



**CropLife**  
EUROPE

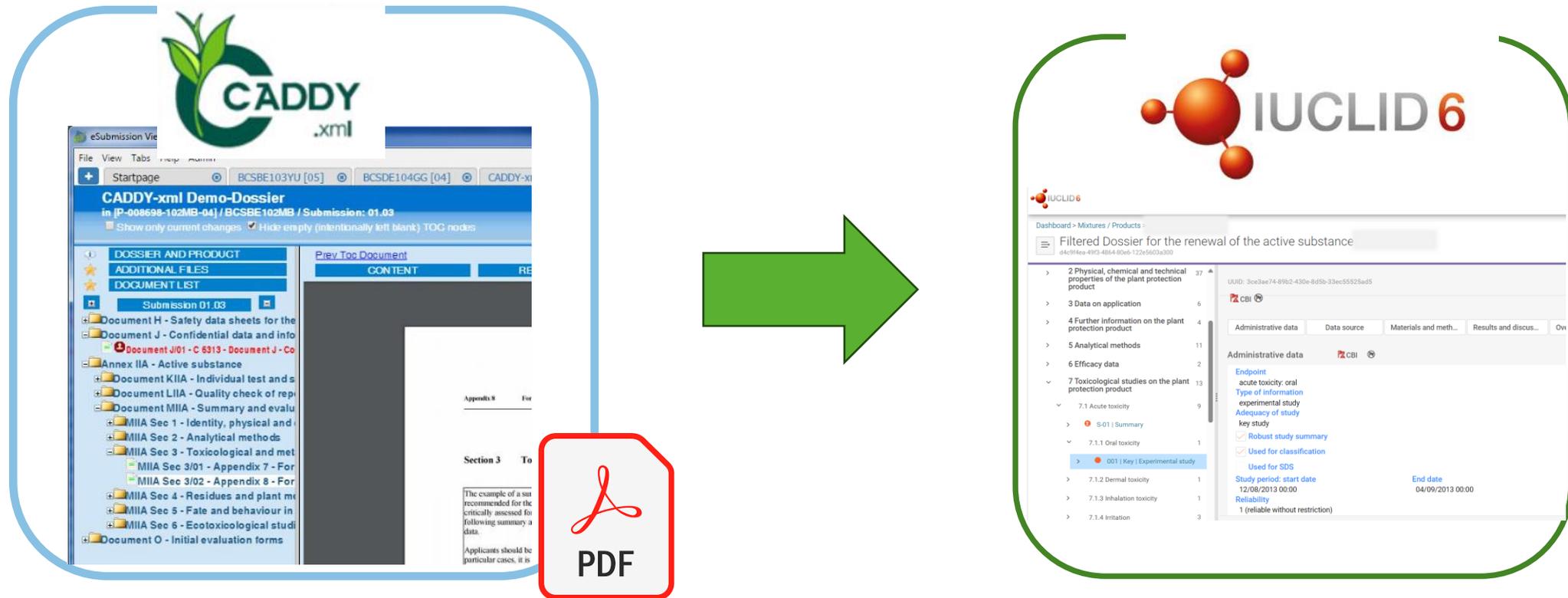
# **IUCLID Integration Platform**

**A companion tool for IUCLID**

**Georg Schifferdecker**

CLE Conference 2024 - March 6

# IUCLID – not just a new tool for Dossier submissions



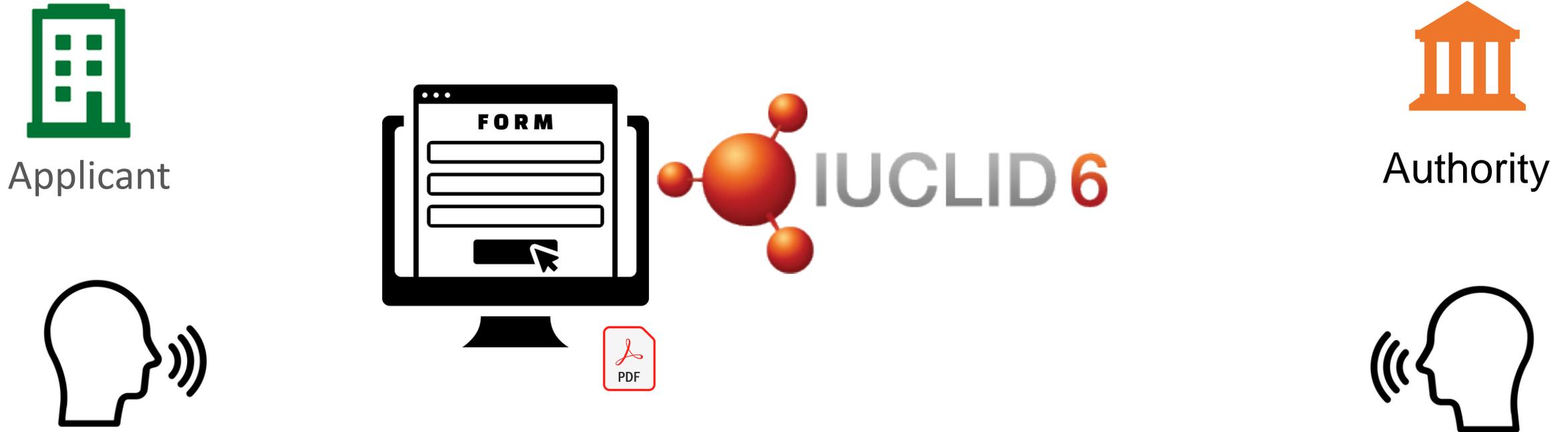
**Paradigm Shift – from document-centric to data-centric submission**  
Promising move towards digitalisation

# The EU submission process – prior to IUCLID



- Data requirements – information content
- Data format
- Dossier / Submission handover

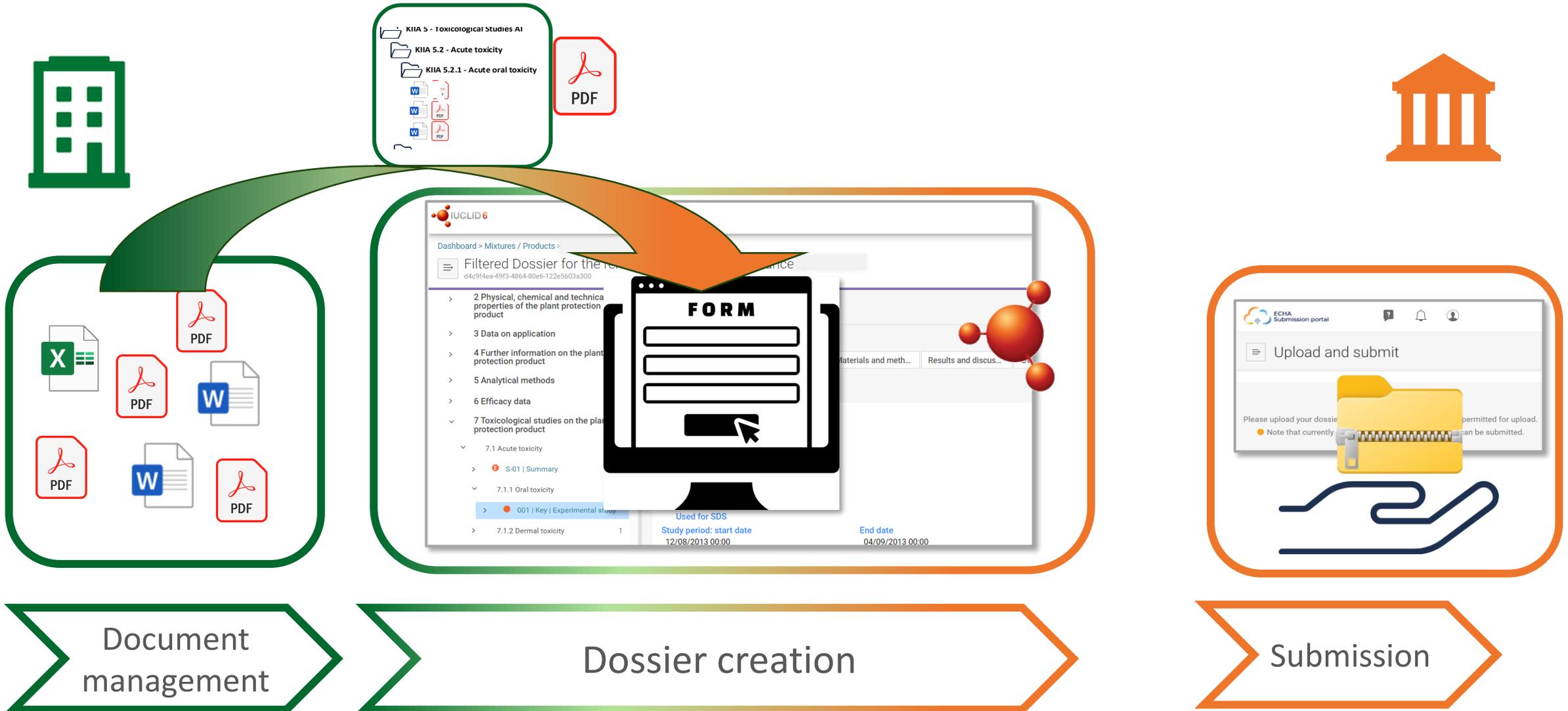
# The EU submission process – from 2021 (for AS)



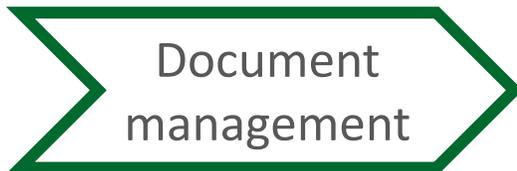
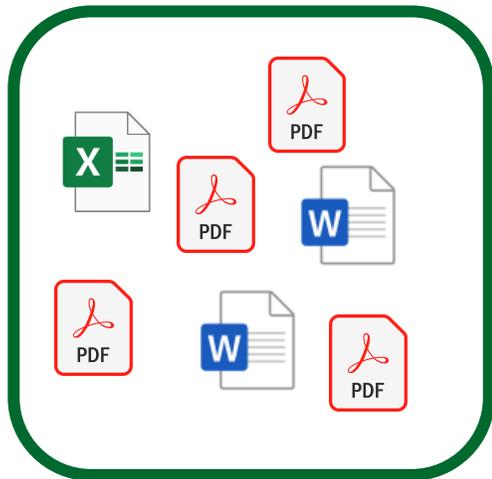
Major change

- ✓ Data requirements – information content
- ✓ Data format
- ✓ Dossier / Submission handover

# The EU submission process - IUCLID



# The EU submission process - IUCLID



700 forms (“document” types) with fields

- 📄 Groundwater conc.: 26 fields
- 📄 GAP: 61 fields
- 📄 OHT - Residues Rot Crops: 185 fields
- 📄 OHT - AnalyticalMethods: 284 fields



# The EU submission process - IUCLID



Estimation of concentrations in ground water



Table 8 Tier 1 PEC<sub>gw</sub> for [redacted] and its metabolites following application of 3 x 45 g ha<sup>-1</sup> (interval 10 d) to vines (BBCH 11)

Model	Crop	Scenario	90 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth [µg L <sup>-1</sup> ]		
PEARL 5.5.5	Vines	Châteaudun	0.006	0.221	1.818
		Hamburg	0.010	0.560	2.402
		Kremsmünster	0.006	0.259	1.406
		Piacenza	0.011	0.222	1.179
		Porto	0.003	0.182	0.842
		Sevilla	0.002	0.112	0.986
PELMO 6.6.4	Vines	Thiva	0.001	0.070	0.771
		Châteaudun	0.004	0.193	1.589
		Hamburg	0.009	0.696	2.970
		Kremsmünster	0.007	0.371	1.950
		Piacenza	0.020	0.276	1.224
		Porto	0.006	0.269	1.039
MACRO 5.5.4	Vines	Sevilla	<0.001	0.095	0.860
		Thiva	<0.001	0.099	0.871
		Châteaudun	<0.001	0.132	1.248

PEC ground water

#	Use descrip...	Parent / me...	Substance	Tier	Model	Scenario	PECgw
1	GAP 001	parent	Sample Substance	Tier1	PEARL		
2	GAP 001	parent	Sample Substance	Tier1			
3	GAP 001	parent	Sample Substance	Tier1	PEARL		
4	GAP 001	parent	Sample Substance	Tier1	PEARL		



Use description  
● GAP 001

Parent / metabolite  
parent

Substance  
● Sample Substance

Tier  
Tier1

Model  
PEARL

Scenario  
Chateaudun

PECgw  
0.006 µg/L

Remarks

Parent / metabolite

Please select

- metabolite
- parent

Model

Please select

- MACRO
- PEARL
- PELMO
- PRZM
- other:

PECgw

< 129 µg/L >

ca.

<

<=

>

>=

Select Substance

Sample Substance 6

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID 8f6ce1b3-c647-4506-82f5-7b556a667f21

Sample Substance 5

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID 267fa5b0-f8ac-4622-bb04-73919ebd35a7

Sample Substance 4

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID 7a48f6f0-8186-4253-87cf-803645ef7f

Sample Substance 3

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID cd87b1ce-e903-4e0a-a878-6f847a7f34c

Sample Substance 2

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

Document management

Dossier creation



# The IIP project



Sponsored by CLE - Supported by external partners

## Milestones:

- Requirements collection - Q3/2023
- Implementation - since Q4/2023
- Next release: March 2024
- End of project: Q1/2025

The screenshot displays a web application interface for document management. The top navigation bar shows the current document: "Estimation of concentrations in ground water.001". The left sidebar lists document types and names, with "EstConcGroundwater" selected. The main content area is divided into sections: "Administrative data", "Description of key information", "PEC ground water", and "Additional information". The "PEC ground water" section contains a table with the following data:

#	Use description	Parent / metabolite	Substance	Tier	Model	Scenario	PECgw	Remarks
1.	GAP 001	parent	Sample Substa	Tier1	PEARL	Chateaudun	0.006 µg/L	Remark 1
2.	GAP 001	parent	Sample Substa	Tier1	PEARL	Hamburg	0.01 µg/L	Remark 2
3.	GAP 001	parent	Sample Substa	Tier1	PEARL	Kremsmunste	0.006 µg/L	Remark 3
4.	GAP 001	parent	Sample Substa	Tier1	PEARL	Piacenza	0.011 µg/L	Remark 4
5.								
6.								
7.								

Free to download and use – register at <https://esubmission.croplifeeurope.eu>

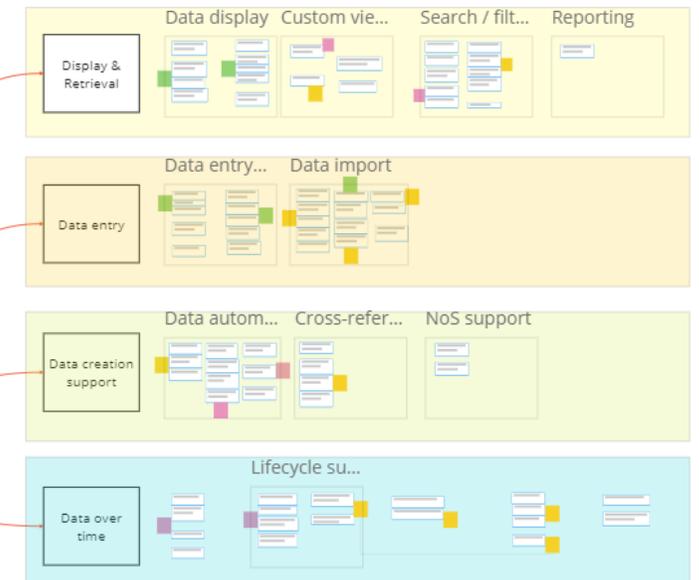
# CLE IIP project – collected requirements



- Efficiency gains
  - Data entry
  - Data display
  - Data import (from inhouse databases)
- Functionality gains
  - Search
  - Version control
  - Collaboration support
- Risk mitigation
  - Quality issues
  - Compliance issues

Current focus

IIP vision



# IIP – data entry (tables and blocks)



## Estimation of concentrations in ground water



	A	B	C	D
1	Max of PECgw(µg/L)( )			Name(Substance)
2	GAPcrop	BBCH	Scenario	
18	Vines, early	BBCH 11	Chateaudun	0,006
19			Hamburg	0,010
20			Kremsmünster	0,006
21			Piacenza	0,011
22			Porto	0,003
23			Sevilla	0,002
24			Thiva	0,001

#	Use descrip...	Parent / me...	Substance	Tier	Model	Scenario	PECgw
1	GAP 001	parent	Sample Substance	Tier1	PEARL	Chateaudun	0.006 µg/L
2	GAP 001	parent	Sample Substance	Tier1	PEARL	Hamburg	0.01 µg/L
3	GAP 001	parent	Sample Substance	Tier1	PEARL	Kremsmunster	0.006 µg/L
4	GAP 001	parent	Sample Substance	Tier1	PEARL	Piacenza	0.011 µg/L

Scenario <sup>1</sup> ^

Please select

- Chateaudun ✓
- Hamburg
- Jokioinen
- Kremsmunster
- Okehampton
- Piacenza
- Porto
- Sevilla



## GAP

- Number of applications (range)  
3
- Re-treatment interval (in days)  
5
- Application rate per treatment (product) - range  
0.3 - 0.6 L/ha
- Remarks on application rate  
Rate at BBCH 10-12: 0.3 L/ha  
Rate at BBCH 13-14: 0.6 L/ha  
Rate at BBCH 15-18: 0.6 L/ha
- Water amount per treatment / spray volume  
150 - 400 L/ha
- Concentration of formulation in dilution  
0.75 - 4 mL/L
- Safener / synergist / adjuvant added  
no
- Application rate per treatment for target a.s. (range)  
50 - 100 g/ha
- Maximum annual application rate (a.s.)  
250 g/ha



	A	B
1	Column1	Column2
2	Number of applications (range)	3
3	Re-treatment interval (in days)	5
4	Application rate per treatment (product) - range	0.3 - 0.6 L/ha
		Rate at BBCH 10-12: 0.3 L/ha Rate at BBCH 13-14: 0.6 L/ha Rate at BBCH 15-18: 0.6 L/ha
5	Remarks on application rate	
6	Water amount per treatment / spray volume	150 - 400 L/ha
7	Concentration of formulation in dilution	0.75 - 4 mL/L
8	Safener / synergist / adjuvant added	no
9	Application rate per treatment for target a.s. (range)	50 - 100 g/ha
10	Maximum annual application rate (a.s.)	250 g/ha

# IIP – data entry (tables and blocks)



## Estimation of concentrations in ground water



1	A	B	C	D
1	Max of PECgw(µg/L)( )			Name(Substance)
2	GAPcrop	BBCH	Scenario	d
18	Vines, early	BBCH 11	Chateaudun	0,006
19			Hamburg	0,010
20			Kremsmünster	0,006
21			Piacenza	0,011
22			Sherry	0,003
23			Sevilla	0,002
24			Thiva	0,001

PEC ground water								
#	Use description	Parent / metabolite	Substance	Tier	Model	Scenario	PECgw	Remarks
1.	GAP 001	parent	Sample Substan	Tier1	PEARL	Chateaudun	0.006 µg/L	Remark 1
2.	GAP 001	parent	Sample Substan	Tier1	PEARL	Hamburg	0.01 µg/L	Remark 2
3.	GAP 001	parent	Sample Substan	Tier1	PEARL	Kremsmunster	0.006 µg/L	Remark 3
4.	GAP 001	parent	Sample Substan	Tier1	PEARL	Piacenza	0.011 µg/L	Remark 4
5.	GAP 001	sibling	Sample Substan	Tier1	PEARL	other:Sherry	0.01 µg/L	Remark 5
6.	GAP 001	parent	Sample Substan	Tier1	PEARL	Sevilla		Remark 6
7.	GAP 001	parent	Sample Substan	Tier1	PEARL	Thiva	other:Sherry	Remark 5



## GAP



1	A	B
1	Column1	Column2
2	Number of applications (range)	3
3	Re-treatment interval (in days)	5
4	Application rate per treatment (product) - range	0.3 - 0.6 L/ha
		Rate at BBCH 10-12: 0.3 L/ha Rate at BBCH 13-14: 0.6 L/ha Rate at BBCH 15-18: 0.6 L/ha
5	Remarks on application rate	
6	Water amount per treatment / spray volume	150 - 400 L/ha
7	Concentration of formulation in dilution	0.75 - 4 mL/L
8	Safener / synergist / adjuvant added	no
9	Application rate per treatment for target a.s. (range)	50 - 100 g/ha
10	Maximum annual application rate (a.s.)	250 g/ha

↔ Number of applications (ra...	3
↔ Re-treatment interval (in da...	5
↔ Application rate per treatm...	0.3 0.6 L/ha
A Remarks on application rate	Rate at BBCH 10-12: 0.3 L/ha Rate at BBCH 13-14: 0.6 L/ha Rate at BBCH 15-18: 0.6 L/ha
↔ Water amount per treatme...	150 400 L/ha
↔ Concentration of formulati...	0.75 4 mL/L
☰ Safener / synergist / adjuva...	no
↔ Application rate per treatm...	50 100 g/ha
↔ Maximum annual applicati...	250 g/ha

# IIP – data display – document structure



Analytical Method (284 fields – 17 blocks, 18 tables, max. 11 columns / table)



Administrative data	Data source	Background	Materials and met...	Results and discu...	Overall remar
---------------------	-------------	------------	----------------------	----------------------	---------------



ENDPOINT\_STUDY\_RECORD.AnalyticalMethods Analytical methods.001

Σ 107 Q Search

Field

- Administrative data
- Attached justification
- Cross-reference
- Data source
- Background
- Materials and methods
  - Test guideline
  - Test material
  - Analytical (primary) method
  - Enforcement method (if applicable)
  - Confirmatory method (if applicable)
  - Independent Laboratory Validation - ILV (if applicable)
  - Any other information on materials and methods incl. tables
- Results and discussion
  - Results using analytical (primary) method
    - Recovery
    - Repeatability
    - LOQ/LOD
    - Calibration
  - Results using enforcement method (if applicable)
    - Recovery
    - Repeatability
    - LOQ/LOD
    - Calibration
  - Results using confirmatory method (if applicable)
    - Recovery
    - Repeatability
    - LOQ/LOD
    - Calibration
  - Independent laboratory validation (if applicable)
    - Recovery
    - Repeatability
    - LOQ/LOD
    - Calibration
  - Any other information on results incl. tables
- Overall remarks, attachments
- Attachments
- Applicant's summary and conclusion

Hide fields

Σ 4 / 107 Q Residue

Field

Residue method	<input type="checkbox"/>

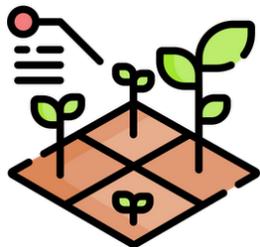
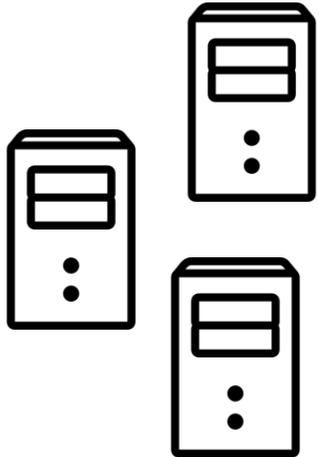
Field search

MRL applications	
<b>Crop information</b>	<input type="checkbox"/>
Crop / treated object	<input type="checkbox"/>
Genetical modification of ...	<input type="checkbox"/>

<b>Crop information</b>	
Crop / treated object	3ALMC (Almond crops)
Genetical modification of cr...	no
Crop destination(s)	

Filled: yes / no

# IIP – Data import with duplicate detection



100  
001

Potential duplicate(s)



GeneralInfo.Company	IEF_ORIGINID	GeneralInfo.Li	GeneralInfo.Name	GeneralInfo.Author	GeneralInfo.Year	GeneralInfo.Type
788-00		study report	14C- 127: Metabol	Anonymous et al.	2002	unpubl
54-00		study report	14C-Pyridine and 14C-Phe	Anonymous et al.	2002	unpubl
184927/0202		study report	18-month carcinogenicity	Anonymous et al.	1992	
IEF_EMPTY		study report	28-day repeated dose derm	Anonymous et al.	1989	
IEF_EMPTY		study report	3-month oral toxicity in mi	Anonymous et al.	1989	
27/0669		study report	A field study to monitor the	Anonymous et al.	1998	
27/4778		study report	A toxicity test to Determine	Anonymous et al.	2001	
File No	27/4694	study report	A-7957 C: Report on auto-	Anonymous et al.	1997	
File No	27/4766					
File No	27/4766					
File No	27/4820					
QF 3021/90/0181 No. 074918		Project report 7/90				
IEF_EMPTY						
IEF_EMPTY						
IEF_EMPTY						

IIP Import Format

Jobs Σ 138

Identifier	Name
1 788-00	14C-CGA 184927: Me
1 54-00	14C-Pyridine and 14C
1 184927/0202	18-month carcinogen
0	28-day repeated dose
0	3-month oral toxicity
2	A field study to monit
1 7/4778	A toxicity test to Dete
0 File No	7/4694 A-7957 C: Report on
0 File No	7/4766 A-7957 C: Report on
0 File No	7/4766 A-7957 C: Report on
1 27/4820	A-7957 C: Report on
1 QF 3021/90/0181 No. 074918	Absorption, distribut
0	Acute dermal irritation
0	Acute Dermal Irritatio
0	Acute Dermal Toxicity
1 CGA184927/4739	Acute Dose-Response
0	Acute eye irritation /

Update Candidates Σ 1

Identifier	Name
1 /4778	A toxicity test to Determine th

LITERATURE A toxicity test to Determine the Effects of on Vegetative Vigor of Six Species of Pla...

Σ 14 Search

General information

Reference Type study report

A Title A toxicity test to Determine the Effects of on Vegetative Vigor of Six Species of Plants.

A Author

Year 2001

A Bibliographic source

A Testing facility

Report date 2003-06-11

A Report number 108-433

A Study sponsor

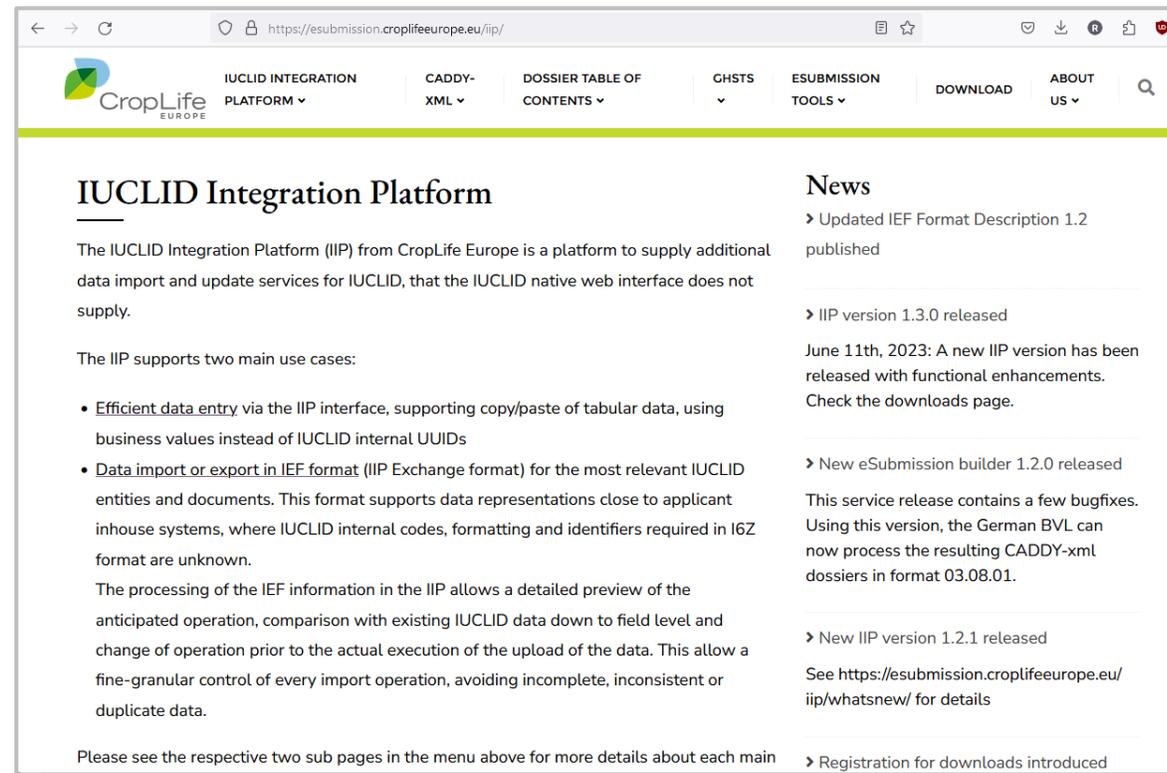
A Study number

Other study identifier(s)

#	Study ID type	A Study ID	A Remarks
1.		sdfsdf	sdfsdf

# For more information

- <http://esubmission.croplifeeurope.eu>

A screenshot of the website <https://esubmission.croplifeeurope.eu/iip/>. The page has a navigation menu with items: IUCIID INTEGRATION PLATFORM, CADDY-XML, DOSSIER TABLE OF CONTENTS, GHSTS, ESUBMISSION TOOLS, DOWNLOAD, and ABOUT US. The main content area is titled "IUCIID Integration Platform" and describes the platform's purpose and use cases. A "News" section on the right lists updates such as "Updated IEF Format Description 1.2 published", "IIP version 1.3.0 released", "New eSubmission builder 1.2.0 released", "New IIP version 1.2.1 released", and "Registration for downloads introduced".

Please feel free to contact me

- during the conference
- by email - [esubmission@croplifeeurope.eu](mailto:esubmission@croplifeeurope.eu)

# Thank you!

Questions?

Comments?

Suggestions?