Pesticide Steering Network
IUCLID Subgroup

15th meeting

15 – 16 April

EACL

European Association of Regulatory Consultants and Contract Research Laboratories

Points for discussion

- Active substance – Environmental fate
- Mixture – Environmental fate
- IUCLID – dissemination preview
- Ask a question
- Re-submission process
- IUCLID – reporting function

IUCLID improvements

Active substance - Environmental fate

- Required information for degradation kinetics (relevant for 7.1.1, 7.1.2. and 7.2.2.2, in single cases also for 7.2.1.1 and 7.2.1.2), i.e. specific parameters, quality criteria and graphs that need to be reported in the context of degradation studies are currently included under „additional information“.

  Specific fields would be helpful for the sake of clarity (see next slide).

IUCLID improvements

IUCLID_- Information for kinetic assessments

Executive summary

Description of key information

freetext

Material and Methods

freetext: include input parameter tables and describe conceptual models and data preparation

Normalisation

freetext

Table for persistence and modelling endpoints

IUCLID improvements

Soil	Texture (USDA)	Study $DT_{50/90}$ [d] a)	Kinetic model	Study Temp a) (Tact)	Study moisture content a) (q)		Grav. water content (q_{REF}) c)	Correction factor soil		Norm. $DT_{50/90}$ [d] b)
					Unit	Grav-%		Moisture $(q/q_{REF})^{0.7}$	Temperature e) $(2.58^{Tact-Tref/10})$	
Soil x	...	.../ ...	HS	30	50 % MWHC	41.1	22	0.953	2.580	.../ ...

MWHC: Maximum water holding capacity
a) Values under study conditions
b) Values at pF 2 and 20° C
c) Values at pF 2 / 100 % FC
d) Reference water contents as given in FOCUS (2000, 2014, 2021, 2023) and PPR Panel (2007)
e) Temperature correction factor: 2.58^(Tact-Tref/10) with Tref = temperature at reference conditions (20 °C), Tact = temperature under study conditions [°C]

IUCLID improvements

Results and discussion

freetext: describe the selection procedure for a specific kinetic model

optional: include this as remarks column in the following table

upload function for plots

Table according to Appendix H of the administrative guidance on peer review of pesticide active substances

Sub-stance	Soil	Kinetic model	Mo	Parameter (K, K1, k2, g, tb,α, β)	χ2, %-error	Prob>t	Lower CI	Upper CI	DT_{50} [days]	DT_{90} [days]	ff	R e-mark
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		
		DFOP	...	k1= k2= g=		... ...	... ...	... ...				
		HS	...	k1= k2= tb=		... ...	... ...	... ...				

- include formation fraction to metabolite into remark column or prepare additional column within the table

Overall summary and conclusion

freetext to summarize relevant/selected endpoints

IUCLID improvements

Active substance - Environmental fate

- Required information for batch equilibrium studies (relevant for 7.1.3): Specific information as requested in EFSA technical report doi:10.2903/sp.efsa.2017.EN-1326 currently have to be included as additional information.

  Specific fields for the requested information would increase clarity.

IUCLID improvements

IUCLID_- Information for adsorption/desorption chapter (7.1.3.1)

Executive summary

Description of key information

freetext

Results and discussion

include an upload function for plots according to the EFSA evaluator´s checklist EXCEL tool

Table according to data evaluation according to EFSA

IUCLID improvements

Table x: Summary of results of data evaluation according to EFSA for x

Soil/Matrix	**X1**	**X2**
Adsorption method	Direct/indirect	Direct/indirect
Soil solution ratio (g dw/mL)	x	x
Mass balance	x	x
Adsorbed percentage	x	x
Kd x soil:solution ratio	x	x
ads Kd [L/kg dw]	x	x
ads Kd,OC [L/kg OC]	x	x
Kfe/Kf	x	x

Overall summary and conclusion

freetext to summarize relevant/selected endpoints

IUCLID improvements

Active substance - Environmental fate

- “Local and global effects” could be moved from 7.6 to 7.3 as the assessment is based on the fate and behaviour in air guidance reflected in chapter 7.3.

IUCLID improvements

Drinking water treatment assessment

New data points related to the recent EFSA guidance on the impact of water treatment processes in drinking water (EFSA Journal 2023;21(8):8194) are reflected in the “draft amended data requirements (COM Reg. (EU) 283/2013 and 284/2013)” under CA 7.2.4 and CP 9.2.6 “Effects of water treatment processes”.

Will those points be included in the new IUCLID version which will be released in April 2026?

IUCLID improvements

Mixture - Environmental fate

We were asked by MSs to provide within the AIR process as well as in the product authorization process PEC raw data for several uses, several scenarios and several mitigations.

Providing such data within IUCLID is not possible due to the amount of data (could be several GB!) only possible using a work around [separate ES e.g. under IUCLID point 9.2.5; as the actual summary was already too large to append any files at all].

Who will decide whether such data should be filed via IUCLID?

In case such data should be provided the issue will be even greater for product dossiers due to the amount of data for several uses.

IUCLID improvements

Change log

In case data could only be added as additional information in IUCLID
(e.g. PEC reports / raw data),
a related reference could not be included in the change log.

IUCLID – dissemination preview

- Setting of the CBI flag in IUCLID dossiers for active substance (re-)approvals discussed with EFSA:

IUCLID point containing the composition of plant protection product (chapter 1.4 in the mixture dataset) allows setting the CBI flag for each line containing co-formulant data.

This line is correctly removed when generating the filtered dossier and the co-formulant information seems inaccessible in the filtered dossier. However, we noted that the dissemination preview still lists the related reference substances for the co-formulant as ‘published’.

The same is the case for impurities (setting the CBI flags in the tables with e.g. batch composition led to removal of the impurity data in the filtered dossier but reference substance information was still given in the dissemination preview).

To be on the safe side, CBI flags could be set in each reference substance related to co-formulants and impurities, but this is a lot of work and led to the need for creation of additional reference substances for compounds that are both an impurity and a metabolite (which is rather common for chemical active substances). In such cases, for the same substances a reference substance including CBI (as impurity) and one without CBI (as metabolite) were created.

IUCLID – dissemination preview

- Thus, we discussed with EFSA if it is really needed to set CBI flags in each reference substance that should not be published or if the dissemination preview might be misleading.
- EFSA confirmed that Reference Substance Entities should not be flagged confidential, also to facilitate their reuse across different dossiers/legislations. The outcome of the simulation of the Filtered Dossier is correctly reflecting this and corresponds to what the outcome would be if EFSA were to filter the dossier and publish it.
- The apparent discrepancy between the filtered dossier and the outcome of the Dissemination Preview were flagged to ECHA by EFSA.

Is there the intention to fixed it in the upcoming IUCLID 6 v. 10 release, scheduled for go-live on 27 April 2026?

Ask a question

- Is it possible that specific replies to questions raised via “Ask a question” could be published by EFSA (in a „sanitised“ / generalised version)?

  Related replies could also be helpful for other applicants.

IUCLID reporting

GHS classification and labelling report

Why is there a hint to the Australian Regulatory Controls included (for details see next slide)?

IUCLID reporting – cont.

Australian Regulatory Controls – Human health hazards

Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement	Reason for no classification	Reason for classification
Acute toxicity - oral:	Acute Tox. 4	H302: Harmful if swallowed.		based on the substance itself; Acute oral toxicity study in rats, CA 5.2.1/02
Acute toxicity - dermal:			data conclusive but not sufficient for classification	
Acute toxicity - inhalation:			data conclusive but not sufficient for classification	
Skin corrosion / irritation:			data conclusive but not sufficient for classification	
Serious damage / eye irritation:			data conclusive but not sufficient for classification	
Respiratory sensitisation:			data conclusive but not sufficient for classification	
Skin sensitisation:			data conclusive but not sufficient for classification	
Aspiration hazard:			data conclusive but not sufficient for classification	
Reproductive Toxicity:			data conclusive but not sufficient for classification	
Reproductive Toxicity: Effects on or via lactation:			data conclusive but not sufficient for classification	
Germ cell mutagenicity:			data conclusive but not sufficient for classification	
Carcinogenicity:			data conclusive but not sufficient for classification	
Specific target organ toxicity – single exposure:	STOT Single Exp. 3 Route of exposure: inhalation	H335: May cause respiratory irritation.		based on the substance itself; Medical data CA 5.9.3/03
Specific target organ toxicity – repeated exposure:	STOT Rep. Exp. 2 Route of exposure: oral	H373: May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.		based on the substance itself; Repeated dose toxicity study in rats and dogs, CA 5.3.2/02, CA 5.3.2/03
Endocrine disruption for human health				

Australian Regulatory Controls – Environmental hazards

IUCLID – re-submission process

During re-submission the following business rule has been received:

BR 911: “When submitting an update for a successful notification, the same ´European reference number´ must be used to ensure that the dossiers are correctly linked. There is already a successful notification for the same dossier type, legal entity, and active substance. Therefore, it appears that this notification should have used the same ´European reference number´ XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX.”

[The received text is different from the one published in “IUCLID for PPP – validation submission rules”.]

We learnt that EFSA’s internal processing system is strongly dependent on the European Reference Number (ERN) and on the parameters associated to it - Legal Entity (LE) and active substance identifiers.

IUCLID – re-submission process

Stronger submission checks have been introduced with the IUCLID 6.9 release in 2025 and the following steps might be needed:

Generate a new ERN and paste the ERN of the last successful submission in the dossier submission remarks field of the dossier header also mentioning that this change was agreed with EFSA. Please never change the ERN without agreeing this with EFSA.

BR908 failure (which will subsequently be triggered as a consequence of the above) requires a change to the substance identifiers. In this case as you have already provided all the identifiers, the only way forward is to change the IUPAC name (current IUPAC name could be added under the Description field below)

Do we have the correct understanding of the whole process?

Are further rules planned to be introduced at submission portal stage?

IUCLID – reporting function

- Literature reference:

  Interest to get a report in which IUCLID data set, the references are cited [as a kind of submission viewer].

Thank you very much!

