



CropLife
EUROPE

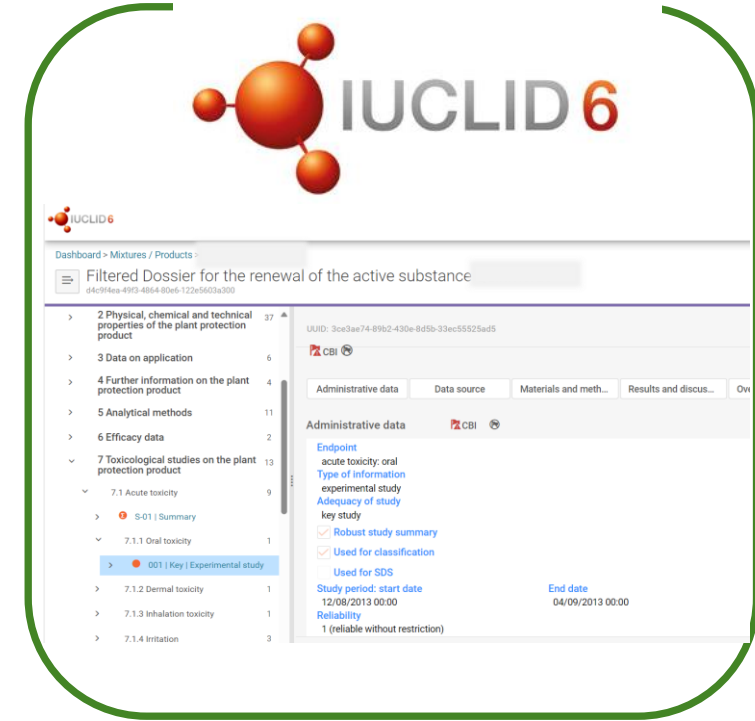
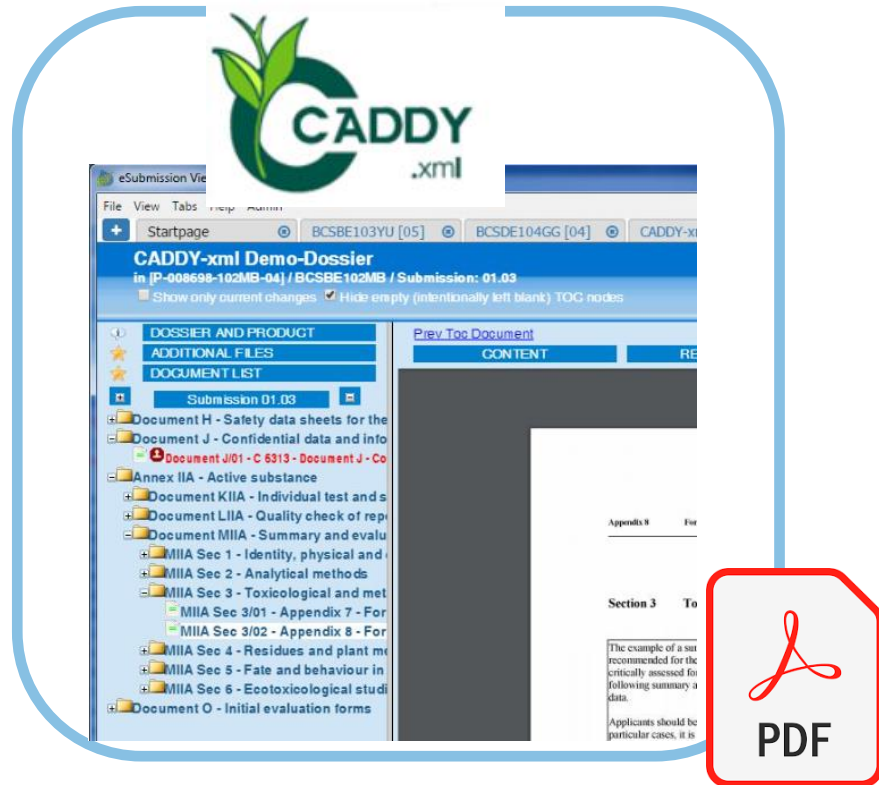
IUCLID Integration Platform

A companion tool for IUCLID

Georg Schifferdecker

CLE Conference 2024 - March 6

IUCLID – not just a new tool for Dossier submissions



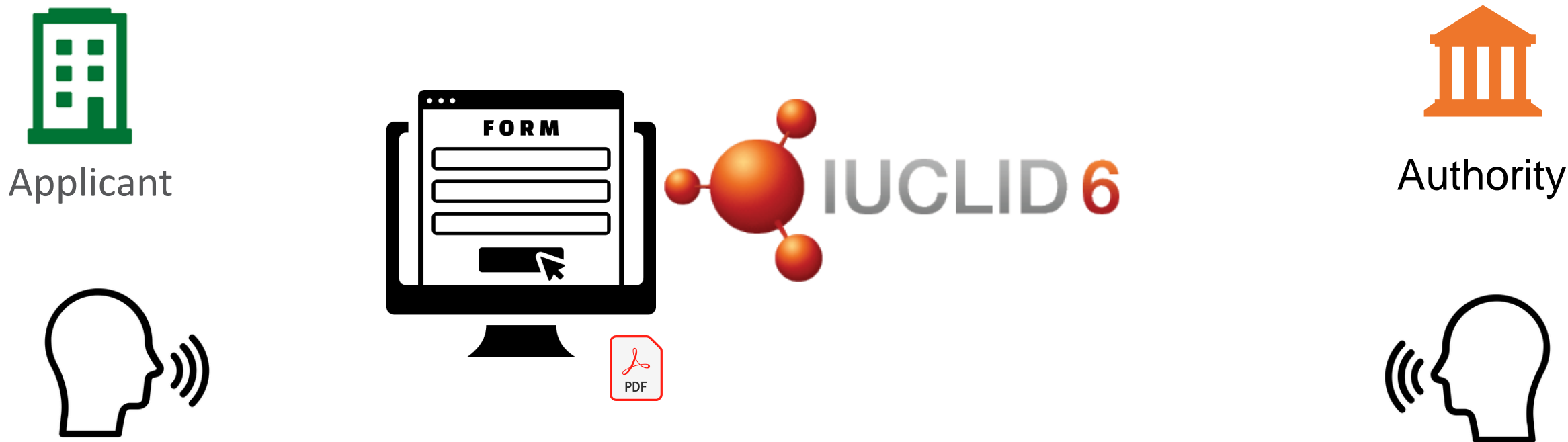
Paradigm Shift – from document-centric to data-centric submission
Promising move towards digitalisation

The EU submission process – prior to IUCLID



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

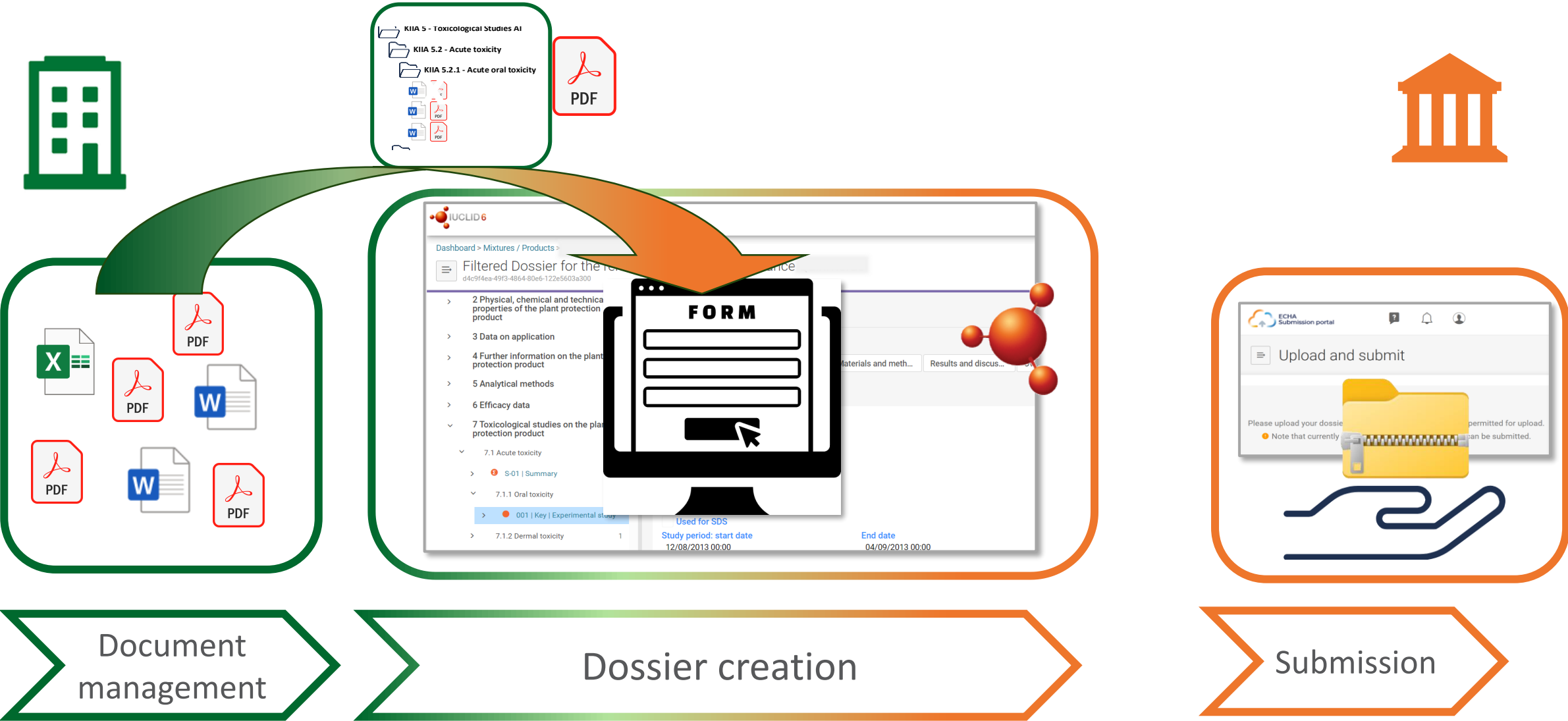
The EU submission process – from 2021 (for AS)



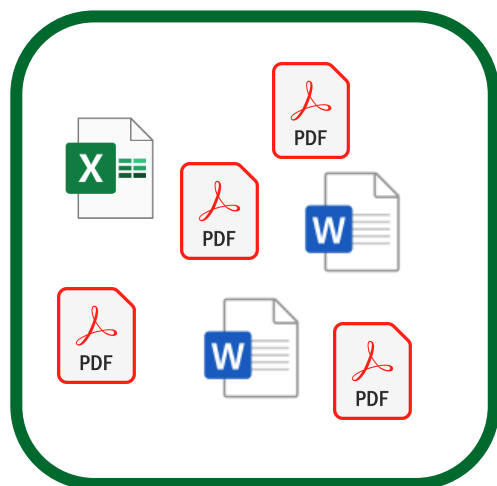
Major change

- ✓ 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



Document
management

Dossier creation



The EU submission process - IUCLID



Estimation of concentrations in ground water



Table 8 Tier 1 PEC_{gw} for [redacted] and its metabolites following application of 3 x 45 g ha⁻¹ (interval 10 d) to vines (BBCH 11)

Model	Crop	Scenario	90 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]		
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
		Placenza	0.011	0.222	1.179
		Porto	0.003	0.162	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
		Placenza	0.020	0.276	1.224
		Porto	0.006	0.269	1.039
MACRO 5.5.4	Vines	Sevilla	<0.001	0.098	0.890
		Thiva	<0.001	0.099	0.871
		Châteaudun	<0.001	0.132	1.248



Document management

Dossier creation

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

Select Substance

Sample Substance 6

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

Sample Substance 5

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

Sample Substance 4

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

Sample Substance 3

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

Sample Substance 2

Inventory number CAS number IUPAC name

Legal Entity Legal entity UUID

ca.

<

<=

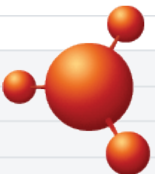
>

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Populating IUCLID – nested blocks



Residues In Rotational Crops



Content: Administrative April, 2022 M-CA Section 6 Page 85

RESIDUES DATA FROM SUPERVISED TRIALS - SUMMARY

Active substance (common name):
Crop/Crop group: **Wheat**

Responsible body for reporting (name & address):

Content of active substance (g/Kg or g/L):
Formulation number:
Formulation (e.g. WP):

Commercial Product (name):
Other active substance in the formulation (common name and content): (22.8 g/kg) and (68.3 g/kg)
Producer of commercial product:

Indoor/Glasshouse/Outdoor: Outdoor
Residues calculated as: mg/kg
Residue method and LOQ: 0.01 mg/kg LOQ

Study no. Report Reference:

1	2	3	4	5	6	7	8	9	10	11				
Trial code/ Location, Country	Crop/Variety	Date of: 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment	No. of trt(s)	Dates of treatments	Growth stage at treatments	Portion analysed	Residues (mg/kg)	Average Recovery (%)	PHI (days)	Remarks:		
	(a)	(b)	(c)	kg a.s./hL Water (L/ha)	kg a.s./ha	(d)	(e)	(a)			(f)	(g)		
S11-00971-01 40057, Granarolo, Bologna, Italy	Wheat/ Blasco	1) 26 Oct 10 2) May 11 3) 22 Jun 11	Overall application, boom sprayer with LD 015- F110 Lurmark nozzles	0.006	227	0.017	1	14 Apr 11	BBCH 39	Grain Straw	ND* ND*	94 93	69	No spray adjuvant
				0.006	293	0.018	1	14 Apr 11	BBCH 39	Grain Straw	ND* ND*	94 93	69	Codacide spray adjuvant added to spray mixture at ~ 2.45 L/h

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying, spreading, dusting etc, overall, broadcast, - type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: climatic conditions; references to analytical method; information concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.002 mg/kg; n/d = not detectable Note: All entries to be filled as appropriate N/A = Not applicable, **ND - Not detected.

Field

- Administrative data
 - Attached justification
 - Cross-reference
- Data source
- Materials and methods
 - Test guideline
 - Test material
 - Analytical methods
 - Analytical method (1/1)
 - Combinations of substance and analysed sample portion (1/1)
 - Fortification
 - Residue trials
 - Trial information (1/1)
 - Geographic location and soil characteristics
 - Plot description
 - Plot (1/1)
 - Application
 - Application (1/1)
 - Applied test material (1/1)
 - Active ingredients (a.i.) (1/1)
 - Sampling
 - Sampling and analysis of soil
 - Any other information on materials and methods incl. tables
 - Results and discussion
 - Summary of residues
 - Sampling and residues (1/1)
 - Residue levels (1/1)
 - Any other information on results incl. tables
 - Overall remarks, attachments
 - Attachments
 - Applicant's summary and conclusion

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 the IIP project web application interface. The top navigation bar shows the current document path: 'Testing March 2023 > complete document list > Estimation of concentrations in ground water.001'. Below this, a search bar and a 'Save' button are visible. The main content area is divided into three panels. The left panel, titled 'Document Type', lists various document types with their corresponding names: 'AnalyticalMethods' (Analytical methods.001), 'EstConcGroundwater' (Estimation of concentrations), 'GAP' (GAP 001), 'ResiduesInRotationalCrops' (Residues in crops (field trials)), and 'Short-termToxicityToFish_EU_PPP' (Short-term Toxicity to fish.00). The middle panel, titled 'Field', shows a list of fields for the selected document: 'Administrative data' (dataProtection), 'Link to relevant summary record(s)' (Summaries used as input parameters), 'Description of key information' (rich text), 'PEC ground water' (Input parameters in FOCUS ground water, Agronomic input parameters), 'Additional information' (rich text), and 'Attached background material'. The right panel, titled 'FLEXIBLE_SUMMARY.EstConcGroundwater Estimation of concentrations in ground water.001', contains a rich text editor with placeholder text and a table for 'PEC ground water'. The table has columns for '#', 'Use description', 'Parent / metabolite', 'Substance', 'Tier', 'Model', 'Scenario', 'PECgw', and 'Remarks'. It lists four entries for 'GAP 001' with different scenarios (Chateaudun, Hamburg, Kremsmunster, Piacenza) and remarks. Below the table is an 'Additional information' section with a rich text editor containing placeholder text.

#	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	Kremsmunster	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>

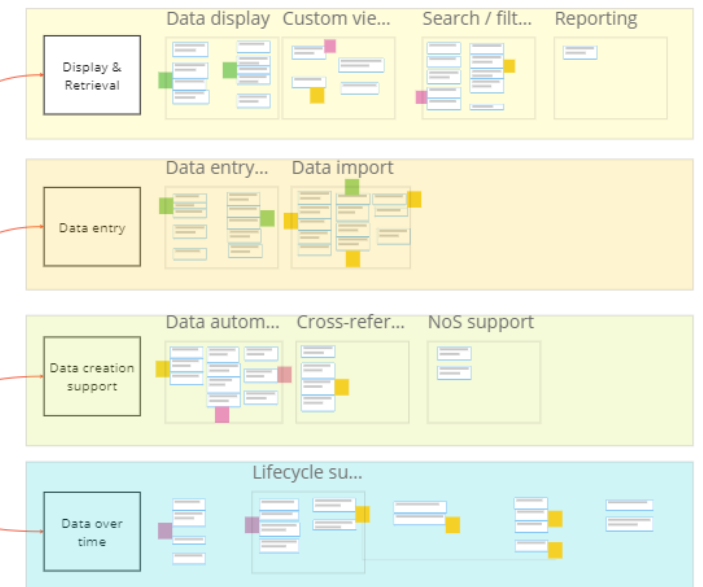
CLE IIP project – collected requirements



- 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



1	A	B	C	D
2	Max of PECgw(µg/L)()			Name(Substance)
3	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



GAP

Number of applications (range)
3

Re-treatment interval (in days)
5

Application rate per treatment (product) - range
0.3 - 0.5 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

Scenario ⁱ ^

Please select

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



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
5	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
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
2	Max of PECgw(µg/L)()			Name(Substance)
3	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		Remark 5



GAP



1	A	B
2	Column1	Column2
3	Number of applications (range)	3
4	Re-treatment interval (in days)	5
5	Application rate per treatment (product) - range	0.3 - 0.6 L/ha
6	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
7	Water amount per treatment / spray volume	150 - 400 L/ha
8	Concentration of formulation in dilution	0.75 - 4 mL/L
9	Safener / synergist / adjuvant added	no
10	Application rate per treatment for target a.s. (range)	50 - 100 g/ha
11	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
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)



Navigation bar with tabs: Administrative data, Data source, Background, Materials and met..., Results and discu..., Overall remar

Endpoint study record structure (Analytical methods.001):

- 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

Field search results (Σ 4 / 107):

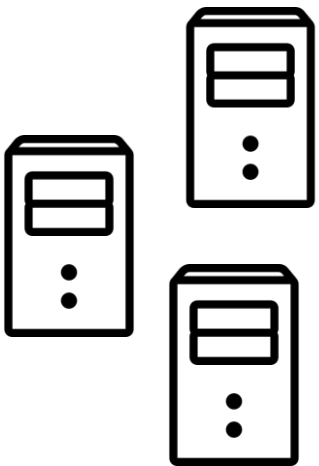
Field	
Residue method	
Residue method	
Residue method	
Residue method	

Field search

MRL applications	
Crop information	
Crop / treated object	3ALMC (Almond crops)
Genetical modification of cr...	no
Crop destination(s)	

Filled: yes / no

IIP – Data import with duplicate detection



AutoSave ☐ LIT_12of178.ief.csv

1	##Generated at 2024-03-01T18:36:07.372Z				
2	VERSION	IIP 1.4.0-SNAPSHOT			
3	TEMPLATE_VERSION	1.0			
4	IUCLID_VERSION	7.10.1			
5	DATE	YYYY-MM-DD			
6	TYPE	LITERATURE			
7	GeneralInfo.Company	IEF_ORIGINID	GeneralInfo.Li	GeneralInfo.Name	GeneralInfo.Author
8	788-00		study report	14C- i27: Metabol	Anonymous et al.
9	54-00		study report	14C-Pyridine and 14C-Phe	Anonymous et al.
10	184927/0202		study report	18-month carcinogenicity	Anonymous et al.
11	IEF_EMPTY		study report	28-day repeated dose derm	Anonymous et al.
12	IEF_EMPTY		study report	3-month oral toxicity in mi	Anonymous et al.
13	27/0669		study report	A field study to monitor the	Anonymous et al.
14	27/4778		study report	A toxicity test to Determine	Anonymous et al.
15	File No 27/4694		study report	A-7957 C: Report on auto-	Anonymous et al.
16	File No 27/4766				
17	File No 27/4766				
18	27/4820				
19	QF 3021/90/0181 No. 074918 Project report 7/90				
20	IEF_EMPTY				
21	IEF_EMPTY				

IIP Import Format

Jobs 138

Identifier	Name
788-00	14C-CGA 184927: Me
54-00	14C-Pyridine and 14C
184927/0202	18-month carcinogen
	28-day repeated dose
	3-month oral toxicity
27/0669	A field study to monit
7/4778	A toxicity test to Dete
File No 7/4694	A-7957 C: Report on i
File No 7/4766	A-7957 C: Report on i
File No 7/4766	A-7957 C: Report on i
27/4820	A-7957 C: Report on i
QF 3021/90/0181 No. 074918 Project report 7/90	Absorption, distribut
	Acute dermal irritation
	Acute Dermal Irritatio
	Acute Dermal Toxicity
CGA184927/4739	Acute Dose-Response
	Acute eye irritation / i

Update Candidates 1

Identifier	Name
7/4778	A toxicity test to Determine th

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

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	
A Year	2001
A Bibliographic source	
A Testing facility	
A Report date	2003-06-11
A Report number	108-433
A Study sponsor	
A Study number	

Other study identifier(s)

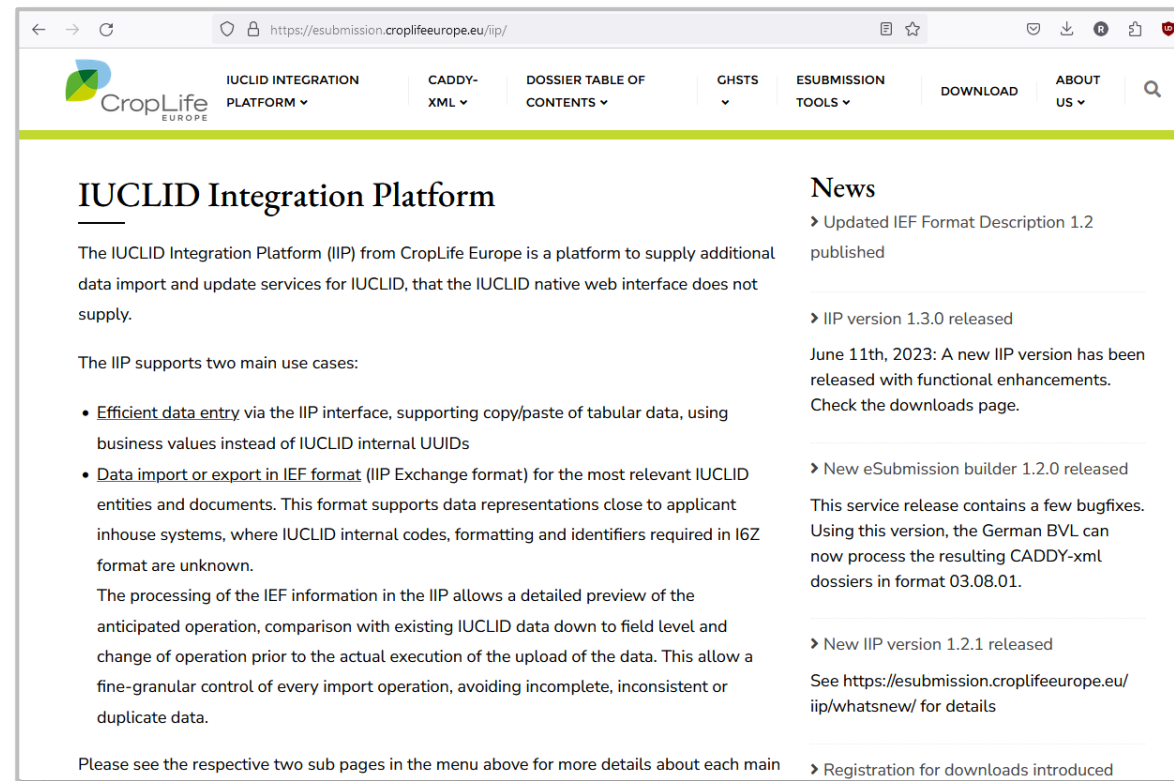
#	Study ID type	A Study ID	A Remarks
1.		sdfdsf	sdfdsf

Potential duplicate(s)



For more information

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



Please feel free to contact me

- during the conference
- by email - esubmission@croplifeeurope.eu

Thank you!

Questions?

Comments?

Suggestions?