

Expert Group on General Food Law, 26 June 2020



EFSA technical group IUCLID for Pesticides

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Trusted science for safe food

International **U**niform **C**hemical **I**nformation **D**atabase

What is it used for?

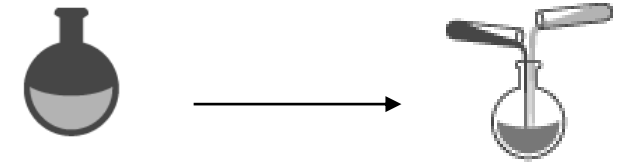
- IUCLID is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances in a structured format.
- In the EU it is used in the regulatory framework of the Biocidal Products Regulation, CLP Regulation, REACH Regulation.
- IUCLID will be used to support Plant Protection Products, active substances dossiers (Regulation (EC) No 1107/2009) and for MRL applications (Regulation (EC) No 396/2005).
- Minimum Viable Product (MVP) under development for the submission and management of pesticides dossiers by March 2021 in collaboration between ECHA and EFSA.

For Whom

- Regulatory bodies (EU and non-EU), Industry, General public (published data)

- EFSA Technical Group on IUCLID for PESTICIDES (Nov 2019 – June 2021)
 - Representatives of MSs (x7), Industry representatives (x3), ECHA
 - Creation of several submission types (x8)

- EU PPP Active Substance (representative product)
- EU PPP Plant protection product authorisation
- EU PPP Other substance for assessment
- EU PPP Active substance applications (representative product)
- EU PPP Other mixtures (mixture not a product, not a representative product)



As of March 2020

- EU PPP Maximum Residue Level
- EU PPP Microorganisms (representative product and product authorisation)
- EU PPP Basic substance information

Submission Type:

EU PPP Active substance information



- 1. Identity of the active substance 8
- 2. Physical and chemical properties of the active substance 72
- 3. Further information on the active substance 8
- 4. Analytical methods 56
- 5. Toxicological and metabolism studies on the active substance 93
- 6. Residues in or on treated products, food and feed 61**
- 7. Fate and behaviour in the environment 56
- 8. Ecotoxicological studies on the active substance 93
- 10. Classification and labelling of the active substance 3
- 11. Summary and evaluation 11

Submission Type: EU PPP Active substance information

EU PPP Active substance information

- 1. Identity of the active substance 1
- 2. Physical and chemical properties of the active substance
- 3. Further information on the active substance 2
- 4. Analytical methods
- 5. Toxicological and metabolism studies on the active substance
- 6. Residues in or on treated products, food and feed**
- 7. Fate and behaviour in the environment 1
- 8. Ecotoxicological studies on the active substance 4
- 10. Classification and labelling of the active substance
- 11. Summary and evaluation 1

6 Residues in or on treated products, food and feed + New

6.1 Storage stability of residues + New

6.2 Metabolism, distribution and expression of residues + New

6.2.1 (Cf. 6.6.1) Plants

6.2.2 (Cf. 6.2) Poultry

6.2.3 (Cf. 6.2) Lactating ruminants

6.2.4 (Cf. 6.2) Pigs

6.2.5 (Cf. 6.2) Fish

6.3 Magnitude of residue trials in plants + New

6.4 Feeding studies + New

6.4.1 (Cf. 6.4) Poultry

6.4.2 (Cf. 6.4) Ruminants

6.4.3 (Cf. 6.4) Pigs

6.4.4 (Cf. 6.4) Fish

6.5 Effects of processing

6.5.1 Nature of the residue + New

6.5.2 (Cf. 6.3) Distribution of the residue in peel and pulp

6.5.3 Magnitude of residues in processed commodities + New

6.6 Residues in rotational crops

6.6.1 Metabolism in rotational crops + New

6.6.2 (Cf. 6.3) Magnitude of residues in rotational crops

6.7 (Cf. 11) Proposed residue definitions and maximum residue levels

6.7.1 (Cf. 11) Proposed residue definitions

6.7.2 (Cf. 6.9) Proposed MRLs and justification of the acceptability of the levels

6.7.3 (Cf. 6.9) Proposed MRLs and justification of the acceptability for imported

products, imp. tolerance

6.8 (Cf. 3.8) Proposed safety intervals

Estimation of the potential and actual exposure through diet

6.9 + New

and other sources

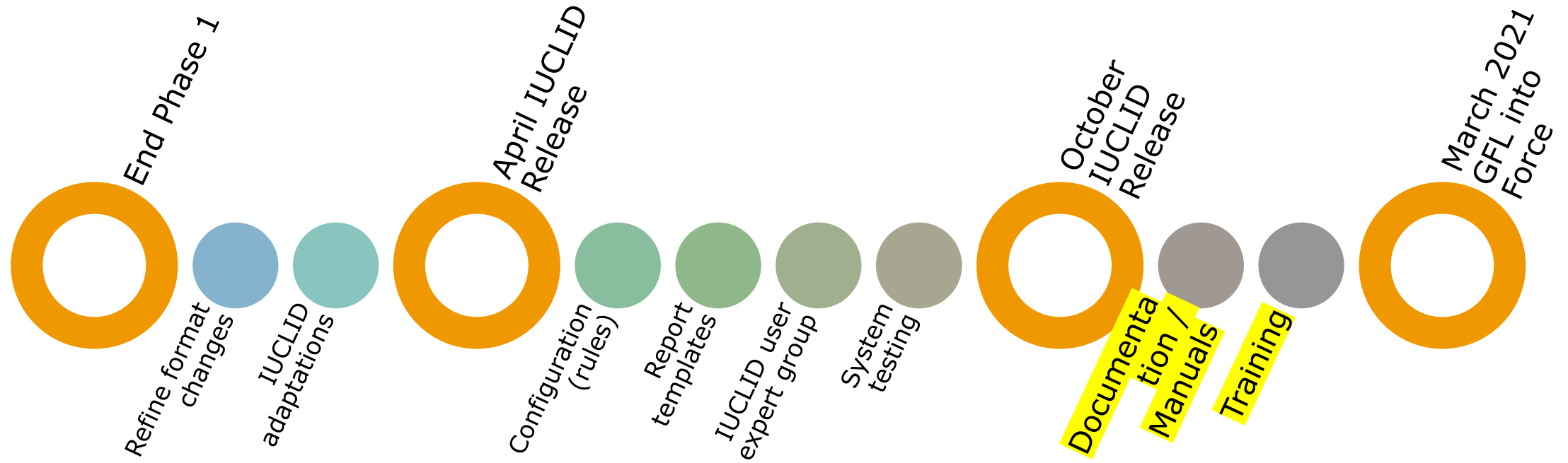
6.10 Other studies + New

6.11 Summary of information on residues in livestock and crops + New

6.12 Migration of residues into and their behaviour on food or feeding stuffs + New

↑ TOP

IUCLID - Next Phase



ANNEX

■ Preparation of the product dossier



PPP dossier is created based on a pesticides mixture / product dataset



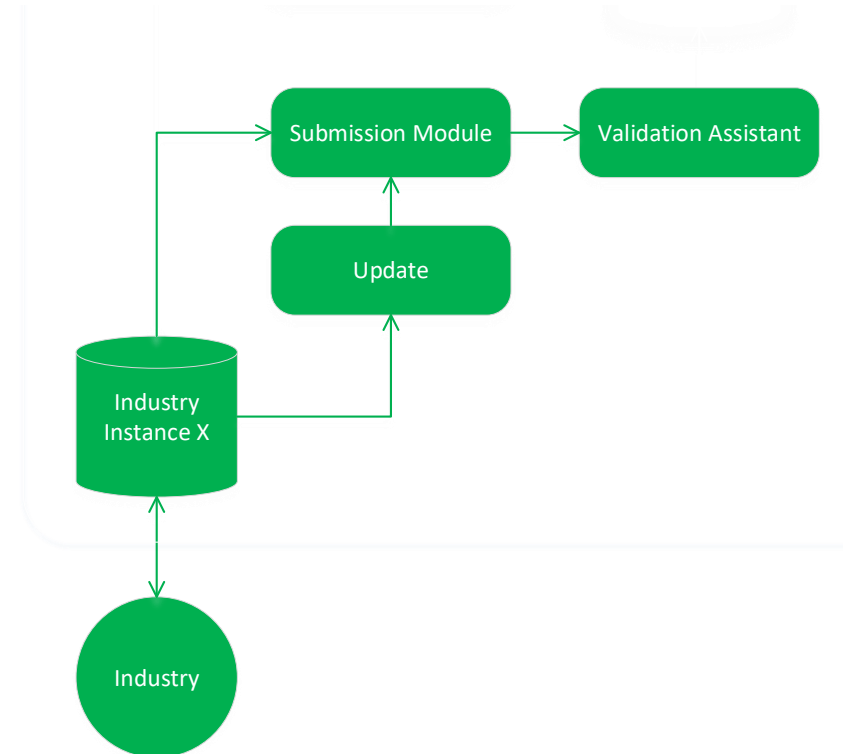
Pesticides datasets:

- editable
- prepared by the applicant
- can be updated

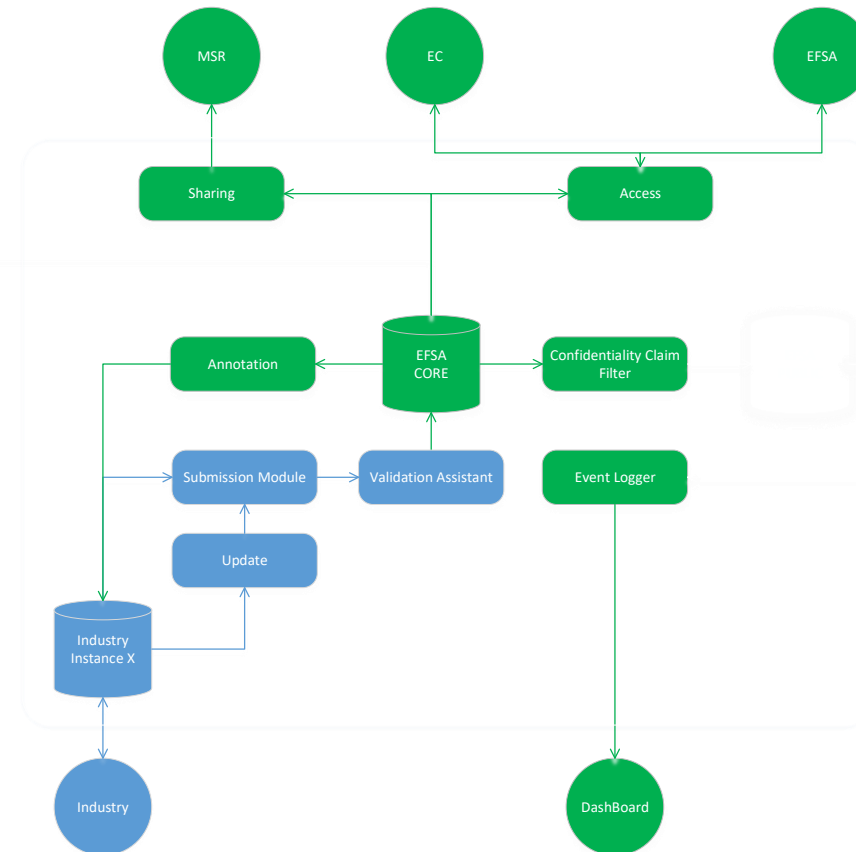
Pesticides dossier:

- read only for submission
- evaluated by the RMS or EFSA
- two dossier types:
 - PPP Active substance application (representative product)
 - PPP Plant protection product authorisation

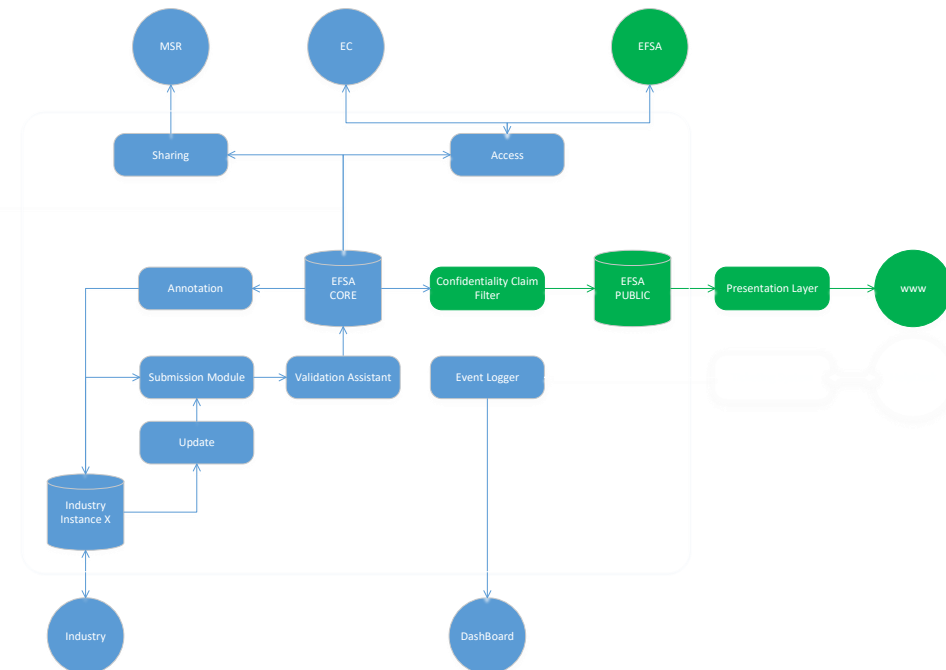
- Authenticated and hosted PPP authorisation platform supporting
 - Dossier Preparation
 - Confidentiality Claiming
 - Dossier Submission and Updating
 - Dossier Validation
 - Dossier Versioning
 - Reuse of datasets
- Submission support for
 - New Submissions
 - Renewal Submissions
 - Update to ongoing authorisation

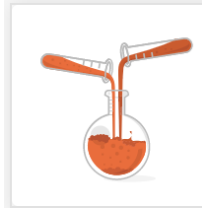


- Automated Actions on Dossiers
 - Dossier Validation
 - Cross Checking with related data
 - Notifications
 - Dossier public data readied for publication
- Assessment Tools
 - Dossier dashboard
 - Commenting / Annotation
 - Contextual menu for operations



- Accessible website hosting all public aspects of dossiers (dossier viewer)
- Sanitised dossiers only hosted on public instance i.e. all confidential items are removed and a public consumable dossier generated
- Means to transfer public dossiers between instances to support EFSA dossier review in advance of publication





- 1) Agreement on the structure of the sections
- 2) Check of existing **OECD endpoint study records (OHTs)** to report results from individual studies for their suitability for the residue area and highlighting for future improvements
- 3) Creation of **endpoint summary reports** for several studies and highlighting for future adaptations.
- 4) Agreement to report some data as attachments for interim period until final endpoint study and summary records will be available (after March 2021)



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