

# Format changes: Submission types for pesticides

2nd Technical Group meeting

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## Submission types in the pilot phase

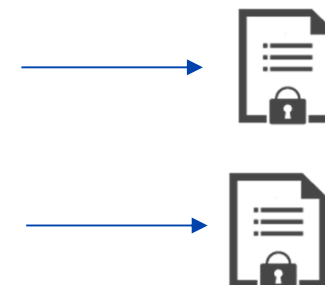


- **EU PPP Active substance information**
- EU PPP Microorganisms
- **EU PPP Basic information (substance)**
- EU PPP Other substance for assessment

Function:  
active  
substance



- **EU PPP Active substance application (representative product)**
- EU PPP Plant protection product authorisation





## Proposed changes: substances

- Basic substance described in Article 23 of REGULATION (EC) No 1107/2009 <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF> could be reported under new submission type: **'EU PPP Basic substance information'**
- All non-active substances currently reported under 'EU PPP Other substance for assessment' and 'EU PPP Basic information (substance)' could be reported under **'EU PPP Other substance'**

## Open point: substances



- Should we plan the additional submission type for the technical equivalence?
  - ✓ dossier created based on the substance dataset
  - ✓ limited number of sections

## Substance submission types in IUCLID 6.5 – summarised proposal



- EU PPP Active substance information
- EU PPP Basic substance information
- EU PPP Microorganisms
- EU PPP Other substance
- EU PPP: Technical equivalence (?)

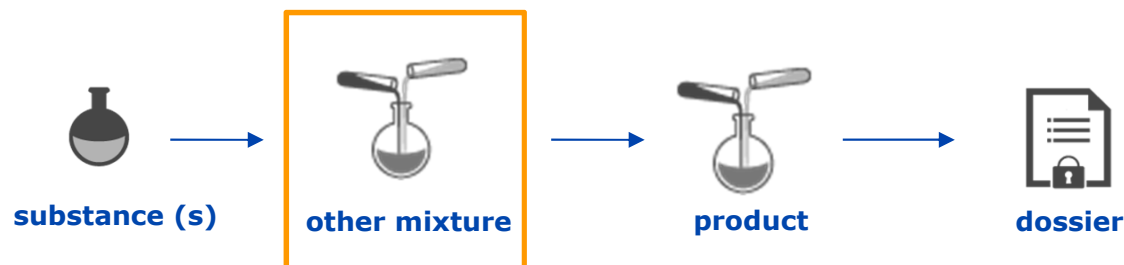
} Function:  
active  
substance





## Proposed changes: mixture/product

- Mixture which is not a product (or a representative product), could be reported under a new submission type: **EU PPP Other mixture**





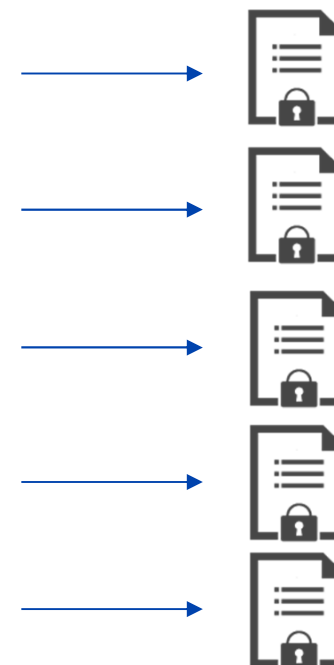
## Proposed changes: mixture/product

- Microorganisms data could be reported under following submission types: **EU PPP Microorganisms (representative product)** and **EU PPP Microorganisms product authorisation**
- New submission type: **EU PPP Maximum residue level**

## Mixture/product submission types in IUCLID 6.5 – summarised proposal



- EU PPP Active substance application (representative product)
- EU PPP Plant protection product authorisation
- EU PPP Microorganisms (representative product)
- EU PPP Microorganisms product authorisation
- EU PPP Maximum residue level
- EU PPP Other mixture



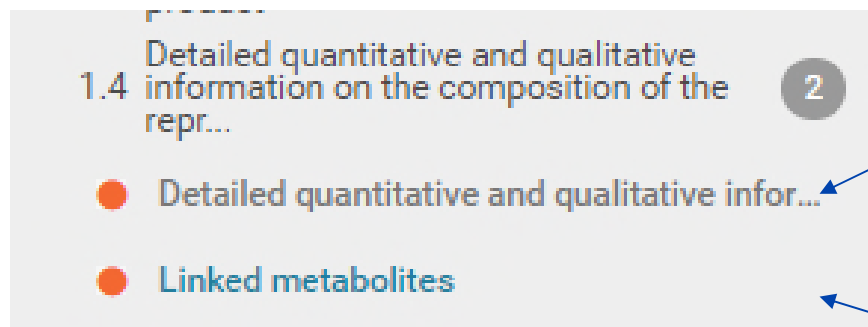


## Which dataset to complete

- Study where the active substance is test material  
→ EU PPP Active substance information
- Study where the test material is a relevant impurity  
→ EU PPP Other substance
- Study where the test material is a relevant metabolite  
→ EU PPP Other substance
- Study where the test material is a mixture  
→ EU PPP Other mixture
- Study where the test material is a substance in a mixture  
→ relevant TOC for a substance and EU PPP Other mixture

Any other, especially more complicated scenario?

## Pilot: Representative product composition



active substance,  
additives, impurities  
linked

datasets for metabolites  
linked



Where to report studies  
related to metabolites?

- ✓ metabolite dataset
- ✓ assessment entity
- ✓ other solution

# All submission types: reference sections

## ✓ 2 Biological properties of the microorganism

### ✓ 2.1 History of the microorganism and its uses. Natural occurrence and geographical distribution

● **History of the microorganism and its uses. Natural occurrence and geographical distribution.001**  
Last Modified:27/02/2020 08:54

2.1.1 (Cf. 2.1) Historical background

2.1.2 (Cf. 2.1) Origin and natural occurrence

### ✓ 2.2 Information on target organism(s)

● **Information on target organism(s).001**  
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2.2.1 (Cf. 2.2) Description of the target organism(s)

2.2.2 (Cf. 2.2) Mode of action

### ✓ 2.3 Host specificity range and effects on species other than the target harmful organism

● **Host specificity range and effects on species other than the target harmful organism.001**  
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2.4 (Cf. 2.1) Development stages/life cycle of the microorganism

2.5 (Cf. 2.1) Infectiveness, dispersal and colonisation ability

2.6 (Cf. 2.1) Relationships to known plant or animal or human pathogens

2.7 (Cf. 2.1) Genetic stability and factors affecting it

2.8 (Cf. 2.1) Information on the production of metabolites (especially toxins)

## Current approach:

Reference sections  
when one IUCLID  
document covers more  
than one requirement

- ✓ to align the numbering and naming with the legislation
- ✓ to make the navigation easier (but it turned out to be confusing)

## All submission types: reference sections

### ✓ 2 Biological properties of the microorganism

#### ✓ 2.1 History of the microorganism and its uses. Natural occurrence and geographical distribution

● [History of the microorganism and its uses. Natural occurrence and geographical distribution.001](#)  
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#### ✓ 2.2 Information on target organism(s)

● [Information on target organism\(s\).001](#)  
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#### ✓ 2.3 Host specificity range and effects on species other than the target harmful organism

● [Host specificity range and effects on species other than the target harmful organism.001](#)  
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### Approach to be discussed:

#### Use of reference sections minimized

- ✓ name of the section indicates what is the content (numbering and naming differs from the legislation, but navigation is more intuitive)
- ✓ only (or almost only) editable sections
- ✓ mapping could be provided in the manual


## All submission types: reference sections

### Current approach

▼ 5.3 Short-term toxicity

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▼ 5.3.1 Oral 28-day study




**Oral 28-day study.001**  
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▼ 5.5 Long-term toxicity and carcinogenicity

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 ▼ 5.5.1 (Cf. 5.3) Long-term toxicity

 5.5.1.1 (Cf. 5.3.1) Oral


**Endpoint ? ▼**

Please select

- short-term repeated dose toxicity: oral
- sub-chronic toxicity: oral
- chronic toxicity: oral
- repeated dose toxicity: oral, other

### Approach to be discussed

**Repeated dose toxicity: oral \***



**Repeated dose toxicity: oral.001**  
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**Endpoint ? ▼**

Please select

- short-term repeated dose toxicity: oral
- sub-chronic toxicity: oral
- chronic toxicity: oral
- repeated dose toxicity: oral, other

Questions?

Feedback?