

IUCLID Feedback

14th IUCLID PSN meeting Monika Bross, Marc Teiwes, Yoko Owaki & Andrew Whyte

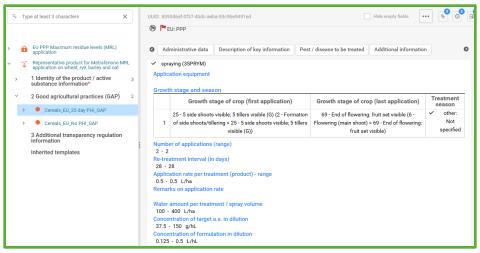
4th November 2025

IUCLID DAR & MRL Evaluation reports

- Several request received to check the completeness and correctness of reports in full
 - > Beyond what is described in Admissibility checklist

Reports can be insufficient/fail for various reasons

- Dossier has been compiled under an earlier IUCLID Version
- Applicant has used different fields than the ones used in the report
- **9** Bug in report template





		F, G or I	Pests controlled	Preparation		Application				Application rate per treatment					
Crop / situation	MS / country			Type	Conc. a.s.	Method / kind	Growth stage and season	No. min- max	Interval (days) min-max	Conc. a.s. in dilution min- max (g/hL)	Water min-max (L/ha)	A.s. rate min-max	Unit	(days)	Remarks
Avera sativa (Common oat) (AVESA): Hordeum vulgare (Barley) (HORVX): Secula coreale (Rye) (SECCE): Titicum aestivum (Bread wheat) (TRZAX): Triticum spela (Spel) Triticum spela (Spel) (TRZDY): X Triticoscale sp. (Tritica) (TTLSX): X Triticoscale sp. (TT	CEU (EU)	F	Not specified (Erysiphe graminis) Not specified (Oculimacula yallundae (PSDCHE)) Not specified (Pyrenophora teres (PYRNTE))	SC Suspension concentrate (= flowable concentrate)	300 g/L	spraying (SSPRYM) on follage/plant	BBCH 25 - 69 (Not specified)	2 - 2	28 - 28	37.5 - 150	100 - 400	150 - 150	g/ha	35	Crop destination: grown harvesting fresh (3HFR relevant. User: professi App. rate product: 0.5 - ha.
Avera sativa (Common oat) (Aversa); Hordeum vulgare (Barley) (HORVX); Secale cereale (Rye) (SECCE); Triticum aestivum (Bread wheat) (TRZAX); Triticum spita (Spita); Triticum spita (Spita); Triticum spita (Spita); X Triticosecale spita; Trit	CEU (EU)	F	Not specified (Erystphe graminis) Not specified (Oculimacula yallundae (PSDCHE)) Not specified (Pyrenophora teres (PYRNTE))	SC Suspension concentrate (= flowable concentrate)	300 g/L	spraying (SSPRYM) on foliage/plant	BBCH 25 - 61 (Not specified)	2 - 2	21 - 21	37.5 - 150	100 - 400	150 - 150	g/ha	n.a.	Crop destination: grow harvesting fresh (3HFR) relevant. User: professi App. rate product: 0.5 - hs. PHI remarks: Not applicable

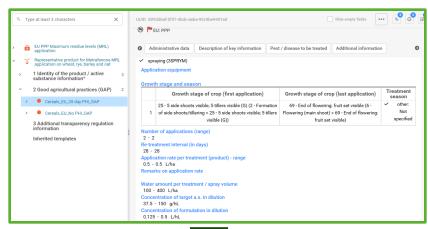


IUCLID DAR & MRL reports

Such requests pose a Problem for applicants

- DAR/RAR/MRL Evaluation report are not in the applicant's responsibility
- Checking of reports is a very time-consuming task
- Report templates (ftl Format) are not human readable hence we search for the needle in the haystack in a black box
- The IUCLID Version issue is currently unsolvable without creating endless update cycles causing a new layer of delays to the processes

RMS/EMS would likely face the same issues







Report generator



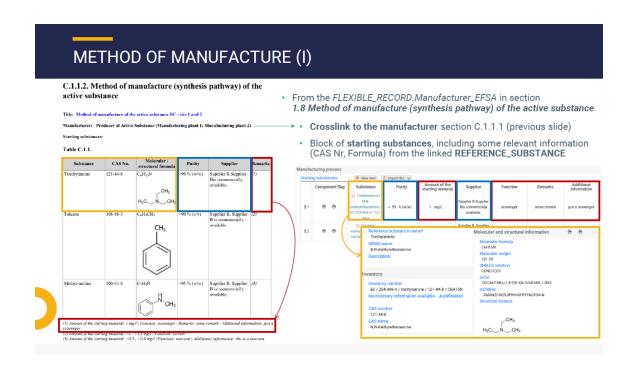
∃l	Crep / situation	MS / country	F.	Pests controlled	Preparation		Application				Application rate per treatment					
IUCLID 6 v9.0.1					Туре	Conc. a.s.	Method / kind	Growth stage and season	No. min- max	Interval (days) min-max	Conc. a.s. in dilution min- max (g/hL)	Water min-max (L/ha)	A.s. rate min-max	Unit	PHI (days)	Remarks
MRI Report	Avens astiva (Common out) (AVESA): Herdeum velgare (Barley) (HORVX): Seatle create (Rye) (SECCE): Trittom sentivam (Bread wheat) (TREAN): Trittom duran (Darum wheat) (TREAN): Trittom gelat (Spel) (TREAN): a Trittom gelat (Spel)	CEU (EU)	F	Not specified (Erysiphe graminis) Not specified (Oculimacula yallundae (PSDCHE)) Not specified (Pyresophora teres (PYRNTE))	SC Suspension concentrate (= flowable concentrate)		spraying (SSPRYM) on foliage/plant	BBCH 25 - 69 (Not specified)	2 - 2	28 - 28	37.5 - 150	100 - 400	150 - 150	g/ha	35	Crop destination: grow harvesting fresh (3HF) relevant. User: profess App. rate product: 0.5 ba.
Panort	Avens sulvo (Cormon out) (AVESA): Indicate volgare (Barley) (#GREVS): Secale corease (Rye) (SECCE): Triticum aestivum (Bread wheat) (TRZAM): Triticum dueum spelus (SPCE): Triticum spelus (SPCE): Triticum spelus (SPCE): Triticum spelus (TRZAM): Tr	CEU (EU)	F	Not specified (Erysiphe graminis) Not specified (Oculimacula yallundae (PSDCHE)) Not specified (PSDCHE)) Not specified (Pyrenophora teres (PYRNTE))	SC Suspension concentrate (= flowable concentrate)		spraying (SSPRYM) on foliage/plant	BBCH 25 - 61 (Not specified)	2-2	21 - 21	37.5 - 150	100 - 400	150 - 150	g/ha	na.	Crop destination: grow harvesting fresh (3HF) relevant. User: profess App. rate product: 0.5 ha. PHI remarks: Not applicable



IUCLID DAR & MRL reports – next steps

The need for QC of the Report is clear and understood, but pushing it to the applicant is not the solution

- More guidance on how IUCLID and resulting report go together (as e.G. done in the WP on Confidential Volume 4)
- More detailed Validation rules ? difficult to keep robust to cover for exceptional cases
- Keep older report Versions alive ? mititgation of the Version issue



Further ideas ??



Streamlining MRL Submissions: New Option to Reduce Duplicate Efforts

Current situation:

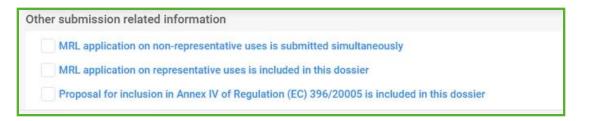
• If the GAP relevant for the MRL dossier is different from the representative use of the AS dossier, a separate MRL dossier is required.

3.1-b: If the GAP(s) relevant for the MRL dossier is/are different compared to the GAPS(s) for representative use(s) of the approval/renewal dossier, a separate MRL dossier is required. GAP document(s) relevant for the MRL application (e.g. GAP for non-representative uses) must be created only in the MRL dossier. GAP document(s) relevant for the representative uses (within the approval/renewal application) must be created only in the approval/renewal dossier.

- However, there are cases that same residue data package is used for both AS approval/renewal and critical GAP for MRL setting.
- ▲ This creates additional efforts for Applicants to generate two dossiers without new scientific evidence and for RMS to review two dossiers.

Proposal:

 Add/modify "Other submission related information" in the dossier header of AS dossier



- Add the 4th option
 - MRL application on non-representative uses is included in the dossier using the same residue data as representative uses OR
 - Other + free text field to provide a description
- Modify the 2nd option to "MRL application on representative uses or non-representative uses is included in this dossier using the same residue data"



