Trusted science for safe food

TG IUCLID PESTICIDES meeting
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Submission types on Micro-organisms

Dimitra Kardassi, Scientific officer
PREV Unit
Dorota Burchard-Sosnowska
ECHA

efsa
European Food Safety Authority

Pesticides micro-organisms

- Regulation (EC) No 1107/2009
  - Provides a definition for 'micro-organisms'
    - "..any microbiological entity, including lower fungi and viruses, cellular or non cellular, capable of replication or of transferring genetic material"
- Regulations (EU) No 283 and 284, part B
  - Data requirements for micro-organisms including viruses
  - Data requirements for preparations of micro-organisms including viruses
- Regulation (EC) No 546 (Annex part ii)
  - 'uniform principles'

Pesticides micro-organisms

- Requirements include:
  - Identity
  - Biological properties
    - Relationship to known pathogens
    - Genetic stability
    - Resistance or sensitivity to antibiotics
  - Analytical methods
  - Effects on human health
  - Residues in/on treated products, food and feed
  - Fate and behaviour
    - persistence and multiplication
    - Mobility
  - Ecotoxicology

Pesticides MO – areas of improvement for the da requirements

- Identity
  - "best available technology should be used to identify and characterise the MO at strain level"
  - already the same wording in Directive 91/414, Annex IIB
  - WGS data are not required
- Metabolites
  - Data on metabolites should be submitted, if
    - the metabolites contribute to the MoA (mode of action)
    - Significant residues are expected
- Antimicrobial Resistance (AMR)

Pesticides MO ongoing activities

- WGS data and use in pesticides identification

- Potential uses of WGS analysis:
  - Identification of the microorganism at strain level
  - Identification of genes
    - Related to the production of secondary metabolites / toxins
    - Related to the possible antimicrobial resistance

Pesticides MO ongoing activities

- Commission 'WG on biopesticides'
  - Draft guidance document on secondary metabolites produced by micro-organisms
  - Draft guidance document on AMR
    - Taking into consideration the FEED GD
  - **Discussion on the amendment for the data requirements for micro-organisms**
    - COM to collate and circulate comments on all chapters but chapter 2 (chapters 1, 3, 4, 5, 6, 7, 8, 9)

- **IUCLID - Submission Type Micro-organisms**

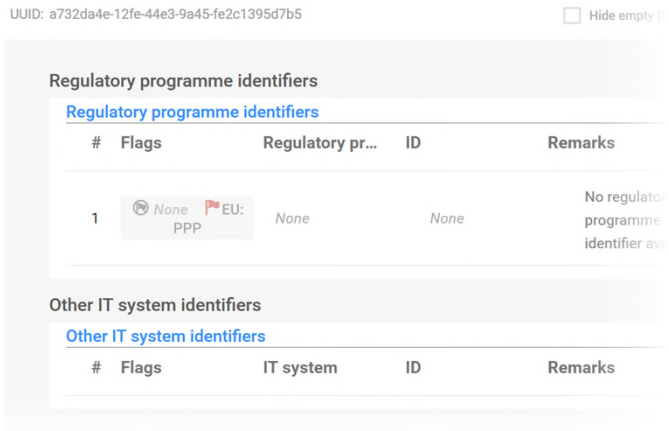
IUCLID Submission type micro-organisms

The contractor (Knoell) will work on one IUCLID dossier and develop the proof of concept for the micro-org. active substance

- Submission type to be used for the active substance dataset: *EU PPP Microorganisms* already available in IUCLID
- Submission type to be used for the (representative) plant protection product: *EU PPP Active substance application (representative product)* – a 'chemical product' dataset – known limitation

IUCLID Submission type micro-organisms

A	B	C
Section name as displayed in IUCLID TOC for chemical product	**IUCLID Document Identifier**	**IUCLID Document name**
1.3 Trade name or proposed trade name of the plant protection product	MIXTURE	Mixture
1.3.1 Producer's development code number	FLEXIBLE_RECORD.Identifiers	Identifiers
1.4 Detailed quantitative and qualitative information on the composition of the plant protection product	FLEXIBLE_RECORD.MixtureComposition	Composition



IUCLID Submission type micro-organisms

A	B	C	D
Section name as displayed in IUCLID TOC for chemical product	**IUCLID Document Identifier**	**IUCLID Document name**	**Planned TOC for microorganisms preparation (Reg. 284/2013 Part B)**
1.3 Trade name or proposed trade name of the plant protection product	MIXTURE	Mixture	1.3 Trade name or proposed trade name of the plant protection product
1.3.1 Producer's development code number	FLEXIBLE_RECORD.Identifiers	Identifiers	1.3.1 Manufacturer's development code number
1.4 Detailed quantitative and qualitative information on the composition of the plant protection product	FLEXIBLE_RECORD.MixtureComposition	Composition	1.4 Detailed quantitative and qualitative information on the composition of the preparation

A	B	C	D
Section name as displayed in IUCLID TOC for chemical product	**IUCLID Document Identifier**	**IUCLID Document name**	**Planned TOC for microorganisms preparation (Reg. 284/2013 Part B)**
6 Efficacy data	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation	Additional toxicological information	6 Efficacy data
6 Efficacy data	ENDPOINT_STUDY_RECORD.EfficacyData	Efficacy data	6 Efficacy data
			6.1 Preliminary tests
			6.2 (Cf. 3.2) Testing effectiveness
			6.3 (Cf. 3.2) Information on the occurance or possible occurence of the development of resistance
			6.4. Effects on the yield of treated plants or plant products in terms of quantity and/or quality
			6.4.1. Effects on the quality of plants or plant products
			6.4.2. Effects on transformation processes
			6.4.3. Effects on the yield of treated plants or plant products
			6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products

IUCLID Submission type micro-organisms

D	E	F	G
Planned TOC for microorganisms preparation (Reg. 284/2013 Part B)	**Comments (Dorota)**	**Potential need of format changes in existing IUCLID documents**	**Existing IUCLID backlog item to be taken into account / considered**
3.1 Field of use envisaged	This document for the chemical product will be probably replaced by newly created document compatible with GAP tables. So, maybe, the analysis should focus on what are the differences between chemical and microorganisms GAP tables. And the decision should be made if there is a need of a completely new document for microorganisms.	yes	1897, 1898, 1687, 1689
3.2 Mode of action	Summary depends on the content of endpoint study record.	yes	
3.2 Mode of action	Here also, the discussion is foreseen if this document will be kept or replaced by the document following the GAP table (discussion on 21 April). The decision should be made if there is a need of a completely new document for microorganisms.	yes	

IUCLID backlog:
https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LlaauHozq9BSfv6a5EgFDM1GgtmfQ/edit#gid=0

How to work with the mapping file (product)

- The most easy and effective way of checking the mapping of existing documents is to open at the same time IUCLID and the xls file
- Relevant table of contents in IUCLID:
  - *EU PPP Active substance application (representative product)* for all sections except 9
  - *EU PPP Microorganisms* for section 8 and 9 (substance dataset)
- Comment in the xls (both positive and negative comments are welcome)
- Identify in which sections new documents are needed:
  - What type of documents (to report studies, summaries)?
  - Which data should be stored in each document?

Discussion