

2nd Sounding Board meeting
20 July 2020

IUCLID for Pesticides

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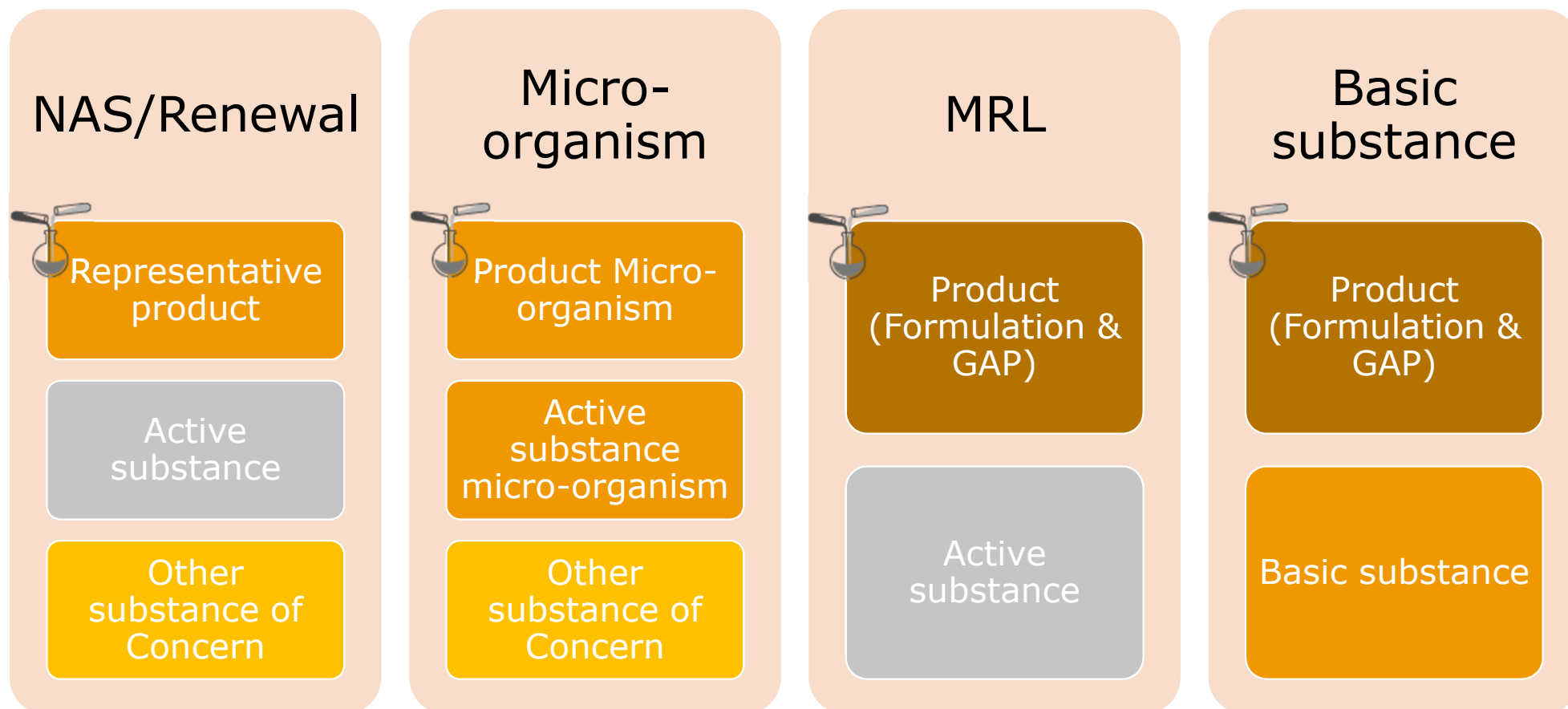
Trusted science for safe food

- EFSA Technical Group on IUCLID for PESTICIDES (Nov 2019 – June 2021)
 - Representatives of MSs (x7), ECHA, Business and Food Industry (x3)
 - Creation of several submission types in IUCLID
 - ECHA implementing for next release IUCLID OCT 2020

Available in IUCLID today:

- Three **Proof of Concept** dossiers
 - New Active Substance
 - Renewal
 - Micro-organism

PESTICIDE Submission types in IUCLID OCT 2020





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

6.1 Storage stability of residues

6.2 Metabolism, distribution and expression of residues

- 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

6.4 Feeding studies

- 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

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

6.5.3 Magnitude of residues in processed commodities

6.6 Residues in rotational crops

6.6.1 Metabolism in rotational crops

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 and other sources

6.10 Other studies

6.11 Summary of information on residues in livestock and crops

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

Support until March 2021

Trainings

- **Documentation** (e.g. user manual, video tutorials, quick guides) will be provided to define and explain how to use IUCLID for PESTICIDES
- **Online training** will be provided
- **Helpdesk** hosted by EFSA will be provided for IUCLID related questions

Next **IUCLID Core Team meetings** will be held in October 2020 and January 2021

PRIORITIES POST MARCH 2021

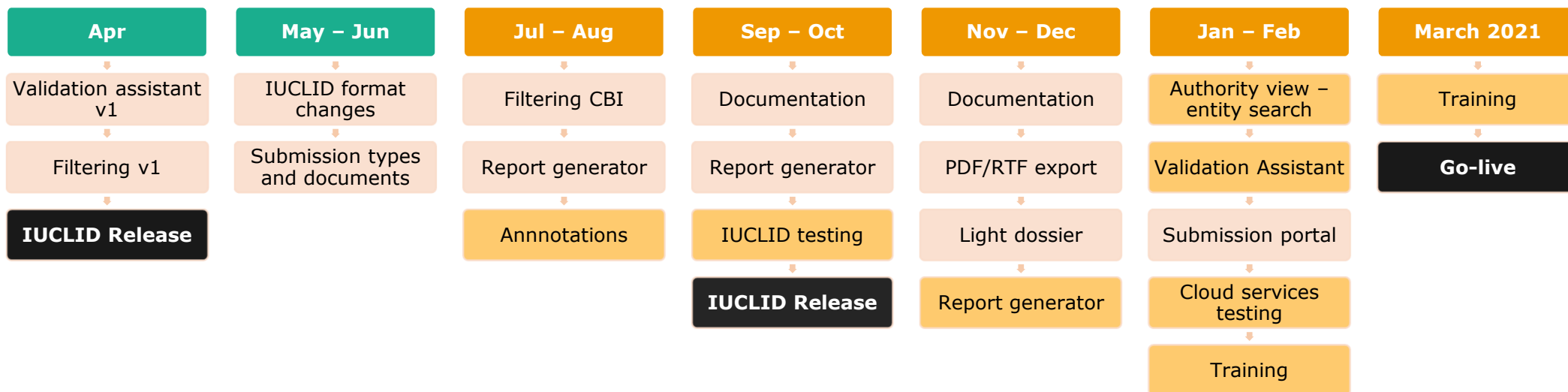
- **Very high priority:**

- **Report** generator
- **Rich Text Field** formats to support evaluation report preparation

- **High priority:**

- Defining and managing the **dossier life-cycle** (versioning)
- **Annotations** for evaluators; with a focus on the format for integration within evaluation reports
- **Interoperability** with national systems and databases
- Renewal dossiers; aggregation and information sharing between applicants
- Further adaptations to IUCLID format (higher tier studies and risk assessment) and alignment with data requirements revision for micro-organisms
- Advanced **validation assistant** for pesticides (within and between document checks)
- Enhancements to **confidentiality** and filtering

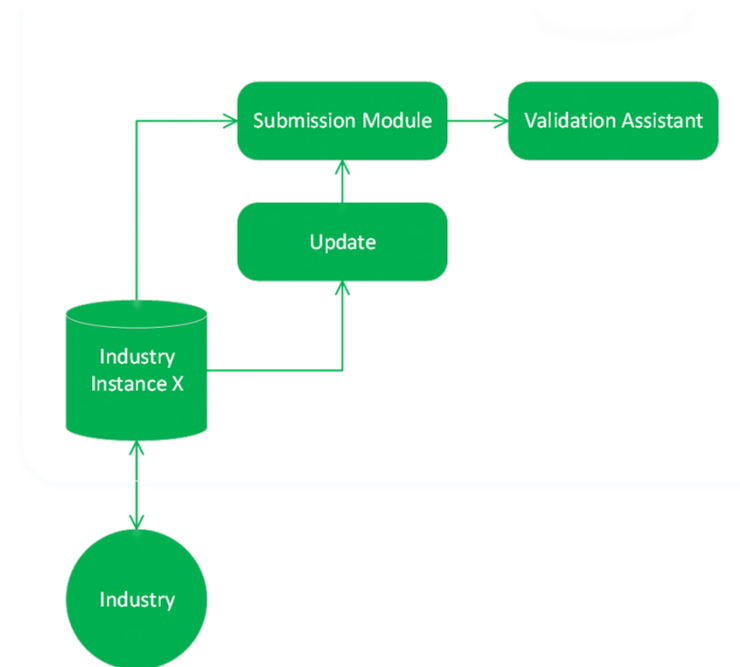
MILESTONES AND DELIVERABLES



ANNEX

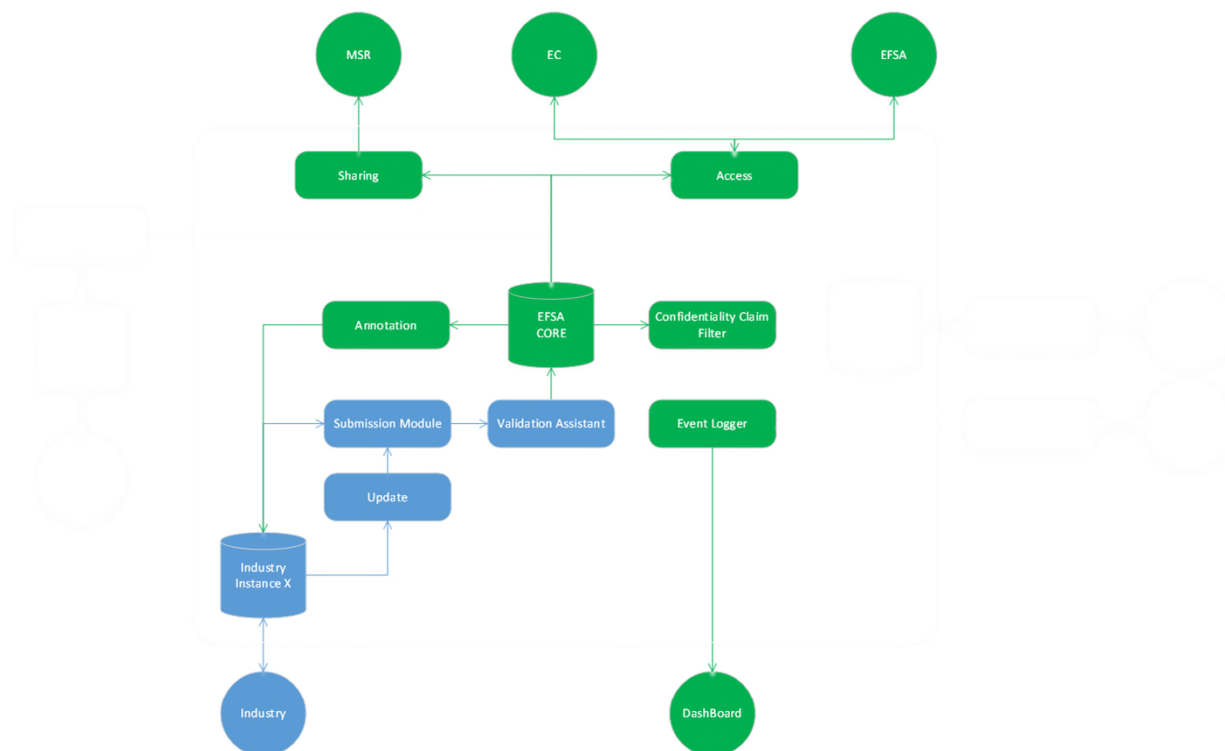
ECHA-EFSA MVP - Industry Users

- 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



ECHA-EFSA MVP - Authorities

- 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



ECHA-EFSA MVP - Public Users

- 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

