2 Genotoxicity testing – in vivo MNT 5.5.2 Carcinogenicity 5.6.1 Generational studies 5.6.2 Developmental toxicity studies 5.8 Other toxicological studies + 1 RSS for metabolite</p>	118h	<p>4 RSS</p> <p>5.2.7 Phototoxicity 5.7 Neurotox 5.8.2.1: Immuntox 5.8.3: ED properties</p>	27h
6. Residues in or on treated products, food and feed	<p>6 RSS (5 for a.s. & 1 for metabolite)</p> <p>6.1 Storage stability of residues + 1 RSS for one metabolite 6.2.1 (Cf. 6.6.1) Metabolism, distribution and expression of residues, plants 6.2.2 Metabolism, distribution and expression of residues, poultry 6.3 Magnitude of residue trials in plants 6.6.1 Metabolism in rotational crops</p>	61h	No new RSS	21h
7. Fate and behaviour in the environment	<p>14 RSS</p> <p>7.1.1 Route of degradation in soil 7.1.1.3 Soil Photolysis 7.1.2 Rate of degradation in soil 7.1.3.1 Adsorption/Desorption 7.1.4 Mobility in soil (3 summaries) 7.2.1.1 Hydrolytic degradation 7.2.1.2 Direct photochemical degradation 7.2.2.1 Ready biodegradability 7.2.2.3 Water/sediment study 7.3.1 Route and rate of degradation in air (2 summaries) 7.5. Monitoring data</p>	46h	<p>2 RSS (1 for a.s. & 1 for metabolite)</p> <p>7.2.2.2 aerobic mineralisation in surface water + 1 RSS for metabolite (7.1.1. route of degradation in soil)</p>	18h

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IUCLID section	Active substance pesticide dossier the list of RSS & time needed*		Renewal of active substance pesticide dossier the list of new RSS & time needed*	
8. Ecotoxicological studies on the active substance	<p>18 RSS</p> <p>8.1.1 Effects on birds – acute oral toxicity</p> <p>8.1.1 Effects on birds – dietary toxicity</p> <p>8.1.1 Effects on birds – dietary reproductive toxicity</p> <p>8.2.1. Acute toxicity to fish</p> <p>8.2.2.1 Fish early life stage toxicity</p> <p>8.2.2.3 Bioconcentration in fish</p> <p>8.2.4 Acute toxicity to aquatic invertebrates- acute toxicity Daphnia</p> <p>8.2.4 Acute toxicity to aquatic invertebrates- acute toxicity mysid</p> <p>8.2.5.1 Reproductive and dev. Toxicity to Daphnia magna</p> <p>8.2.5.4 Sediment dwelling organisms</p> <p>8.2.6 Effects on algal growth</p> <p>8.2.7 Effects on aquatic macrophytes</p> <p>8.2.8 Further testing on aquatic organisms</p> <p>8.3 Effects on arthropods- acute contact and oral bees</p> <p>8.3 Effects on arthropods- Effects on Typhlodromus pyri</p> <p>8.4 Effects on non-target soil meso and macrofauna</p> <p>8.5 Effects on soil nitrogen transformation</p> <p>8.6 Effects on terrestrial non-target higher plants</p>	32h	<p>2 RSS</p> <p>8.1.3 Endocrine disrupting properties</p> <p>8.2.3. Endocrine disrupter testing in aquatic vertebrates – in vivo (Doc I)</p>	11h

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

Table 7: Time spent on the preparation of selected IUCLID sections of the **representative product dataset** vs prepared robust study summaries (RSS) and endpoint summaries

IUCLID section	Active substance pesticide dossier the list of RSS & time needed*		Renewal of active substance pesticide dossier the list of new RSS & time needed*	
2. Physical and chemical properties of the representative plant protection product	<p>18 RSS</p> <p>2.1 Appearance</p> <p>2.2.1 Explosive properties</p> <p>2.2.2 Oxidising properties</p> <p>2.3.1 Flammability</p> <p>2.3.2 Self-heating</p> <p>2.4 Acidity / alkalinity and pH value</p> <p>2.5.1 Viscosity</p> <p>2.5.2 Surface tension</p> <p>2.6 Relative density and bulk density</p> <p>2.7.1 Storage stability tests (5 RSS):</p> <ul style="list-style-type: none"> - 3 RSS for accelerated storage stability 2 weeks, 18 weeks & 30 weeks - 1RSS for shelf life <p>2.7.2 Storage stability at low temperature</p> <p>2.8 Technical characteristics of the representative plant protection product (4RSS):</p> <p>2.8.2. Persistent foaming</p> <p>2.8.6.1. Emulsifiability</p> <p>2.8.6.2. Emulsion stability</p> <p>2.8.6.3 Re-emulsifiability</p>	16h	No new RSS	19h
5. Analytical methods	<p>1 RSS</p> <p>5.1.1 Methods for the analysis of the plant protection product</p>	7h	No new RSS	9h
7. Toxicological studies	<p>6 RSS</p> <p>7.1.1 Acute toxicity. Oral</p> <p>7.1.2 Acute toxicity. Dermal</p> <p>7.1.4 Skin Irritation</p> <p>7.1.5 Eye Irritation</p> <p>7.1.6 Skin Sensitisation</p> <p>7.3 Dermal Absorption</p>	25h	No new RSS	3h
8. Residues in or on treated products, food and feed	<p>There were no specific study triggered on the formulation in addition to those already submitted for the a.s.</p>	4h	No new RSS	0h

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IUCLID section	Active substance pesticide dossier the list of RSS & time needed*		Renewal of active substance pesticide dossier the list of new RSS & time needed*	
9. Fate and behaviour in the environment	<p>No RSS for PPP</p> <p>Fields studies performed on the formulated product were copied from the active substance data set: these studies were included in the original dossier also on the active substance level.</p>	7h	<p>1 RSS</p> <p>9.2. Fate and behaviour in water and sediment. Groundwater modelling</p>	1h
10. Ecotoxicological data	<p>6 RSS</p> <p>10.2.1 Acute toxicity to fish 10.2.4 Acute toxicity to aquatic invertebrates 10.2.6 Effects on algal growth 10.2.7 Effects on aquatic macrophytes 10.3 Effects on arthropods 10.4 Effects on non-target soil meso-and macrofauna 10.6. Toxicity to terrestrial plants</p>	10h	<p>1 RSS</p> <p>10.1.3 Effects on terr. vertebrates</p>	9h

* 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 ones robust study summary per endpoint, whereas usually the pesticide dossier contains more studies per endpoint that would also normally need to be summaries in the dossier
- the time recorded refers only to the inclusion into IUCLID of the available summaries and do 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.

4.10 Dossier lifecycle and annotations

Within the last phase of the project, following completion of the two IUCLID dossiers (the original active substance pesticide and renewal of the active substance pesticide dossiers), the dossier lifecycle was tested. The goal of the exercise was to check and provide recommendation on how the commenting phases of the dossier could be performed.

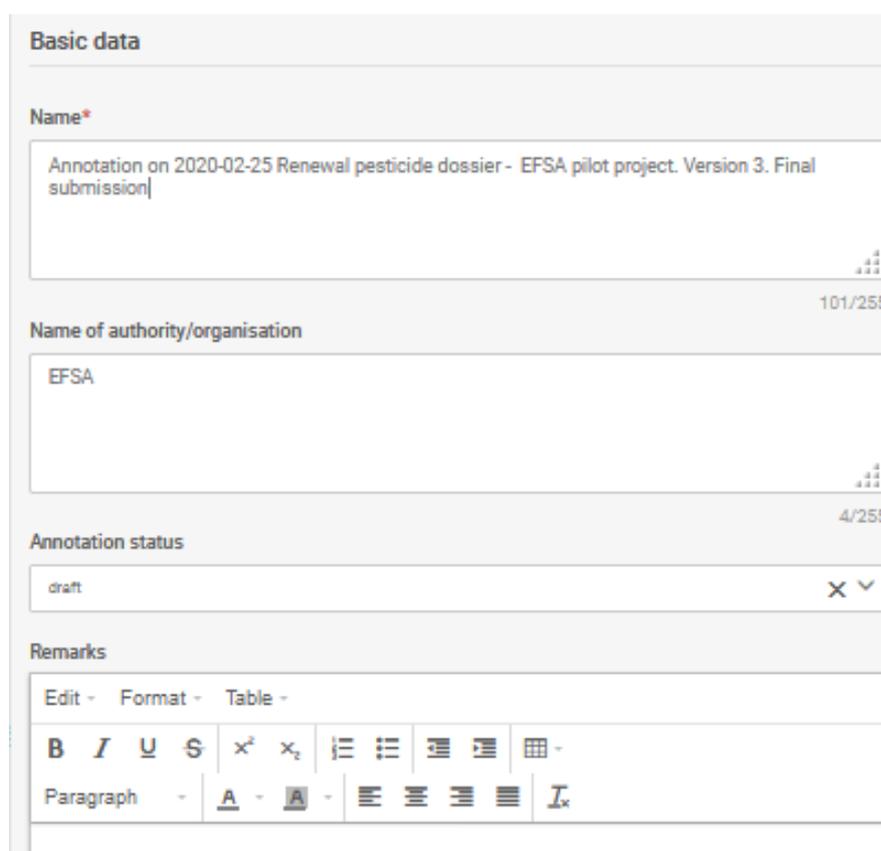
An example simplified dossier lifecycle is provided:

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Applicant dossier in IUCLID → evaluation by the RMS → Preparation of DAR/RAR by RMS using IUCLID → Commenting period on DAR/RAR by EFSA, MS, applicant and public → Comments on DAR/RAR → response of the applicant (answers & explanations in IUCLID, could also be done by directly updating the dossier in IUCLID) → response of the regulatory body (e.g. additional data request) → ...etc.

This simplified process was repeated preparing the dossier in IUCLID and utilising the annotations feature. The annotation feature in IUCLID displays information related to the evaluation of data from a relevant regulatory setting, e.g. by a regulatory body. The ECHA IUCLID guidance recommends a legal entity compiling a substance dataset using this feature, for example, during an internal review process. The use of annotations allows the data to be stored in a structured manner: the annotation as an IUCLID object has one unique identity code (UUID); the author of the comment, content and status of the comment (draft, final) can be included as shown in screenshot below (Figure 39).

Figure 39: Example annotations in IUCLID



The screenshot displays the 'Basic data' section of an IUCLID annotation form. It includes the following fields and elements:

- Name***: A text input field containing the text "Annotation on 2020-02-25 Renewal pesticide dossier - EFSA pilot project. Version 3. Final submission|". A character count "101/255" is visible to the right.
- Name of authority/organisation**: A text input field containing "EFSA". A character count "4/255" is visible to the right.
- Annotation status**: A dropdown menu with "draft" selected and a close button (X) and a dropdown arrow (v).
- Remarks**: A rich text editor with a menu bar (Edit, Format, Table) and a toolbar containing icons for bold, italic, underline, strikethrough, text color, background color, bulleted list, numbered list, indent, outdent, and link.

The annotation can be created based upon the raw data (substance dataset, mixture/product dataset) or on a dossier. To open the annotation feature, the relevant document is selected and opened.

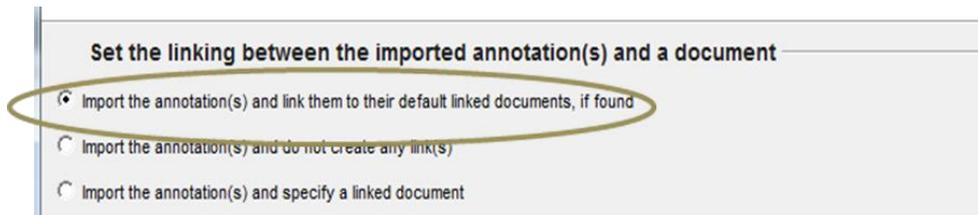
Within this project the regulatory bodies (EFSA and MS) provided comments on various versions of the dossier by including annotations in the IUCLID file provided by the applicant (knoell). These IUCLID dossiers were placed in an EFSA IUCLID cloud-based storage location, providing a central setting for all of the regulatory bodies involved in the project to

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enter comments. This facilitated simultaneous work between the participants as the cloud-based system enables a number of IUCLID users' access to the one dossier – be that the IUCLID cloud or server version. All comments in the form of annotations (without the dossier file) were then collected by EFSA, exported from IUCLID, and provided in IUCLID format to the applicant (knoell).

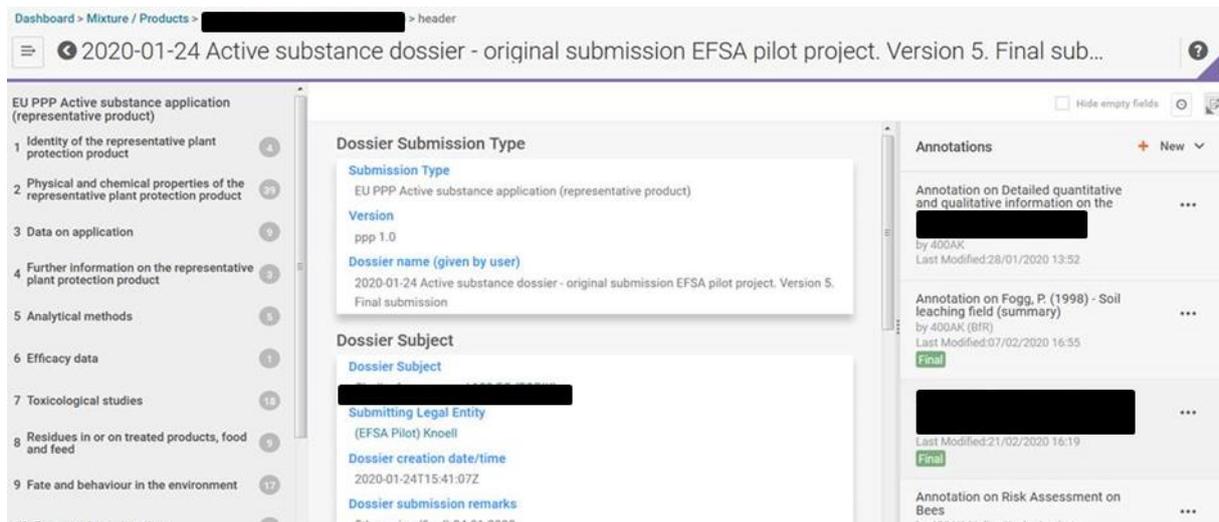
The annotations provided by EFSA, although comprising of 37 separate IUCLID files in .i6z format, could be automatically linked to the commented dossier during the import of annotations into the applicant IUCLID server (knoell) (See Figure 40):

Figure 40: Example import of multiple annotations to the dossier



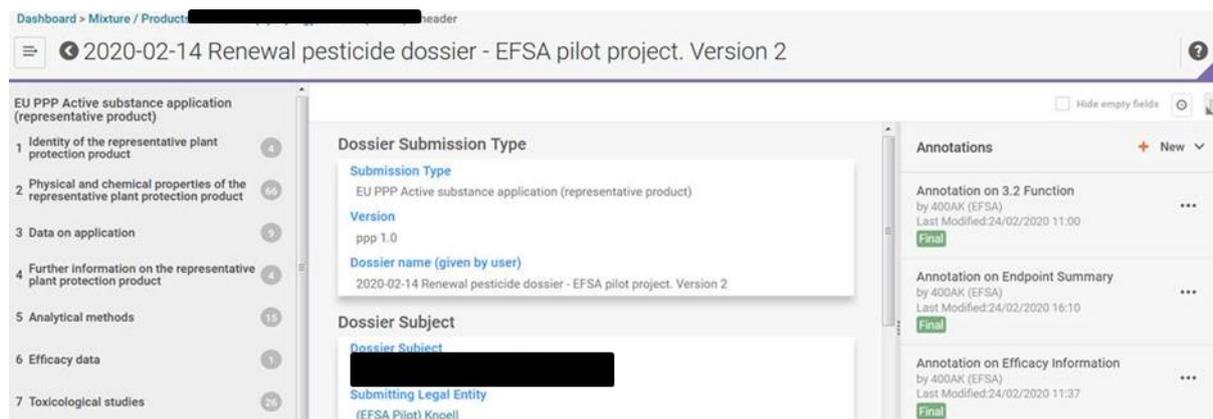
The annotations were linked automatically to two commented dossiers as shown below (Figure 41 and Figure 42):

Figure 41: Image to demonstrate the automatic linking of annotations to two dossiers



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Figure 42: Image to demonstrate the automatic linking of annotations to two dossiers



Furthermore, IUCLID allows linking the annotation included in the various versions of the dossier, to the chosen dossier by selecting the “Link” option within the Annotations feature as shown below (Figure 43):

Figure 43: Example of linking the annotation from different versions of the dossier

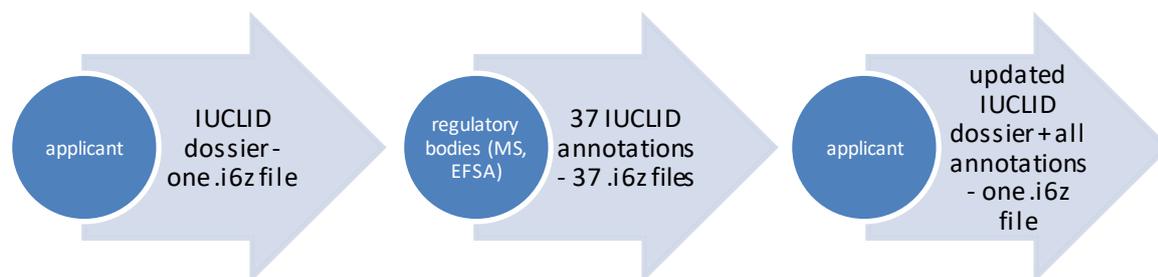
The screenshot shows the "Annotations" tab in the IUCLID interface. It includes a "Link..." button and a table of annotations. The table has columns for Name, Modified, Status, Authority/Organisation, File name, Remarks, Data waiver accept..., Agreement with applicants, and Reliability.

Name	Modified	Status	Authority/Organisation	File name	Remarks	Data waiver accept...	Agreement with applicants	Reliability
Annotation on Det...	Di, 28 Jan 2020 13:52:...						No	
Annotation on 2.8...	Mo, 15 Jan 2020 13:51:...	final	ANSES			not applicable	No	4 not assignable
Annotation on Fo...	Fr, 7 Feb 2020 16:55:5...	final	BFR		<p>Please check if the origi...		No	

This option was used to link the relevant annotations to the latest version of the applicant dossier (final version provided on 25.02.2020). This latter dossier was subsequently updated according to the comments provided by the regulatory bodies.

The applicant, in addition to the updated dossier, provided the responses to the comments by also utilising the annotations feature. In this instance, annotations were created within the non-write-protected (i.e. editable) substance or mixture dataset, respectively. The updated dossier prepared by the applicant contains the linked annotations provided by both the applicant and the regulatory authorities. See Figure 44 for an example of a workflow of this process.

Figure 44: Example workflow for inclusion of comments into one IUCLID dossier



The annotation feature is designed in such a way to enable the regulatory body to provide a direct evaluation of the respective study record, study summary etc. Currently there is no option that could be clearly used by the applicant within the annotation feature to respond to comments made by the authority. Furthermore, enabling the applicant to provide answers to comments could be an option for future consideration and development within the system. However, there is clear limitation of the current version of IUCLID in the context of missing fields for the applicant to respond. A suggestion could be to modify the IUCLID annotations by providing the necessary fields (such as a) short answer: comment implemented, additional explanation provided, b) description and further explanation) specifically designed for the applicant to answer the authority request, which in turn could be commented on by the regulatory body within the same annotation (and where the final conclusion would be included as well).

Since this option is currently not available in IUCLID, within this project the applicant chose an **alternative option** to replying to the comments. This alternate method is performed by creating new annotations and referring in the title of the annotation to the original authority comment. Within the current version of IUCLID, this approach allows applying the annotations in the commenting phase and is highly recommended for the following reasons:

- The annotations feature can be utilised during the internal review of the dataset / dossier file by the applicant and during the review carried out by the regulatory body. This is a smooth way of checking the comments and responding to them and is commented for consideration in both Plant Protection Products and Biocidal Products regulation. Both the evaluator and applicant have the ability to check the database / dossier for comments and respective answers and clarifications and to see the overall improvements performed by reviewing the comparison report.
- Each point highlighted can be commented on by different parties concurrently.
- There is not a requirement to generate an additional report and work on a separate document.
- The dossier can be created with or without annotations.

During the lifecycle testing of the dossier some short-comings of web interface of IUCLID were noted. Within the project two IUCLID interfaces were tested in parallel: the classic and web interface. In the future (estimated timeframe currently October 2020) the web interface will be the only platform available. At the time of testing, the web interface did not have the same level of useful functionalities in comparison with those available in the classic interface. The web interface options were limited with regards to viewing, editing and entering new annotations.

knoell propose the following recommendations for improvement of the web interface of the IUCLID interface:

- Entering annotations to the raw dataset.
- During creation of the dossier an option: 'create without annotations' or 'create with annotations' would be beneficial. Additionally an option for internal (applicant)/external (authority) annotations would be advantageous.
- Compared to the classic interface there is no button available to directly access the annotation inventory
- An intuitive link to locate annotations in the web interface would be helpful.

IUCLID could be improved in the future to allow printing and viewing the annotations referenced to each scientific section (including annotations + responses). At the moment all annotations linked to a dossier or dataset can be viewed however they are not grouped per section or endpoint, making handling of the annotations difficult.

Further recommendations for the future use of annotations are described below:

- An option to import the annotations from a dossier containing comments made by the authorities into a separate report (e.g. .docx or .xlsx formats) and dataset (i6z) should be considered. This would enable the applicant to work on the annotations imported into a dataset (working doc), update the respective points in IUCLID and provide a response. The updated dossier created from the updated dataset, containing the original annotations from regulatory authorities and the responses from the applicant could then be submitted back to the authority; the dialog between the different parties involved would then be easily accomplished and made transparent through the annotations and comments.
- Since different versions of dossiers can be compared, the annotations originally received and the comments provided could be viewed at any time.
- Any subsequent changes made in IUCLID following the annotations can be made visible using the comparison report. A limitation however is that only revised fields are reported and not the change of the text in RTF fields. The highlight or emphasis of changed text parts in the RTF fields would be helpful (currently the applicant dossier and/or DAR/RAR are updated by using a colour highlight in the original dossier. Different updates are highlighted in different colours and it can be easily seen, which parts were changed in the word documents.

5 Overall conclusions

The manual testing of IUCLID proved that the preparation of the applications for pesticides with IUCLID software is feasible and after some improvements also suitable for an efficient collation of data in dossier format. All studies and summaries as well as related documents were included in IUCLID. IUCLID has clear advantages providing all data are entered correctly in the relevant defined fields, or pick-lists of the standardized formats given. Once the data is entered in this standardized harmonized manner the report generator can extract information into word or xml format quite easily. In addition the information can be used for other plug in tools:

- Further report generators, e.g. DAR, reference lists, summary documents e.g. Doc Ns
- Print file
- Completeness check/validation assistant
- Dissemination preview (sanitized version)

Based on the manual testing of IUCLID for pesticide dossiers, knoell would like to recommend performing the following recommended changes:

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- Allow to enter 1:1 the crop dossier from SANCO templates to IUCLID summaries and endpoint summaries should be named in the same consistent way. If some sub-endpoints are still missing – we recommend adding them to the IUCLID structure
- Remove cross-references so that the content is located appropriately and logically within IUCLID

The potential of IUCLID for the preparation of pesticide dossiers is enormous. REACH applications is a good example of the development and implementation of IUCLID to facilitate dossier work and meet applicants and authorities needs. For all REACH applications and registration types the IUCLID plug-ins function well. The chemical safety report (CSR) (similar to the DAR) is created automatically from IUCLID and final formatting of CSR takes only approx. 4h. This report generator is however not yet available for biocide dossiers but can be developed and programmed accordingly.

knoell also finally recommend to perform a second test phase, after implementation of all suggested improvements from phase one of testing. If IUCLID cannot include all suggested improvements, knoell recommend supporting applicants with more a detailed IUCLID guide on how to present the data in IUCLID. Whenever workaround solutions are required (see list of issues), it must be expected that applicants may come to different solutions and harmonization will be more challenging in the future.

Before IUCLID is implemented for pesticide dossiers it is advisable to plan adequately/realistically timeframe for applicants and authorities to get confident to work with IUCLID and to provide training to them. It is advisable that EFSA designate time to the definition of issues associated with data ownership/confidentiality in order to provide to ECHA with a clear illustration and indication of how IUCLID must be improved to mediate forthcoming apparent concerns of applicants.

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Table 8: Identity of the active substance

EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.1	IIA 1.1	Applicant (name, address, contact, telephone, fax, email contact)	y	y	There is no separated point 1.1 in IUCLID template, which could allow to enter the corresponding information. Point 1.1 is not editable. The information on applicant has to be completed in point 1.3	Doc A explaining CONTEXT IN WHICH THE DOSSIER IS SUBMITTED/Task force cannot be attached in section 1	Doc A was attached in section 11 (summary and evaluation)	Improve the software by giving the possibility to edit the corresponding point in the template
CA 1.2	IIA 1.2	Producer / Manufacturing plant (name, address, contact, telephone, fax, email contact)	y	y	Correctly placed. Information on location of manufacturing plants can be easily added and flag as confidential.	No problem was faced		
CA 1.3	IIA 1.3	Common name proposed or ISO-accepted and synonyms	y	y	The corresponding information is summarized in reference substance, which is assigned to this point.	No problem was faced		
CA 1.4	IIA 1.4	Chemical name (IUPAC and CA nomenclature)	y	y	The corresponding information is summarized in reference substance, which is assigned to this point.	No problem was faced		

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.5	IIA 1.5	Producer's development code numbers	y	y	Correctly placed. Information on producer's development code numbers can be easily added.	No problem was faced		
CA 1.6	IIA 1.6	CAS, EC and CIPAC numbers	y	y	There is no separated point 1.6 in IUCLID template, which could allow to enter the corresponding information. Point 1.6 is not editable. The corresponding information has to be completed in point 1.3	No problem was faced		
CA 1.7	IIA 1.7	Molecular and structural formula, molar mass	y	y	There is no separated point 1.6 in IUCLID template, which could allow entering the corresponding information. Point 1.6 is not editable. The corresponding information has to be completed in point 1.3	No problem was faced		

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.8	IIA 1.8	Method of manufacture (synthesis pathway) of the active substance	y	y	There is no separated point 1.8 in IUCLID template, which could allow entering the corresponding information. Point 1.8 is not editable. The corresponding information has to be completed in point 1.9.	Since the manufacturing process had to be summarized in a "Description" box of the document added to point 1.9 (dummy description), there was no direct possibility to flag the corresponding information as a confidential. The documents uploaded (dummy document) could not be flagged as confidential as well.		Improve the software by giving the possibility to edit the corresponding point in the template
CA 1.9	IIA 1.9	Specification of purity of the active substance in g/kg	y	y	Correctly placed. Information on specification of purity on the active substance can be easily summarized.	No problem was faced		
CA 1.10		Identity and content of additives (such as stabilisers) and impurities						

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.10.1	IIA 1.10.2	Additives Chemical name(s), formula, molar mass, min. max. content in g/kg, function	y	y	There is no separated point 1.10 in IUCLID template, which could allow to enter the corresponding information. Point 1.10 is not editable. The sub point 1.10.1 does not exist. The corresponding information has to be completed in point 1.9.	No problem was faced since in point 1.9 the information on additives can be easily summarized.		Improve the software by giving the possibility to edit the corresponding point in the template and to add the required sub point

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.10.2	IIA 1.10.2	Significant impurities (Chemical name(s), formula, molar mass, min. max. content in g/kg, function)	y	y	There is no separated point 1.10 in IUCLID template, which could allow to enter the corresponding information. Point 1.10 is not editable. The sub point 1.10.2 does not exist. The corresponding information has to be completed in point 1.9.	No problem was faced since in point 1.9 the information on significant impurities can be easily summarized (dummy information was provided). Each single impurity can be flagged as confidential. There is however no specified place to provide the information on the toxicological assessment on the respective impurity. Only in the "remarks" field exist the possibility to provide further details and give the reference, where further documentation is attached.		Improve the software by giving the possibility to edit the corresponding point in the template and to add the required sub point

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.10.3	IIA 1.10.2	Relevant impurities (Chemical name(s), formula, molar mass, min. max. content in g/kg, function	y	y	There is no separated point 1.10 in IUCLID template, which could allow to enter the corresponding information. Point 1.10 is not editable. The sub point 1.10.3 does not exist. The corresponding information has to be completed in point 1.9.	No problem was faced since in point 1.9 the information on impurities can be easily summarized. Each single impurity can be flagged as confidential. There is however no specified place to provide the information on the toxicological assessment on the respective impurity. Only in the "remarks" field exist the possibility to provide further details and give the reference, where further documentation is attached,		Improve the software by giving the possibility to edit the corresponding point in the template and to add the required sub point

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EU Data Requirement Number CA Section 1	OECD Data point	Detail on data point / study Identity of the active substance	Information in tested dossier (y, n)	(OHT) template available in IUCLID? (y, n)	If the (OHT) exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA 1.11	IIA 1.11	Analytical profile of batches	y	y	There is no separated point 1.11 in IUCLID template, which could allow to enter the corresponding information. Point 1.11 is not editable. The corresponding information has to be completed in point 1.9 and 4.	No problem was faced since in point 1.9 the information on the outcome of the 5 batch analysis was described and in point 4 the details on the analytical methods for determination of the active substance and all impurities can be described (dummy reports were assigned)		Improve the software by giving the possibility to edit the corresponding point in the template

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Table 9: Physical and chemical properties of the active substance - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD Data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 2		Physical and chemical properties of the active substance						
CA 2.1	IIA 2.1	Melting point and boiling point (purified a.s.)						
	IIA 2.1.1	Melting point for solid Freezing/ solidification point for liquid	y	y	Correctly placed	None		None
	IIA 2.1.2	Boiling point (measurement up to 360° C)	y	y				
	IIA 2.1.3	Decomposition or sublimation temperature	y	n		no sub-point of Decomposition or sublimation temperature available under section 2.1	entered under 2.1.2, but not possible to summary since the template is based on boiling point	create a sub-point of Decomposition or sublimation temperature as 2.1.3 and customize the summary template; OHT also does not exist
CA 2.2	IIA 2.3	Vapour pressure, volatility (purified a.s.)						
	IIA 2.3.1	Vapour pressure, at 20-25° C	y	y	Correctly placed	None		None
	IIA 2.3.2	Henry's law constant	y	n		no sub-point available under section 2.2	entered under 2.2	create a sub-point of Volatility (Henry's Law constant) as 2.3.2; OHT also does not exist

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EU Data Requirement Number	OECD Data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 2		Physical and chemical properties of the active substance						
CA 2.3	IIA 2.4	Appearance						
		Physical state and colour (purified a.s.)	y	y	Correctly placed	None		None
		Physical state and colour (technical a.s.)	y	y	Correctly placed	None		None
CA 2.4	IIA 2.5	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity (purified a.s.)	y	y	Correctly placed	None		None
	IIA 2.5.1.1	UV/VIS	y	y	Correctly placed	None		None
	IIA 2.5.1.2-5	IR, NMR, MS	y	y	Correctly placed	None		None
	IIA 2.5.1.6	optical purity	not relevant for this a.s.	n				
	IIA 2.5.2	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity (for relevant impurities if relevant)	not relevant for this a.s.	n		no sub-point available under section 2.4 for relevant impurity		It would be better to have a sub point to enter spectra of relevant impurity
	IIA 2.5.2.1	UV/VIS	not relevant for this a.s.	n		see above	see above	see above
	IIA 2.5.2.2-4	IR, NMR, MS	not relevant	n		see above	see above	see above

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EU Data Requirement Number	OECD Data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 2		Physical and chemical properties of the active substance						
			for this a.s.					
CA 2.5	IIA 2.6	Solubility in water	y	y	Correctly placed	None		None
CA 2.6	IIA 2.7	Solubility in organic solvents	y	y	Correctly placed	None		None
CA 2.7	IIA 2.8	Partition coefficient n-octanol/water	y	y	Correctly placed	None		None
CA 2.8	IIA 2.9.5	Dissociation in water	y	y	Correctly placed	None		None
CA 2.9	IIA 2.11.2	Flammability and self-heating	y	y	Correctly placed	None		None
		Flammability	y	y	Correctly placed	None		None
		Self-heating	y	y	Correctly placed	None		None
CA 2.10	IIA 2.12	Flash point	y	y	Correctly placed	None		None
CA 2.11	KII 2.13	Explosive properties	y	y	Correctly placed	None		None
CA 2.12	IIA 2.14	Surface tension	y	y	Correctly placed	None		None
CA 2.13	IIA 2.15	Oxidising properties	y	y	Correctly placed	None		None
CA 2.14	IIA 2.18	Other studies	y	y		No further studies was provided		

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Table 10: Further information on the active substance (function, mode of action, handling) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 3	IIA 3	Further information on the active substance						
CA 3.1	new	Use of active substance	y	n	Correctly placed	Template available is biocide related and cannot be transferred to PPP	Text was added in "Field of use description".	One Rich Text Field is sufficient. Normally the information is given as a text.
CA 3.2	IIA 3.1	Function	y	n	Correctly placed	The use of a study record is not needed	Instead an endpoint summary was used	Create dropdown menu based on the possible functions (e.g. acaricide, bactericide, fungicide) as given in Annex Part A No. 3.2 of Reg. (EC) 283/2013 and allow the possibility to enter further info in a RTF field.
CA 3.3	IIA 3.2	Effects on harmful organisms	y	n	Cross-reference to CA 3.2	Cross-reference	Endpoint summary created in CA 3.2	Create dropdown menu based on the possible effects (e.g. Contact action) as given in Annex Part A No. 3.3. of Reg. (EC) 283/2013 and allow the possibility to enter further info in a RTF field.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 3	IIA 3	Further information on the active substance						
CA 3.4	IIA 3.3	Field of use envisaged	y	n	Cross-reference to CA 3.1	Cross-reference	Endpoint summary created in CA 3.2	Create dropdown menu based on the possible fields of use (e.g. Field use) as given in Annex Part A No. 3.4. of Reg. (EC) 283/2013 and allow the possibility to enter further info in a RTF field.
CA 3.5	IIA 3.4	Harmful organism controlled and crops or products protected or created	y	n	Cross-reference to CA 3.2	Cross-reference	Endpoint summary created in CA 3.2	Allow the possibility to enter further info in a RTF field.
CA 3.6		Statement of the mode of action of the active substance in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 3	IIA 3	Further information on the active substance						
	IIA 3.5	Mode of action	y	n	Cross-reference to CA 3.2	Cross-reference	Endpoint summary created in CA 3.2	Allow the possibility to enter further info in a RTF field. According to the Reg. (EC) 283/2013 also further information for active metabolite or breakdown products (where applicable) need to be provided.
CA 3.7	IIA 3.6	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	y	n	Cross-reference to CA 3.2	Cross-reference	Endpoint summary created in CA 3.2	Allow the possibility to enter info in a RTF field.
CA 3.8	IIA 3.7	Methods and precautions concerning handling, storage, transport or fire	y	y	Correctly placed	Template not in line with PPP requirements instead with Biocides requirements	Information was added, where appropriate though spread widely in the given template.	Align with PPP requirements (Reg. 283/2013) i.e. create RTF fields for handling, storage, transport and fire. Also the possibility to upload a Safety Data Sheet should be included.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 3	IIA 3	Further information on the active substance						
CA 3.9	IIA 3.8	Procedures for destruction or decontamination	y	y	Cross-reference to CA 3.8	Template not in line with PPP requirements instead with Biocides requirements	Information was added, where appropriate though spread widely in the given template.	Align with PPP requirements (Reg. 283/2013). One RTF field should be sufficient to allow entering the appropriate information. The cross-reference to CA 3.8 would still be an option.
CA 3.10	IIA 3.9	Emergency measures in case of an accident	y	y	Cross-reference to CA 3.8	Template not in line with PPP requirements instead with Biocides requirements	Information was added, where appropriate though spread widely in the given template.	Align with PPP requirements (Reg. 283/2013). One RTF field should be sufficient to allow entering the appropriate information. The cross-reference to CA 3.8 would still be an option.

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Table 11: Analytical methods of the active substance - evaluation of available OHT templates and issues encountered

EU Data Requirement Number		Detail on data point / study		OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)					
CA 4.1		Methods used for the generation of pre-approval data						
CA 4.1.1	IIA 4.2	Methods for the analysis of the active substance as manufactured	y	y	correctly placed	No issue faced		
	IIA 4.2.1	Analytical methods for the analysis of the active substance as manufactured.	y	y	Correctly placed	No sub data point to insert the endpoint study record.	The respective study record was created under point 4.	Sub data point as 4.1.1 as <i>Methods for the analysis of the active substance as manufactured</i> should be created
	IIA 4.2.3-4	Analytical methods for the analysis of the additives , significant and relevant impurities in the a.s. as manufactured.	y	y	Correctly placed	No sub data point to insert the endpoint study record of analytical method for impurities, additives.	The respective study record was created under point 4.	Sub data point as 4.1.1 as <i>Methods for the analysis of the active substance as manufactured should be created</i> should be created
	IIA 4.2.2	Applicability of existing CIPAC methods	n	n		No issue faced		The field needs to be available to enter possible info according to my understanding.

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EU Data Requirement Number		Detail on data point / study			If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section			
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)		Issue faced	Workaround	Recommendations/ solutions for the future
CA 4.1.2		Methods for risk assessment	y	n		No sub data point to insert the endpoint study record of analytical method for risk assessment		Sub data point as 4.1.2 with data point listed in Regulation 283/2013 (a -g) should be created, if possible
		in support of environmental fate studies	y	n		see above		see above
		in support of efficacy studies	y	n		see above		see above
		in support of toxicological studies	y	n		see above		see above
		in support of operator, worker, resident and bystander exposure studies	y	n		see above		see above
		in support of residue studies	y	n		see above		see above
		in support of ecotoxicology studies	y	n		see above		see above
		used in physical and chemical properties tests	y	n		see above		see above
CA 4.2		Methods for post-approval control and monitoring purposes						

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EU Data Requirement Number		Detail on data point / study			If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section			
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)		Issue faced	Workaround	Recommendations/ solutions for the future
CA 4.2.a	IIA 4.3	Plant matrices:	y	n		No sub data point to insert the endpoint study record of analytical method for plant matrices	The respective study record was created under point 4.	Sub data point as 4.2 .1 such as <i>Methods for plants commodities</i> should be created
		Validation: dry commodities (high protein/high starch content)	y	n		see above	see above	see above
		Validation: high water content	y	n		see above	see above	see above
		Validation: high acid content	y	n		see above	see above	see above
		Validation: high oil content	y	n		see above	see above	see above
		Validation: commodities difficult to analyse (coffee beans, herbal infusions, hops, spices, tea, tobacco)	not relevant					
		Independent laboratory validation (for each method above)	y	n		see above	see above	see above
		ILV: dry commodities (high protein /high starch content)	y	n		see above	see above	see above

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EU Data Requirement Number		Detail on data point / study			If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)				
		ILV: high water content	y	n		see above	see above	see above
		ILV: high acid content	y	n		see above	see above	see above
		ILV: high oil content	y	n		see above	see above	see above
		ILV: commodities difficult to analyse (coffee beans, herbal infusions, hops, spices, tea, tobacco)	not relevant					
		Extraction efficiency - plant	y	n		No data point regarding Extraction efficiency		As this data requirement is specific to crop protection product, a sub data point needs to be created under CA 4.2.a to address this data point
CA 4.2.a		Residue analytical methods for foodstuff of animal origin	y	n		No sub data point to insert the endpoint study record of analytical method for plant matrices	The respective study record was created under point 4.	Sub data point as 4.2 .2 such as <i>Methods for animal origin</i> should be created
		Validation: milk	y	n		see above	see above	see above
		Validation: eggs	y	n		see above	see above	see above
		Validation: meat (bovine/poultry)	y	n		see above	see above	see above
		Validation: fat	y	n		see above	see above	see above

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EU Data Requirement Number		Detail on data point / study			If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section			
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)		Issue faced	Workaround	Recommendations/ solutions for the future
		Validation: liver/kidney	y	n		see above	see above	see above
		Independent laboratory validation (for each method above)	y	n		see above	see above	see above
		ILV: milk	y	n		see above	see above	see above
		ILV: eggs	y	n		see above	see above	see above
		ILV: meat	y	n		see above	see above	see above
		ILV: fat	y	n		see above	see above	see above
		ILV: liver/kidney	y	n		see above	see above	see above
		Extraction efficiency - animal matrices	y	n		No data point regarding Extraction efficiency		As this data requirement is specific to crop protection product, a sub data point needs to be created under CA 4.2.a to address this data point
CA 4.2.b	IIA 4.4	Methods for determination of all components included for monitoring purposes in the residue definitions for soil & water acc. to provisions of point 7.4.2						

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EU Data Requirement Number		Detail on data point / study			If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section			
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)		Issue faced	Workaround	Recommendations/ solutions for the future
		Methods for analysis of soil	y	n		No sub data point to insert the endpoint study record of analytical method for soil	endpoint created under data point 4	Sub data point as 4.2 .3 Methods for the determination of all components included for monitoring purposes in the residue definitions for soil should be created
	IIA 4.5	Methods for analysis of drinking / ground water ILV method	y	n		No sub data point to insert the endpoint study record of analytical method for water	endpoint created under data point 4	Sub data point as 4.2 .4 Methods for the determination of all components included for monitoring purposes in the residue definitions for water should be created
		Methods for analysis of surface water	y	n		see above	see above	see above
CA 4.2.c	IIA 4.7	Analytical methods for residues in air - for the a.s and relevant breakdown products	y	n		No sub data point to insert the endpoint study record of analytical method for air	endpoint created under data point 4	Sub data point as 4.2 .5 Methods for the analysis in air should be created

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EU Data Requirement Number		Detail on data point / study		OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 4	IIA 4	Standards and samples	Information in tested dossier (y, n)					
CA 4.2.d	IIA 4.8	Methods for the analysis in body fluids and tissues for a.s and relevant metabolites.	y	n		No sub data point to insert the endpoint study record of analytical method for body fluids and tissues	endpoint created under data point 4	Sub data point as 4.2.6 Methods for the analysis in body fluids and tissues should be created

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Table 12: Toxicological and metabolism studies on the active substance - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
CA 5.1	IIA 5.1	Studies on absorption, distribution, metabolism and excretion in mammals						
CA 5.1.1	IIA 5.1.1-3	Absorption, distribution, metabolism and excretion by oral route						
		In vivo	y	n	Cross-referenced	Only one section in IUCLID available -> 5.1. The sections 5.1.1 and 5.1.2 should be cross-referenced to 5.1		Reported separately
		In-vitro Comparative in vitro metabolism						
		In-vitro Metabolite detected in vitro in human material	n	n		no data with human material available in the old dossier		
CA 5.1.2	new	Absorption, distribution, metabolism and excretion by other routes	y	n	Cross-referenced	Only one section in IUCLID available -> 5.1. The sections 5.1.1 and 5.1.2 should be cross-referenced to 5.1		Reported separately
CA 5.2	IIA 5.2	Acute toxicity						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
CA 5.2.1	IIA 5.2.1	Oral	y	y	Correctly placed			
CA 5.2.2	IIA 5.2.2	Dermal	y	y	Correctly placed			
CA 5.2.3	IIA 5.2.3	Inhalation	y	y	Correctly placed			
CA 5.2.4	IIA 5.2.4	Skin irritation	y	y	Correctly placed			
CA 5.2.5	IIA 5.2.5	Eye irritation	y	y	Correctly placed			
CA 5.2.6	IIA 5.2.6	Skin sensitisation	y	y	Correctly placed	no specific template for different study designs (e.g. Bühler), different designs are implemented in one IUCLID mask		Reported separately
CA 5.2.7	new	Phototoxicity	n	y	Correctly placed			
CA 5.3	IIA 5.3	Short-term toxicity						
CA 5.3.1	IIA 5.3.1	Oral 28-day study	y	y	Correctly placed	Only one section in IUCLID available -> 5.3.1. The sections 5.3.2 should be cross-referenced to 5.3.1		Reported separately
CA 5.3.2	IIA 5.3.2-3	Oral 90-day study (rat)	y	n	Cross-reference	Only one section in IUCLID available -> 5.3.1. The sections 5.3.2 should be cross-referenced to 5.3.1		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		Oral 90-day study (dog)	y	n	Cross-reference	Only one section in IUCLID available -> 5.3.1. The sections 5.3.2 should be cross-referenced to 5.3.1		Reported separately
CA 5.3.3	IIA 5.3.5-8	Other routes						
		Inhalation route	n	y	Correctly placed			
		Repeated dose (28 days) inhalation toxicity	n	y	Correctly placed	no specific template for this time point;		Reported separately
		Repeated dose (90 days) inhalation toxicity	n	y	Correctly placed	no specific template for this time point		Reported separately
		Dermal route	y	n	Correctly placed			
		Repeated dose (28 days) dermal toxicity	y	y	Correctly placed	no specific template for this time point		Reported separately
		Repeated dose (90 days) dermal toxicity	n	y	Correctly placed	no specific template for this time point		Reported separately
CA 5.4	IIA 5.4	Genotoxicity testing						
CA 5.4.1	IIA 5.4.1-3	In vitro studies						
		Bacterial assay for gene mutation	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		Chromosome aberration test in mammalian cells	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
		Gene mutation in mammalian cells	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
			n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
			n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
CA 5.4.2	IIA 5.4.4-5	In vivo studies in somatic cells						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		Mammalian erythrocyte micronucleus test	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
		Mammalian bone marrow chromosome aberration test	n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
		Unscheduled DNA synthesis test with mammalian liver cells in vivo	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
		Transgenic rodent somatic and germ cell gene mutation assays	n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		In vivo Comet assay	n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
CA 5.4.3	IIA 5.4.6	In vivo studies in germ cells						
		Mammalian chromosome aberration test	n	n	Cross-reference	Only one section in IUCLID available -> 5.4.2. The sections 5.4.3 should be cross-referenced to 5.4.2		Reported separately
		Transgenic rodent somatic and germ cell gene mutation assays	n	n	Cross-reference	Only one section in IUCLID available -> 5.4.2. The sections 5.4.3 should be cross-referenced to 5.4.2		Reported separately
CA 5.5	IIA 5.5	Long-term toxicity and carcinogenicity						
		Carcinogenicity study in the rat	y	y	Correctly placed	section 5.5.2 is available; The sections 5.5.1 should be cross-referenced to 5.3		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		Long-term (2 years) oral toxicity in the rat	n	y	Correctly placed	section 5.5.2 is available; The sections 5.5.1 should be cross-referenced to 5.3		Reported separately
		Long-term (2 years) oral toxicity and carcinogenicity in the rat	n	n	Correctly placed	section 5.5.2 is available; The sections 5.5.1 should be cross-referenced to 5.3		Reported separately
		Carcinogenicity study in the mouse	y	y	Correctly placed	section 5.5.2 is available; The sections 5.5.1 should be cross-referenced to 5.3		Reported separately
		Information on historical control data	n	n				
CA 5.6	IIA 5.6	Reproductive toxicity						
CA 5.6.1	IIA 5.6.1-9	Generational studies						
		Two generation reproductive toxicity in the rat	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
		Extended one generation reproduction toxicity	n	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
CA 5.6.2	IIA 5.6.10-11	Developmental toxicity studies						
		Prenatal developmental toxicity study	y	y	Correctly placed	no specific template for different study designs		Reported separately
		Developmental neurotoxicity studies in rodents	n	n		neurotoxicity studies can be entered in 5.7		Reported separately
CA 5.7	IIA 5.7	Neurotoxicity studies						
CA 5.7.1	IIA 5.7.1 IIA 5.7.4	Neurotoxicity studies in rodents	n	y	Cross-reference	Only one entry point for the 5.7.1 and 5.7.2 section, the sections should be cross-referenced to 5.7		Reported separately
CA 5.7.2	IIA 5.7.2 IIA 5.7.3 IIA 5.7.5	Delayed polyneuropathy studies	n	y	Cross-reference	Only one entry point for the 5.7.1 and 5.7.2 section, the sections should be cross-referenced to 5.7		Reported separately
CA 5.8	IIA 5.8	Other toxicological studies						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
CA 5.8.1	IIA 5.8	Toxicity studies of metabolites	n	y	Cross-reference	mechanistic studies were entered here, the studies should be cross-reference to 5.8		Reported separately
CA 5.8.2	IIA 5.8	Supplementary studies on the active substance	n	y	Correctly placed	this section is only for imumotox and livestock, so the mechanistic studies were provided in the 5.8 section		Reported separately
CA 5.8.3	new	Endocrine disrupting properties	n	y	Correctly placed			
CA 5.9	IIA 5.9	Medical data						
CA 5.9.1	IIA 5.9.1	Medical surveillance on manufacturing plant personnel and monitoring studies	n	y	Correctly placed			
CA 5.9.2	IIA 5.9.2	Data collected on humans	n	y	Correctly placed			
CA 5.9.3	IIA 5.9.3	Direct observations	n	y	Correctly placed			
CA 5.9.4	IIA 5.9.4	Epidemiological studies	n	y	Correctly placed			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations /solutions for the future
CA Section 5	IIA 5	Toxicological and metabolism studies on the active substance						
CA 5.9.5	IIA 5.9.5	Diagnosis of poisoning (determ. AS, metabolites), spec. signs of poisoning, clinical tests	n	n	Cross-reference	the data should be cross-referenced to section 5.9.3		Reported separately
CA 5.9.6	IIA 5.9.6	Proposed treatment: first aid measures, antidotes, medical treatment	n	n	Cross-reference	the data should be cross-referenced to section 3.8		Reported separately
CA 5.9.7	IIA 5.9.7	Expected effects of poisoning	n	n	Cross-reference	the data should be cross-referenced to section 3.8		Reported separately

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Table 13: Residues in or on treated products, food and feed and plant metabolism - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 6	IIA 6	Residues in or on treated products, food and feed and plant metabolism						
CA 6.1	IIA 6.1	Storage stability of residues	y	y	Correctly placed	No issue faced		
CA 6.1		Stability of residues during storage of samples						
CA 6.1		Stability of residues in sample extracts						
CA 6.2	IIA 6.2	Metabolism, distribution and expression of residues						
CA 6.2.1	IIA 6.2.1	Plants	y	y	Cross-reference	For plants a cross reference to 6.6.1 was made in the IUCLID. Here no endpoint summary can be made.	Studies were included in 6.6.1, But for the missing endpoint summary no workaround is possible	For 6.2.1 the plant metabolism studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.2.2	IIA 6.2.2	Poultry (laying hen)	y	y	Cross-reference	For poultry a cross reference to 6.2 was made in the IUCLID. .	Studies and endpoint summary were included in 6.2.	For 6.2.2 the poultry metabolism studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.2.3	IIA 6.2.3	Lactating ruminants (goat or cow)	y	y	Cross-reference	For ruminants a cross reference to 6.2 was made in the IUCLID. .	Studies and endpoint summary were included in 6.2.	For 6.2.3 the ruminant metabolism studies should be included in this data point and the possibility to include an endpoint summary should be created.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 6	IIA 6	Residues in or on treated products, food and feed and plant metabolism						
CA 6.2.4	IIA 6.2.4	Pigs	y	y	Cross-reference	For pigs a cross reference to 6.2 was made in the IUCLID. .	Studies and endpoint summary were included in 6.2.	For 6.2.4 the pig metabolism studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.2.5	IIA 6.2.5	Fish	y	y	Cross-reference	For fish a cross reference to 6.2 was made in the IUCLID.	Studies and endpoint summary were included in 6.2.	For 6.2.4 the fish metabolism studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.3	IIA 6.3	Magnitude of residue trials in plants	y	y	Correctly placed	No issues		
CA 6.3.1	IIA 6.3.1	Crop 1 (e.g. Wheat - to be adapted acc.to GAP)						
CA 6.4	IIA 6.4	Feeding studies	n	y	Correctly placed			
CA 6.4.1	IIA 6.4.1	Poultry (laying hen)	n	y	Cross-reference	For poultry a cross reference to 6.4 was made in the IUCLID.	Endpoint summary were included in 6.4.	For 6.4.1 the poultry feeding studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.4.2	IIA 6.4.2	Ruminants (goat or cow)	n	y	Cross-reference	For ruminants a cross reference to 6.4 was made in the IUCLID.	Endpoint summary were included in 6.4.	For 6.4.2 the ruminant feeding studies should be included in this data point and the possibility to include an endpoint summary should be created.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 6	IIA 6	Residues in or on treated products, food and feed and plant metabolism						
CA 6.4.3	IIA 6.4.3	Pigs	n	y	Cross-reference	For pigs a cross reference to 6.4 was made in the IUCLID.	Endpoint summary were included in 6.4.	For 6.4.3 the pig feeding studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.4.4	IIA 6.4.4	Fish	n	y	Cross-reference	For fish a cross reference to 6.4 was made in the IUCLID.	Endpoint summary were included in 6.4.	For 6.4.4 the fish feeding studies should be included in this data point and the possibility to include an endpoint summary should be created.
CA 6.5	IIA 6.5	Effects of processing						
CA 6.5.1	IIA 6.5.1	Nature of the residue	n	y	Correctly placed	No issues		
CA 6.5.2	IIA 6.5.2	Distribution of the residue in inedible peel and pulp	n	n	Cross-reference	No issue, the cross reference is correct		
CA 6.5.3	IIA 6.5.3-4	Magnitude of residues in processed commodities	n	y	Correctly placed			
CA 6.6	IIA 6.6	Residues in rotational crops						
CA 6.6.1	IIA 6.6.1	Metabolism in rotational crops	y	y	Correctly placed	No issue		
CA 6.6.2	IIA 6.6.3	Magnitude of residues in rotational crops	n	y	Cross-reference	For residues in rotational crops a cross reference to 6.3 was made in the IUCLID.	Not needed as not data had to be included.	For 6.6.2 the field rotational crop studies should be included in this data point and the possibility to include an endpoint summary should be created.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 6	IIA 6	Residues in or on treated products, food and feed and plant metabolism						
CA 6.7	IIA 6.7	Proposed residue definitions and maximum residue levels						
CA 6.7.1	IIA 6.7.1	Proposed residue definitions	y	n	Cross-reference	For the proposed residue definition a cross reference to chapter 11 was made in IUCLID.	The proposed residue definition was included in Chapter 11	For 6.7.1 the proposed residue definition should be included in this data point.
CA 6.7.2	IIA 6.7.2	Proposed MRLs and justification of the acceptability of the levels proposed	y	n	Cross-reference	No issue		
CA 6.7.3	IIA 6.7.2	Proposed MRLs and justification of the acceptability for imported products, imp. tolerance	n	n				
CA 6.8	IIA 6.8	Proposed safety intervals	n	n	Cross-reference			
CA 6.9	IIA 6.9	Estimation of the potential and actual exposure through diet and other sources	y	y				
CA 6.10	IIA 6.10	Other studies						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 6	IIA 6	Residues in or on treated products, food and feed and plant metabolism						
CA 6.10.1		Residue level in pollen and bee products	n	y	CR	For the residue level in pollen and bee products a cross reference to 6.5.3 was made in the IUCLID.	No workaround was needed as no study had to be included.	For 6.10.1 the residue study in pollen and bee products should be included in this data point and the possibility to include an endpoint summary should be created.

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Table 14: Fate and behaviour in the environment of the active substance - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CA Section 7	IIA 7	Fate and behaviour in the environment						
CA 7.1	IIA 7.1	Fate and behaviour in soil						
CA 7.1.1		Route of degradation in soil						
CA 7.1.1.1	IIA 7.1.1	Aerobic degradation	y	y	Cross-reference	Study has to be entered in Section 7.1.1. Section 7.1.1.1 not available. No differentiation in IUCLID sections between parent and metabolites.		
CA 7.1.1.2	IIA 7.1.2	Anaerobic degradation	y	y	Cross-reference	Study has to be entered in Section 7.1.1 . Section 7.1.1.2 not available. No differentiation in IUCLID sections between parent and metabolites.		
CA 7.1.1.3	IIA 7.1.3	Soil photolysis	y	y	Correctly placed			
CA 7.1.2		Rate of degradation in soil						
CA 7.1.2.1	IIA 7.2	Laboratory studies	y	y	Cross-reference			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.1.2.1.1	IIA 7.2.1-2	Aerobic degradation of the active substance - study	y	y	Cross-reference	Studies have to be entered under IUCLID Section 7.1.1. In IUCLID the following is indicated: "7.1.2.1 (Cf 7.1.1)"		
		Aerobic degradation of the active substance - kinetic evaluation	n	n		No specific IUCLID section available.		
CA 7.1.2.1.2	IIA 7.2.3	Aerobic degradation of metabolites, breakdown and reaction products - study(ies)	y	y	Cross-reference	Studies have to be entered under IUCLID Section 7.1.1. No differentiation in IUCLID sections between parent and metabolites.		Include separate sections for parent and metabolites.
		Aerobic degradation of metabolites, breakdown and reaction products - kinetic evaluation	n	n				
CA 7.1.2.1.3	IIA 7.2.4	Anaerobic degradation of the active substance	y	y	Cross-reference	Study has to be entered in Section 7.1.1 . Section 7.1.2.1.3 not available. No distinction between aerobic and anaerobic degradation.		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.1.2.1.4	IIA 7.2.5	Anaerobic degradation of metabolites, breakdown and reaction products	y	y	Cross-reference	Study has to be entered in Section 7.1.1 . Section 7.1.2.1.5 not available No distinction between aerobic and anaerobic degradation.		
CA 7.1.2.2	IIA 7.3	Field studies	y	n	Cross-reference	Study has to be entered in Section 7.1.2 . Section 7.1.2.2 not available Materials/Methods Section only contains of one free-text field.		
CA 7.1.2.2.1	IIA 7.3.1	Soil dissipation studies - study	n	n		No specific template and IUCLID Section available.		
		Soil dissipation studies - kinetic evaluation	n	n		No specific template and IUCLID Section available.		
CA 7.1.2.2.2	IIA 7.3.2-3	Soil accumulation studies	n	n		No specific template and IUCLID Section available.		
CA 7.1.3		Adsorption and desorption in soil						
CA 7.1.3.1		Adsorption and desorption						
CA 7.1.3.1.1	IIA 7.4.1	Adsorption and desorption of the active substance	y	y	Correctly placed			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.1.3.1.2	IIA 7.4.2	Adsorption and desorption of metabolites, breakdown and reaction products	y	y	Correctly placed	No differentiation in IUCLID sections between parent and metabolites. All data to be entered in IUCLID Section 7.1.3.1		Include separate sections for parent and metabolites.
CA 7.1.3.2	IIA 7.4.5	Aged sorption	n	n		No specific OHT available.		Provide OHT
CA 7.1.4	IIA 7.4	Mobility in soil						
CA 7.1.4.1		Column leaching studies						
CA 7.1.4.1.1	IIA 7.4.3	Column leaching of the active substance	y	n		No specific template available. Materials/Methods Section only contains one free-text field.		Provide OHT
CA 7.1.4.1.2	IIA 7.4.4-5	Column leaching of metabolites, breakdown and reaction products	y	n		No specific template available. Materials/Methods Section only contains one free-text field.		Provide OHT
CA 7.1.4.2	IIA 7.4.7	Lysimeter studies	n	n		No specific template available. Materials/Methods Section only contains one free-text field.		Provide OHT

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.1.4.3	IIA 7.4.8	Field leaching studies	n	n		No specific template available. Materials/Methods Section only contains one free-text field.		Provide OHT
CA 7.2		Fate and behaviour in water and sediment						
CA 7.2.1		Route and rate of degradation in aquatic systems (chemical and photochemical degradation)						
CA 7.2.1.1	IIA 7.5	Hydrolytic degradation	y	y	Correctly placed			
CA 7.2.1.2	IIA 7.6	Direct photochemical degradation	y	y	Correctly placed			
CA 7.2.1.3	new	Indirect photochemical degradation	n	n		Endpoint missing in IUCLID		Include endpoint in IUCLID and provide OHT.
CA 7.2.2	IIA 7.8	Route and rate of biological degradation in aquatic systems						
CA 7.2.2.1	IIA 7.7 IIA 7.8.1 IIA 7.8.2	"Ready biodegradability"	y	y	Correctly placed			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.2.2.2	new	Aerobic mineralisation in surface water	n	n		OECD 309 study to be entered under 7.2.2.1 "Ready biodegradability". Template is not sufficient to cope with the information provided in an OECD 309 study.		Template and endpoint to be provided as available under REACH + BPR.
CA 7.2.2.3	IIA 7.8.3	Water/sediment study -study	y	y	Correctly placed			
		Water/sediment study - kinetic evaluation	y	n		No specific template available.	Entered in IUCLID section 7.2.2.3	
CA 7.2.2.4	IIA 7.8.3	Irradiated water/sediment study	n	n		Studies to be entered under 7.2.2.3 "Water/sediment study". No specific OHT available but OHT in 7.2.2.3 might be applicable.		
CA 7.2.3	IIA 7.9	Degradation in the saturated zone	n	n		Studies to be entered under 7.2.2.1 "Ready biodegradability".		Template and endpoint to be provided.
CA 7.3	IIA 7.10	Fate and behaviour in air						
CA 7.3.1		Route and rate of degradation in air	y	y	Correctly placed			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier	OHT template available	If the OHT exists is it correctly placed	Issue faced	Workaround	Recommendations/solutions for the future
CA 7.3.2		Transport via air	n		Cross-reference to 7.2	Cross-reference makes no sense as the data point is related to the fate and behaviour in air and has nothing to do with fate and behaviour in water and sediment.	Data in 7.3.1	Create new OHT
CA 7.3.3		Local and global effects	n		Cross-reference to 7.2	Cross-reference makes no sense as the data point is related to the fate and behaviour in air and has nothing to do with fate and behaviour in water and sediment.	In 7.3.3 the detailed assessment of POP, PBT and vPvB classification (P-assessment) is included, which was added in the endpoint summary in chapter 7. Normally a short statement is included in 7.3.3 on the possible local and global effects, which is related to the fate and behaviour in air.	Create new OHT
CA 7.4	IIA 7.11	Definition of the residue						
CA 7.4.1		Definition of the residue for risk assessment	n					
CA 7.4.2		Definition of the residue for monitoring	n					
CA 7.5	IIA 7.12	Monitoring data	y	y	Correctly placed			

Table 15: Ecotoxicological studies on the active substance - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.1		Effects on birds and other terrestrial vertebrates						
CA 8.1.1		Effects on birds						
CA 8.1.1.1	IIA 8.1.1	Acute oral toxicity to birds	y	y	cross reference to 8.1.1	no separate template available for 8.1.1.1	entered at section 8.1.1	
CA 8.1.1.2	IIA 8.1.2-3	Short-term dietary toxicity to birds	y	y	cross reference to 8.1.1	no separate template available for 8.1.1.2	entered at section 8.1.1	
CA 8.1.1.3	IIA 8.1.4	Sub-chronic and reproductive toxicity to birds	y	y	cross reference to 8.1.1	no separate template available for 8.1.1.3	entered at section 8.1.1	
CA 8.1.2	new	Effects on terrestrial vertebrates other than birds						
CA 8.1.2.1	new	Acute oral toxicity to mammals	n	n	cross reference to other section 5.2.1			
CA 8.1.2.2	new	Long-term and reproductive toxicity	n	n	cross reference to other section 5.3.1; 5.6.1			
CA 8.1.3	new	Active substance bioconcentration in prey of birds and mammals	n	y	Correctly placed			

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.1.4	new	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	n	y	cross reference to 8.1.3	template available in section 8.1.3 no separate template for 8.1.4		
CA 8.1.5	new	Endocrine disrupting properties	n	y	cross reference to 8.1.3	template available in section 8.1.3 no separate template for 8.1.5		
CA 8.2	IIA 8.2	Effects on aquatic organisms						
CA 8.2.1	IIA 8.2.1	Acute toxicity to fish						
		Acute toxicity to fish - active substance	y	y				
		Acute toxicity to fish - metabolites	y	y				
CA 8.2.2	IIA 8.2.2-3	Long-term and chronic toxicity to fish	y	y		prolonged toxicity to fish available	Data entered ins section 8.2.2.1	
CA 8.2.2.1	IIA 8.2.4	Fish early life stage toxicity test	n	y				
CA 8.2.2.2	IIA 8.2.5	Fish full life cycle test	n	y	cross reference to 8.2.2.1	no separate template for 8.2.2.2 data would need to be entered in section 8.2.2.1		
CA 8.2.2.3	IIA 8.2.6	Bioconcentration in fish	y	y				

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.2.3	new	Endocrine disrupting properties	n	y				
CA 8.2.4	IIA 8.3.1	Acute toxicity to aquatic invertebrates						
CA 8.2.4.1	IIA 8.3.1.1	Acute toxicity to <i>Daphnia magna</i>						
		Acute Immobilisation test to <i>Daphnia</i> sp.- active substance	y	y	cross reference to 8.2.4	no separate template available for 8.2.4.1, data entered in section 8.2.4		
		Acute Immobilisation test to <i>Daphnia</i> sp.- metabolite	y	y	cross reference to 8.2.4	no separate template available for 8.2.4.1, data entered in section 8.2.4		
CA 8.2.4.2	IIA 8.3.1.3	Acute toxicity to an additional aquatic invertebrate species	y	y	cross reference to 8.2.4	no separate template available for 8.2.4.2, data entered in section 8.2.4		
CA 8.2.5	IIA 8.3.2	Long-term and chronic toxicity to aquatic invertebrates						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.2.5.1	IIA 8.3.2.1	Reproductive and development toxicity to <i>Daphnia magna</i>	y	y				
CA 8.2.5.2	IIA 8.3.2.3	Reproductive and development toxicity to an additional aquatic invertebrate species	n	y	cross reference to 8.2.5.1	No separate template for 8.2.5.2, data would need to be entered in section 8.2.5.1		
CA 8.2.5.3	IIA 8.3.2.2	Development and emergence in <i>Chironomus</i> species	n	y				
		Sediment water Chironomid toxicity using spiked water	n	y	cross reference to 8.2.5.1	No separate template for 8.2.5.2, data would need to be entered in section 8.2.5.1		
CA 8.2.5.4	IIA 8.5.2	Sediment dwelling organisms	y	y		Proposal for a BBA-Guideline: Effects of plant protection products on the development of sediment-dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system (1995)		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Sediment-Water Chironomid Toxicity Test Using Spiked Sediment	n	y				
		Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment	n	y				
CA 8.2.6	IIA 8.4	Effects on algal growth						
CA 8.2.6.1	IIA 8.4	Effects on growth of green algae						
		Algae growth inhibition test - active substance	y	y				
		Algae growth inhibition test - metabolites	y	y				
CA 8.2.6.2	IIA 8.4	Effects on growth of an additional algal species						
		Algae growth inhibition test - active substance	y	y	cross reference to 8.2.6	no separate template available for 8.2.6.2. data entered in section 8.2.6		
		Algae growth inhibition test - metabolites	y	y	cross reference to 8.2.6	no separate template available for 8.2.6.2. data entered in section 8.2.6		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.2.7	IIA 8.6	Effects on aquatic macrophytes						
		<i>Lemna</i> sp. Growth Inhibition Test - active substance	y	y				
		<i>Lemna</i> sp. Growth Inhibition Test - metabolites	y	y				
		Additional aquatic macrophyte species tests	n	y				
		Dicotyledoneous species: <i>Myriophyllum aquaticum</i> <i>Myriophyllum spicatum</i>	n	y				
		Monocotyledonous species: <i>Glyceria maxima</i>	y	y				
CA 8.2.8	new	Further testing in aquatic organisms						
		Additional aquatic species tested	n	y				
		Microcosm/ Mesocosm	n	y				
CA 8.3	IIA 8.7-8	Effect on arthropods						
CA 8.3.1	IIA 8.7	Effects on bees						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
CA 8.3.1.1		Acute toxicity to bees	y	y	cross reference to 8.3	No separate template for 8.3.1, data entered in section 8.3		
CA 8.3.1.1.1	IIA 8.7.1	Acute oral toxicity to honey bees	n	y	cross reference to 8.3	No separate template for 8.3.1,1.1 data would need to be entered in section 8.3		
		Acute oral toxicity to bumble bees	n	y	cross reference to 8.3	No separate template for 8.3.1,1.1 data would need to be entered in section 8.3		
		Acute oral toxicity to solitary bee	n	y	cross reference to 8.3	No separate template for 8.3.1,1.1 data would need to be entered in section 8.3		
CA 8.3.1.1.2	IIA 8.7.2	Acute contact toxicity to honey bees	n	y	cross reference to 8.3	No separate template for 8.3.1,1.2 data would need to be entered in section 8.3		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Acute contact toxicity to bumble bees	n	y	cross reference to 8.3	No separate template for 8.3.1,1.2 data would need to be entered in section 8.3		
		Acute contact toxicity to solitary bee	n	y	cross reference to 8.3	No separate template for 8.3.1,1.2 data would need to be entered in section 8.3		
CA 8.3.1.2	new	Chronic toxicity to bees	n	y	cross reference to 8.3	No separate template for 8.3.1.2, data would need to be entered in section 8.3		
		Honey bee chronic feeding study in the laboratory	n	y	cross reference to 8.3	No separate template for 8.3.1.2, data would need to be entered in section 8.3		
		Bumble bee chronic feeding study in the laboratory	n	y	cross reference to 8.3	No separate template for 8.3.1.2, data would need to be entered in section 8.3		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Solitary bee chronic feeding study in the laboratory	n	y	cross reference to 8.3	No separate template for 8.3.1.2, data would need to be entered in section 8.3		
CA 8.3.1.3	IIA 8.7.4	Effects on honeybee development and other honeybee life stages	n	y	cross reference to 8.3	No separate template for 8.3.1.3, data would need to be entered in section 8.3		
		Acute honey bee larvae laboratory test, test duration: 8d	n	y	cross reference to 8.3	No separate template for 8.3.1.3, data would need to be entered in section 8.3		
		21 d honey bee larvae toxicity test	n	y	cross reference to 8.3	No separate template for 8.3.1.3, data would need to be entered in section 8.3		
		Larvae toxicity test with bumble bee	n	y	cross reference to 8.3	No separate template for 8.3.1.3, data would need to be entered in section 8.3		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Larvae toxicity test with solitary bee	n	y	cross reference to 8.3	No separate template for 8.3.1.3, data would need to be entered in section 8.3		
CA 8.3.1.4	new	Sub-lethal effects	n	n				
CA 8.3.2	IIA 8.8	Effects on non-target arthropods other than bees	y	y	cross reference to 8.3	No separate template for 8.3.2, data entered in section 8.3		
CA 8.3.2.1	IIA 8.8.1.1 IIA 8.8.2.1	Effects on <i>Aphidius rhopalosiphi</i>	y	y	cross reference to 8.3	No separate template for 8.3.2, data entered in section 8.3		
CA 8.3.2.2	IIA 8.8.1.2 IIA 8.8.2.2	Effects on <i>Typhlodromus pyri</i>	y	y	cross reference to 8.3	No separate template for 8.3.2, data entered in section 8.3		
CA 8.4	IIA 8.9	Effects on non-target soil meso- and macrofauna						
CA 8.4.1	IIA 8.9.2	Earthworm, sub-lethal effects	y	y		acute earthworm study available		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Earthworm Reproduction Test (<i>Eisenia fetida</i>) - active substance	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		
		Earthworm Reproduction Test (<i>Eisenia fetida</i>) - metabolite	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		
CA 8.4.2	new	Effects on non-target soil meso- and macrofauna (other than earthworms: <i>Folsonia candida</i> and <i>Hypoaspis aculeifer</i>)	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		
CA 8.4.2.1	new	Species level testing	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		
		Collembolan Reproduction Test in Soil (<i>Folsonia candida</i>)	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Predatory mite (Hypoaspis aculeifer) reproduction test in soil	n	y	cross reference to 8.4	no separate template for 8.4.1 and 8.4.2, data would need to entered in section 8.4		
CA 8.5	IIA 8.10	Effects on soil nitrogen transformation	y	y				
CA 8.6	IIA 8.12	Effects on terrestrial non-target higher plants						
CA 8.6.1	IIA 8.12	Summary of screening data						
		Vegetative Vigour Test	n	y	cross reference to 8.6	No separate template for 8.6.1, data entered in section 8.6		
		Seedling Emergence and Seedling Growth Test	y	y	cross reference to 8.6	No separate template for 8.6.1, data entered in section 8.6		
CA 8.6.2	IIA 8.12	Testing on non-target plants						
		Vegetative Vigour Test	n	y	cross reference to 8.6	No separate template for 8.6.2, data entered in section 8.6		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CA Section 8	IIA 8	Ecotoxicological studies on the active substance						
		Seedling Emergence and Seedling Growth Test	n	y	cross reference to 8.6	No separate template for 8.6.2, data entered in section 8.6		
CA 8.7	IIA 8.14	Effects on other terrestrial organisms (flora and fauna)	n	y	cross reference to 8.3.1			
CA 8.8	IIA 8.15	Effects on biological methods for sewage treatment	y	n	cross reference to 7.2.2.3	no template available	data entered in section 8.2.8: further testing on aquatic organisms	
CA 8.9		Monitoring data						

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Table 16: Identity of the Plant Protection Product (PPP) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
CP 1.1	IIIA 1.1	Applicant	y	y	Cross-referenced		There is no separated point 1.1 in IUCLID template, which could allow to enter the corresponding information. Point 1.1 is not editable. The information on applicant has to be completed in point 1.3	remove cross-reference and add possibility to enter data in section 1.1
CP 1.2	IIIA 1.2	Producer of the PPP and the active substance	y	y	Correctly placed	Information on location of producer of the plant protection product and manufacturing plants can be easily added and flagged as confidential. The naming of point 1.2 in IUCLID refers wrongly only to plant protection product without mentioning active substance. The possibility however exists to summarize both information.		Improve the naming of the point

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
CP 1.3	IIIA 1.3	Trade name or proposed trade name and producer's development code number of the PPP if appropriate	y	y	Correctly placed			
CP 1.4		Detailed quantitative and qualitative information on the composition of the PPP						
CP 1.4.1	IIIA 1.4	Composition of the PPP Content of:						
		Technical active substance	y	y				
		Pure active substance	n	y				
		Correspondent content of variants (salts, esters)	n	y				
		Safeners, synergists, co-formulants	y	y				
		Relevant impurities	n	y				
CP 1.4.2	IIIA 1.4.1	Information on the active substances						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
		Names and codes identifying the active substance	y	y				The corresponding information can be added in remarks field of the component describing the active substance. Alternatively the reference substance can be updated accordingly.
		ISO common name proposed or accepted for active substances, and synonyms	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
		Existing CIPAC, EINECS and ELINCS numbers for the active substance(s)	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
		Salt, ester, anion or cation present for each active substance	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
CP 1.4.3	IIIA 1.4.3	Information on safeners, synergists and co-formulants						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
		Chemical name as in Part 3 of Annex VI to Regulation (EC) No 1272/2008 if not included in that Annex, in accordance with IUPAC and CA nomenclature	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
		Structural formula	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
		Existing CAS, CIPAC, EINECS and ELINCS numbers	y	y				The corresponding information is summarized in reference substance, which is assigned to this point.
		Trade name	n	n		Confidential information - was not available to knoell		
		Specification of each formulant	n	n				The references to SDS can be added.

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
		Function of each formulant	y	y	Correctly placed. In the description of "items" components of the plant protection product, the information on function of each formulant can be easily added.			Improve the software by giving the possibility to upload SDS of each co-formulant directly in the item description
		Description of the formulation process	y	y	There is no separated point in IUCLID template, which could allow to enter the corresponding information. The information can be only provided in the field "Brief description". There is no possibility to flag that field however as confidential. There is no possibility to upload the manufacturing process document.	No problem was faced. The references are provided to Section 13.		Improve the software by giving the possibility to upload any document in that study record and to flag the description provided as confidential

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	Template available in IUCLID? (y, n)	If the template exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 1	IIIA 1	Identity of the Plant Protection Product (PPP)						
CP 1.5	IIIA 1.5	Type and code of the plant protection product	y	y	There is no separated point 1.5 in IUCLID template, which could allow to enter the corresponding information. Point 1.5 is not editable. The corresponding information has to be completed in point 1.4			Improve the software by giving the possibility to edit the corresponding point in the template
CP 1.6	IIIA 1.6	Function (herbicide, insecticide etc.)	y	y	There is no separated point 1.6 in IUCLID template, which could allow to enter the corresponding information. Point 1.6 is not editable. The corresponding information has to be completed in point 3.2			Improve the software by giving the possibility to edit the corresponding point in the template

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Table 17: Physical and chemical properties of the Plant Protection Product (PPP) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 2		Physical and chemical properties of the Plant Protection Product (PPP)						
CP 2.1	IIIA 2.1	Appearance	y	y	Correctly placed	None		None
CP 2.2	IIIA 2.2	Explosive and oxidising properties	y	y	Correctly placed	None		None
	IIIA 2.2.1	Explosive properties	y	y	Correctly placed	None		None
	IIIA 2.2.2	Oxidising properties	y	y	Correctly placed	None		None
CP 2.3	IIIA 2.3	Flammability and self-heating						
	IIIA 2.3.1	Flashpoint (liquids)	y	y	Correctly placed	The template is not applicable to describe the flash point of liquid	Summarized as other information	The sub point of 2.3.1 flammability has to be adapted with inclusion of entities for liquid
		Flammability						
	IIIA 2.3.3	Self-heating	y	y	Correctly placed	None		None
CP 2.4	IIIA 2.4	Acidity/alkalinity and pH value						
	IIIA 2.4.1	Acidity	y	y	Correctly placed	Specific sub data point for acidity/alkalinity /pH not available	Information assigned under data point 2.4	The sub data point of 2.4.1 Acidity / alkalinity should be created

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 2		Physical and chemical properties of the Plant Protection Product (PPP)						
		Alkalinity	y	y	Correctly placed	Specific sub data point for acidity/alkalinity /pH not available	see above	see above
		pH value of neat PPP	y	y	Correctly placed	Specific sub data point for acidity/alkalinity /pH not available	Information assigned under data point 2.4	The sub data point of 2.4.2 pH value should be created
	IIIA 2.4.2	pH of a 1% dilution	y	y	Correctly placed	Specific sub data point for acidity/alkalinity /pH not available	see above	see above
CP 2.5		Viscosity and surface tension						
	IIIA 2.5.2	Viscosity	y	y	Correctly placed	None		None
	IIIA 2.5.3	Surface tension	y	y	Correctly placed	None		None
CP 2.6	IIIA 2.6	Relative density and bulk density						
	IIIA 2.6.1	Relative density	y	y	Correctly placed	None		None
	IIIA 2.6.2	Bulk density - pour and tap						
CP 2.7	IIIA 2.7	Storage stability and shelf-life: effects of temperature on technical characteristics						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 2		Physical and chemical properties of the Plant Protection Product (PPP)						
	IIIA 2.7.1	Accelerated test	y	y	Correctly placed	Sub data point has wrong name -general name referring to storage stability tests	assigned under data point 2.7.1	The sub data point name should be replaced with <i>Stability after accelerated storage</i>
	IIIA 2.7.4	Low temperature, storage	y	y	Correctly placed	Specific sub data point missing	assigned under data point 2.7.2	The sub data point as <i>Effect of low temperature on stability of liquid formulation</i> should be created
	IIIA 2.7.5	Shelf life, two years	y	y	Correctly placed	Specific sub data point missing	assigned under data point 2.7.1	The sub data point as <i>Shelf life following storage at ambient temperatures</i> should be created
CP 2.8	IIIA 2.8	Technical characteristics of the plant protection product						
CP 2.8.1	IIIA 2.8.1	Wettability	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.1 as <i>wettability</i> should be created
CP 2.8.2	IIIA 2.8.2	Persistent foaming	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.2 as <i>Persistent foaming</i> should be created
CP 2.8.3.1	IIIA 2.8.3	Suspensibility	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.3.1 as <i>Suspensibility</i> should be created
CP 2.8.3.2	IIIA 2.8.3.2	Spontaneity of dispersion	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.3.2 as <i>Spontaneity of dispersion</i> should be created

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 2		Physical and chemical properties of the Plant Protection Product (PPP)						
CP 2.8.3.3		Dispersion stability	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.3.3 as <i>Dispersion stability</i> should be created
CP 2.8.4	IIIA 2.8.4	Degree of dissolution and dilution stability	y	y				
CP 2.8.5		Particle size distribution, dust content, attrition and mechanical stability						
CP 2.8.5.1.1	IIIA 2.8.6	Particle size distribution	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.5.1.1 as <i>Particle size distribution</i> should be created
CP 2.8.5.1.2	IIIA 2.8.5.2	Wet sieve test	y	n		sub data point missing	assigned under data point 2.8	The sub data point 2.8.5.1.2 as <i>Wet sieve test</i> should be created
CP 2.8.5.2	IIIA 2.8.6.3-4	Dust content	y	n		sub data point missing	assigned under data point 2.8	The sub data point 2.8.5.2 as <i>Dust content</i> should be created
CP 2.8.5.3	IIIA 2.8.6.5	Attrition	y	n		sub data point missing	assigned under data point 2.8	The sub data point 2.8.5.3 as <i>Attrition</i> should be created
CP 2.8.5.4	new	Hardness and integrity	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.5.4 as <i>Hardness and integrity</i> should be created

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 2		Physical and chemical properties of the Plant Protection Product (PPP)						
CP 2.8.6	IIIA 2.8.7	Emulsifiability, re-emulsifiability, emulsion stability	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.6 as <i>Emulsifiability, re-emulsifiability, emulsion stability</i> should be created
CP 2.8.7	IIIA 2.8.8	Flowability, pourability and dustability	y	n		Sub data point missing	assigned under data point 2.8	The sub data point 2.8.7 as <i>Flowability, pourability and dustability</i> should be created
	IIIA 2.8.8.1	Flowability						
		Pourability						
		Dustability						
CP 2.9	IIIA 2.9	Phys.-Chem. compatibility with other products (incl. PPP with which its use is to be authorised)	y	y	Correctly placed	None		None
CP 2.10	IIIA 2.10	Adherence to seed	y	n		Sub data point missing	assigned under data point 2.11	The data point 2.10 as <i>Adherence and distribution to seeds</i> should be created
		Distribution to seeds	y	n		see above	see above	see above
CP 2.11	IIIA 2.15	Other studies	y	y				

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Table 18: Analytical methods of the Plant Protection Product (PPP) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 5	IIIA1 5	Analytical methods						
CP 5.1		Methods used for the generation of pre-authorisation data						
CP 5.1.1	IIIA1 5.2	Methods for the analysis of the plant protection product						
	IIIA1 5.2.1-2	Active substance	y	n		Sub data point for the description of analytical method for determination of a.s. in the formulated product has to be created manually.	Endpoint study record created under data point 5	Sub data point as 5.1.1 as <i>Methods for the analysis of the representative plant protection product</i> should be created
	IIIA1 5.2.4	Relevant impurities identified in the TGAI or formed during manufacturing or degradation during storage	y	n		see above	see above	see above
	IIIA1 5.2.5	Relevant co-formulants	y	n		see above	see above	see above

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/ solutions for the future
CP Section 5	IIIA1 5	Analytical methods						
	IIIA1 5.2.3	Applicability of existing CIPAC methods	n	n		No issue faced		
CP 5.1.2		Methods for determination of residues				Data summarized under CA dataset		
CP 5.2		Methods for post- authorisation control and monitoring purposes				Data summarized under CA dataset		

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Table 19: Toxicological studies on the Plant Protection Product (PPP) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 7	IIIA1 7	Toxicological studies on the plant protection product						
CP 7.1	IIIA1 7.1	Acute toxicity						
CP 7.1.1	IIIA1 7.1.1	Oral toxicity	y	y	Correctly placed			
CP 7.1.2	IIIA1 7.1.2	Dermal toxicity	y	y	Correctly placed			
CP 7.1.3	IIIA1 7.1.3	Inhalation toxicity	n	y	Correctly placed			
CP 7.1.4	IIIA1 7.1.4	Skin irritation	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
CP 7.1.5	IIIA1 7.1.5	Eye irritation	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately
CP 7.1.6	IIIA1 7.1.6	Skin sensitisation	y	y	Correctly placed	no specific template for different study designs, different designs are implemented in one IUC mask		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 7	IIIA1 7	Toxicological studies on the plant protection product						
CP 7.1.7	new	Supplementary studies on the plant protection product	n	y	Correctly placed			
CP 7.1.8	IIIA1 7.1.7	Supplementary studies for combinations of plant protection products	n	n	Cross-reference			
CP 7.2		Data on exposure			See below			
CP 7.2.1	IIIA1 7.3	Operator exposure				no OHT template available; data are included as endpoint summary, no sub-chapters included in IUC (only chapter 7.2)		Reported separately
CP 7.2.1.1	IIIA1 7.3.1-2	Estimation of operator exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.2.1.2	IIIA1 7.3.3	Measurement of operator exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 7	IIIA1 7	Toxicological studies on the plant protection product						
CP 7.2.2	IIIA1 7.4	Bystander and resident exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.2.2.1	IIIA1 7.4.1	Estimation of bystander and resident exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.2.2.2	IIIA1 7.4.2	Measurement of bystander and resident exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.2.3	IIIA1 7.5	Worker exposure				no OHT template available; data are included as endpoint summary, no sub-chapters included in IUC (only chapter 7.2)		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 7	IIIA1 7	Toxicological studies on the plant protection product						
CP 7.2.3.1	IIIA1 7.5.1-3	Estimation of worker exposure	y	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.2.3.2	IIIA1 7.5.4	Measurement of worker exposure	n	n		no OHT template available; data are included as endpoint summary		Reported separately
CP 7.3	IIIA1 7.6	Dermal adsorption	y	y	Correctly placed			
CP 7.4	IIIA1 7.9	Available toxicological data relating to non-active substances				no chapter 7.4 included in IUC		Reported separately

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Table 20: Fate and behaviour in the environment on the Plant Protection Product (PPP) - evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 9	IIIA1 9	Fate and behaviour in the environment						
CP 9.1		Fate and behaviour in soil						
CP 9.1.1	IIIA1 9.1	Rate of degradation in soil						
CP 9.1.1.1	IIIA1 9.1.1-2	Laboratory studies	n	y	Correctly placed			
CP 9.1.1.2	IIIA1 9.2	Field studies	y	y	Correctly placed			
CP 9.1.1.2.1	IIIA1 9.2.1	Soil dissipation studies	n	n	Covered in CP 9.1.1.2			
CP 9.1.1.2.2	IIIA1 9.2.3	Soil accumulation studies	n	n	Covered in CP 9.1.1.2			
CP 9.1.2	IIIA1 9.3	Mobility in the soil						
CP 9.1.2.1	IIIA1 9.3.1	Laboratory studies	y	y	Correctly placed			
CP 9.1.2.2	IIIA1 9.3.2	Lysimeter studies	n	n	Covered in CP 9.1.2.1			
CP 9.1.2.3	IIIA1 9.3.3	Field leaching studies	n	n	Covered in CP 9.1.2.1			
CP 9.1.3	IIIA1 9.4-5	Estimation of concentrations in soil	y	n	Correctly placed	Estimations of concentrations in water and air also need to be listed here		

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 9	IIIA1 9	Fate and behaviour in the environment						
CP 9.2		Fate and behaviour in water and sediment						
CP 9.2.1	new	Aerobic mineralisation in surface water	n	n	Correctly placed			
CP 9.2.2	new	Water/sediment study	n	y	Correctly placed			
CP 9.2.3	new	Irradiated water/sediment study	n	n	Cross reference to CP 9.2.2			Allow entering of study at datapoint without cross-reference
CP 9.2.4	IIIA1 9.6	Estimation of concentrations in groundwater	y	n	Cross-reference to CP 9.1.3			
CP 9.2.4.1	IIIA1 9.6.1-2	Calculation of concentrations in groundwater	y	n	See above			
CP 9.2.4.2	IIIA1 9.6.3	Additional field tests	n	n	See above			
CP 9.2.5	IIIA1 9.7-8	Estimation of concentrations in surface water and sediment	y	n	Cross-reference to CP 9.1.3			
CP 9.3	IIIA1 9.9	Fate and behaviour in air						
CP 9.3.1	IIIA1 9.3.4-5	Route and rate of degradation in air and transport via air	y	y				

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 9	IIIA1 9	Fate and behaviour in the environment						
CP 9.4	new	Estimation of concentrations for other routes of exposure	n	n	Cross-reference to CP 9.2			

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Table 21: Ecotoxicological studies on the Plant Protection Product (PPP) – evaluation of available OHT templates and issues encountered

EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.1		Effects on birds and other terrestrial vertebrates						
CP 10.1.1	IIIA1 10.1	Effects on birds	n	y				
		For pellets, granules , treated seeds	n	y				
		For baits	n	y				
		Acute toxicity exposure ratio (TERA) for birds	n	y				
CP 10.1.1.1	IIIA1 10.1.1	Acute oral toxicity	n	y	cross reference 10.1.1	no separate template for 10.1.1.1. data to be entered in 10.1.1		Reported separately
CP 10.1.1.2	IIIA1 10.1.9	Higher tier data on birds	n	y	cross reference 10.1.1	no separate template for 10.1.1.2. data to be entered in 10.1.1		Reported separately
CP 10.1.2	IIIA1 10.3	Effects on terrestrial vertebrates other than birds	n	n				
CP 10.1.2.1	IIIA1 10.3.1.1-2	Acute oral toxicity to mammals	n	n				

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.1.2.2	KIIA1 10.3.1 KIIA1 10.3.2	Higher tier data on mammals	n	n				
CP 10.1.3	new	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)	n	y				
CP 10.2	IIIA1 10.2	Effects on aquatic organisms						
CP 10.2.1	IIIA1 10.2.1 IIIA1 10.2.2 KIIA1 10.8.2	Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes			cross reference 10.2.2.1	template available in section 10.2.2.2		Reported separately
		Acute toxicity to fish	y	y				
		Acute toxicity to aquatic invertebrates	y	y	cross reference 10.2.4	template available in section 10.2.4		Reported separately
		Acute toxicity to aquatic algae	y	y	cross reference 10.2.6	template available in section 10.2.6		Reported separately
		Acute toxicity to aquatic macrophytes	y	y	cross reference 10.2.7	template available in section 10.2.7		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.2.2	IIIA1 10.2.1.10 IIIA1 10.2.1.11 ...	Add. Long-term and chronic tox. Studies on fish, aquatic invert., sediment dwelling org.	n	y				
		Chronic toxicity studies on fish	n	n	cross reference 10.2.2.1	template available in section 10.2.2.1		Reported separately
		Chronic toxicity studies on aquatic invertebrates	n	n	cross reference 10.2.5	template available in section 10.2.5		Reported separately
		Chronic toxicity studies on sediment dwelling organisms	n	n		template available in section 10.2.5.4		Reported separately
CP 10.2.3	new	Further testing on aquatic organisms	n	n		template available in section 10.2.8		Reported separately
CP 10.3		Effects on arthropods						
CP 10.3.1		Effects on bees						
CP 10.3.1.1	IIIA1 10.4.2	Acute toxicity to bees	y	y				
CP 10.3.1.1.1	IIIA1 10.4.2.1	Acute oral toxicity to honey bees	y	y		template available in section 10.3.		Reported separately
		Acute oral toxicity to bumble bees	n	y		template available in section 10.3.		Reported separately
		Acute oral toxicity to solitary bees	n	y		template available in section 10.3.		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.3.1.1.2	IIIA1 10.4.2.2	Acute contact toxicity to honey bees	y	y		template available in section 10.3.		Reported separately
		Acute contact toxicity to bumble bees	n	y		template available in section 10.3.		Reported separately
		Acute contact toxicity to solitary bees	n	y		template available in section 10.3.		Reported separately
CP 10.3.1.2	IIIA1 10.4.3	Honey bee chronic feeding study in the laboratory	n	y		template available in section 10.3.		Reported separately
		Bumble bee chronic feeding study in the laboratory	n	y		template available in section 10.3.		Reported separately
		Solitary bee chronic feeding study in the laboratory	n	y		template available in section 10.3.		Reported separately
CP 10.3.1.3	new	Effects on honey bee development and other honey bee life stages						
		Acute Honey bee larvae laboratory test, test duration: 8d	n	y		template available in section 10.3.		Reported separately
		21 d honeybee larvae toxicity test	n	y		data can be entered in template available in section 10.3.		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
		Larvae toxicity test with bumble bee	n	y		data can be entered in template available in section 10.3.		Reported separately
		Larvae toxicity test with solitary bee	n	y		data can be entered in template available in section 10.3.		Reported separately
CP 10.3.1.4	IIIA1 10.4.6	Sub-lethal effects						
		HPG (hypopharyngeal glands) laboratory test (10-d chronic adult)	n	y		data can be entered in template available in section 10.3.		Reported separately
		Homingflight studies	n	y		data can be entered in template available in section 10.3.		Reported separately
CP 10.3.1.5	IIIA1 10.4.4 + 7	Cage and tunnel tests						
		Oomen (honey bee)	n	y		data can be entered in template available in section 10.3.		Reported separately
		Cage test (honey bee)	n	y		data can be entered in template available in section 10.3.		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
		Brood test under semi-field conditions (honey bee)	n	y		data can be entered in template available in section 10.3.		Reported separately
		Semi-field (bumble bee and solitary bee)						
CP 10.3.1.6	IIIA1 10.4.5	Field tests						
		Field tests with honey bees	n	y		data can be entered in template available in section 10.3.		Reported separately
		Field tests with bumble bees	n	y		data can be entered in template available in section 10.3.		Reported separately
CP 10.3.2	IIIA1 10.5	Effects on non-target arthropods other than bees	y	y		no separate template available, data to be entered in section 10.3		Reported separately
CP 10.3.2.1	IIIA1 10.5.1	Standard laboratory testing for non-target arthropods	y	y		no separate template available, data to be entered in section 10.3		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
		Effects on <i>Aphidius rhopalosiphi</i> , glass plate study design	y	y		no separate template available, data to be entered in section 10.3		Reported separately
		Effects on <i>Typhlodromus pyri</i> , glass plate study design	y	y		no separate template available, data to be entered in section 10.3		Reported separately
CP 10.3.2.2	IIIA1 10.5.2	Extended laboratory testing, aged residue studies with non-target arthropods	y	y		no separate template available, data to be entered in section 10.3		Reported separately
		Effects on <i>Aphidius rhopalosiphi</i> , extended study design	y	y		no separate template available, data to be entered in section 10.3		Reported separately
		Effects on <i>Typhlodromus pyri</i> , extended study design	y	y		no separate template available, data to be entered in section 10.3		Reported separately
		add. Species tested (e.g. <i>Coccinella</i> , <i>Pardosa</i> etc.)	n	y		no separate template available, data to be entered in section 10.3		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.3.2.3	IIIA1 10.5.3	Semi-field studies with non-target arthropods	n	y		no separate template available, data to be entered in section 10.3		Reported separately
CP 10.3.2.4	IIIA1 10.5.4	Field studies with non-target arthropods	n	y		no separate template available, data to be entered in section 10.3		Reported separately
CP 10.3.2.5	new	Other routes of exposure for non-target arthropods	n	y		no separate template available, data to be entered in section 10.3		Reported separately
CP 10.4	IIIA1 10.6	Effects on non-target soil meso- and macrofauna						
CP 10.4.1	IIIA1 10.6.1-2	Earthworms	y	y		no separate template available, data to be entered in section 10.4		Reported separately
CP 10.4.1.1	IIIA1 10.6.3	Earthworms – sub-lethal effects	n	y		no separate template available, data to be entered in section 10.4		Reported separately
CP 10.4.1.2	IIIA1 10.6.4	Earthworms – field studies	n	y		no separate template available, data to be entered in section 10.4		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.4.2	IIIA1 10.6.6	Effects on non-target soil meso- and macrofauna (other than earthworms)	n	y		no separate template available, data to be entered in section 10.5		Reported separately
CP 10.4.2.1	IIIA1 10.6.6	Species level testing	n	y		no separate template available, data to be entered in section 10.6		Reported separately
		<i>Collembolan</i> Reproduction Test in Soil	n	y		no separate template available, data to be entered in section 10.7		Reported separately
		Predatory mite (<i>Hypoaspis aculeifer</i>) reproduction test in soil	n	y		no separate template available, data to be entered in section 10.8		Reported separately
CP 10.4.2.2	IIIA1 10.6.6	Higher tier testing	n	y		no separate template available, data to be entered in section 10.9		Reported separately
CP 10.5	IIIA1 10.7	Effects on soil nitrogen transformation	n	y				
CP 10.6	IIIA1 10.8	Effects on terrestrial non-target higher plants						

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.6.1	IIIA1 10.8	Summary of screening data	n	y		no separate template available, data to be entered in section 10.6		Reported separately
		Vegetative Vigour Test	n	y		no separate template available, data to be entered in section 10.6		Reported separately
		Seedling Emergence and Seedling Growth Test	n	y		no separate template available, data to be entered in section 10.6		Reported separately
CP 10.6.2		Testing on non-target plants	n	y		no separate template available, data to be entered in section 10.6		Reported separately
		Vegetative Vigour Test	n	y		no separate template available, data to be entered in section 10.6		Reported separately
		Seedling Emergence and Seedling Growth Test	n	y		no separate template available, data to be entered in section 10.6		Reported separately

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EU Data Requirement Number	OECD data point	Detail on data point / study	Information in tested dossier (y, n)	OHT template available in IUCLID? (y, n)	If the OHT exists is it correctly placed in IUCLID or cross-referenced to other section	Issue faced	Workaround	Recommendations/solutions for the future
CP Section 10	IIIA1 10	Ecotoxicological studies on the plant protection product						
CP 10.6.3		Extended laboratory studies on non-target plants	n	y		no separate template available, data to be entered in section 10.6		Reported separately
CP 10.6.4		Semi-field and field tests on non-target plants	n	y		no separate template available, data to be entered in section 10.6		Reported separately
CP 10.7	IIIA1 10.9	Effects on other terrestrial organisms (flora and fauna)	n	n				
CP 10.8	new	Monitoring data	n	y				