



**CropLife**  
EUROPE

# IUCLID Feedback

14<sup>th</sup> IUCLID PSN meeting

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# 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

The screenshot shows the IUCLID application form for a Pesticide (PPP). The left sidebar lists the application type as 'EU PFP Maximum residue levels (MRL) application' and the product as 'Representative product for Metrafenone MRL application on wheat, rye, barley and oat'. The main form is divided into sections: Administrative data, Description of key information, Pest / disease to be treated, and Additional information. The 'Additional information' section is expanded, showing 'Application equipment' and 'Growth stage and season'. The 'Growth stage and season' table has two rows: 'Growth stage of crop (first application)' and 'Growth stage of crop (last application)'. The first row shows '25 - 5 side shoots visible; 5 tillers visible (G) (2 - Formation of side shoots/tillering > 25 - 5 side shoots visible; 5 tillers visible (G))'. The second row shows '69 - End of flowering: fruit set visible (6 - Flowering (main shoot) > 69 - End of flowering: fruit set visible)'. The 'Treatment season' column is checked for 'other: Not specified'.

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
- ⚡ Bug in report template



INCLID 6 v9.0.1

MRL Report

Table Appendix A.1.

Crop / situation	MS / country	P. G or I	Pests controlled	Preparation		Application		Application rate per treatment				PHI (days)	Remarks		
				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/L)	Water min max (L/ha)	A.s. rate min max	Unit		
Avena sativa (Common oat) (AVESA) ; Hordeum vulgare (Barley) (HCRVX) ; Secale cereale (Rye) (SECCB) ; Triticum aestivum (Bread wheat) (TEZAX) ; Triticum durum (Durum wheat) (TRZDX) ; Triticum spelta (Spelt) (TRZSP) ; * Triticosecale sp. (Triticale) (TTLSS)	CEU (EU)	F	Not specified (Erysiphe graminis)	SC Suspension concentrate (= flowable concentrate)	300 g/L	spraying (USPRYM) on foliage/plant	HBCH 25 - 69 (Not specified)	2 - 2	28 - 28	37.5 - 150	100 - 400	150 - 150	g/ha	35	Crop destination: grown for harvesting fresh (SHEFRED), not relevant. User: professional. App. rate product: 0.5 - 0.5 L/ha.
			Not specified (Oculimacula yallandae (PSDCHB))												
			Not specified (Pyrenopeziza teres (PYRNTE))												
Avena sativa (Common oat) (AVESA) ; Hordeum vulgare (Barley) (HCRVX) ; Secale cereale (Rye) (SECCB) ; Triticum aestivum (Bread wheat) (TEZAX) ; Triticum durum (Durum wheat) (TRZDX) ; Triticum spelta (Spelt) (TRZSP) ; * Triticosecale sp. (Triticale) (TTLSS)	CEU (EU)	F	Not specified (Erysiphe graminis)	SC Suspension concentrate (= flowable concentrate)	300 g/L	spraying (USPRYM) on foliage/plant	HBCH 25 - 61 (Not specified)	2 - 2	21 - 21	37.5 - 150	100 - 400	150 - 150	g/ha	n.a.	Crop destination: grown for harvesting fresh (SHEFRED), not relevant. User: professional. App. rate product: 0.5 - 0.5 L/ha. PHI remarks: Not applicable
			Not specified (Oculimacula yallandae (PSDCHB))												
			Not specified (Pyrenopeziza teres (PYRNTE))												



# 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 ? – mitigation of the Version issue

## METHOD OF MANUFACTURE (I)

### C.1.1.2. Method of manufacture (synthesis pathway) of the active substance

Title: Method of manufacture of the active substance BC-site 1 and 2

Manufacturer: Producer of Active Substance (Manufacturing plant 1; Manufacturing plant 2)

Starting substances:

Table C.1.1.

Substance	CAS No.	Molecular / structural formula	Purity	Supplier	Remarks
Triethylamine	121-44-8	<chem>CCN(CC)CC</chem>	>99 % (w/w)	Supplier B. Supplier B is commercially available.	(7)
Toluene	108-88-3	<chem>Cc1ccccc1</chem>	>90 % (v/v)	Supplier B. Supplier B is commercially available.	(2)
Methyl-aniline	100-61-8	<chem>CN(C)Cc1ccccc1</chem>	>95 % (w/w)	Supplier B. Supplier B is commercially available.	(3)

(1) Amount of the starting material: 1 mg/l; Function: scavenger; Remarks: some remark; Additional information: just a scavenger  
(2) Amount of the starting material: >0.5 - <0.8 mg/l; Function: solvent  
(3) Amount of the starting material: >0.5 - <0.8 mg/l; Function: reagent; Additional information: this is a reagent

- From the *FLEXIBLE\_RECORD.Manufacturer\_EFSA* in section 1.8 Method of manufacture (synthesis pathway) of the active substance

- Crosslink to the manufacturer section C.1.1.1 (previous slide)

- Block of starting substances, including some relevant information (CAS Nr, Formula) from the linked REFERENCE\_SUBSTANCE

Component flag	Substance	Purity	Amount of the starting material	Supplier	Function	Remarks	Additional information
I1	Triethylamine N,N-diethylethanamine EC 204-469-4 / 121-44-8	> 99 % (w/w)	1 mg/L	Supplier B. Supplier B is commercially available.	scavenger	some remark	just a scavenger
I2	methy... Reference substance name* Triethylamine IUPAC name N,N-diethylethanamine Description Inventory Inventory number EC / 204-469-4 / triethylamine / 121-44-8 / C6H15N No inventory information available - Justification CAS number 121-44-8 CAS name N,N-diethylethanamine						

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 GAP(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

### Other submission related information

- ☐ MRL application on non-representative uses is submitted simultaneously
- ☐ MRL application on representative uses is included in this dossier
- ☐ Proposal for inclusion in Annex IV of Regulation (EC) 396/20005 is included in this 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“

**Goal: Minimize unnecessary efforts for Applicant and RMS**



The background of the slide is a close-up photograph of lush green leaves, likely from a citrus tree, showing detailed vein patterns and vibrant color. A large, dark green rounded rectangle is overlaid on the right side of the image.

**Thank You!**