Harmonisation of endpoint summaries

Pesticide Steering Network meeting IUCLID sub-group

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Harmonisation of endpoint summaries

- Endpoint summaries are used in IUCLID under several different legislations to summarise and justify key information at endpoint level
- Parallel, partially overlapping formats created in 2020 for some endpoints to be used in the EU PPP and New Zealand HSNO contexts
- The on-going project aims to fuse the overlapping formats per endpoint into one single endpoint summary for all the relevant contexts
  - Harmonisation between legislations (cf. One Substance One Assessment)
- Ultimate aim to include endpoint summaries as OECD Harmonised templates (OHTs), as requested by IUCLID users

Scope and timeline of the work

- The harmonisation of overlapping formats following analysis and discussions with stakeholders
  - E.g. EFSA, NZ EPA, AICIS, ECHA, OECD IUCLID User Group Expert Panel, OHT Expert Group
- Besides overlapping formats, aim to review the remaining endpoint summaries against principles set in the project, for structural consistency
  - Physico-chemical endpoints, remaining (eco)toxicological and environmental fate endpoints
  - Endpoint summaries on efficacy and residues excluded for now; pending an expert review
- Proposals to be ready for OECD consultation by September 2022
- Implementation of changes in the April 2023 release of IUCLID, promotion of endpoint summaries as OHTs

EU PPP endpoint summaries for harmonisation

Ecotoxicological

- Long-term toxicity to fish
- Long-term toxicity to aquatic invertebrates
- Short-term toxicity to fish
- Short-term toxicity to aquatic invertebrates
- Toxicity to aquatic algae and cyanobacteria
- Toxicity to plants
- Sediment toxicity
- Toxicity to soil macroorganisms except arthropods (Effects on non-target soil meso- and macrofauna)
- Toxicity to terrestrial plants
- Toxicity to soil microorganisms
- Effects on biological methods for sewage treatment
- Toxicity to other above-ground organisms (wild mammals)
- Toxicity to birds

Ecotoxicological

- Bioaccumulation: aquatic / sediment
- Toxicity to terrestrial arthropods (Effects on arthropods including bees) – as part of the OHT 50-2 project

Fate and behaviour in the environment

- Biodegradation in water and sediment: simulation tests (EU PPP)
- Route of degradation in water and sediment (EU PPP)
- Biodegradation in soil (EU PPP)
- Route of degradation in soil (EU PPP)

Toxicological

- Carcinogenicity (EU PPP)
- Toxicity to reproduction (EU PPP)
- Dermal absorption

Overview of proposed changes

Revisions to contents

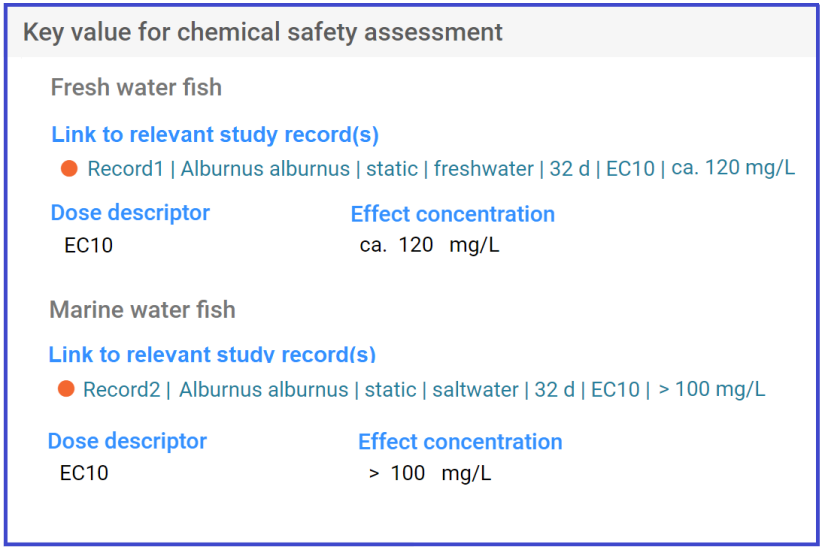
- Picklist values, helptexts

Revisions to structure

- No repeatable blocks
  - No unique assessment outcome; using fixed fields instead
- Avoiding additional freetext fields, fields for material & method description
  - Only the most relevant data for further assessment
  - For reporting purposes, information extracted from the endpoint study records
- No substance references (parent/metabolite)
  - Assumed linkage to the dataset of the assessed substance/entity
- Streamlining of the header structure

Further improvements

- More specific linking to relevant study records
  - Links to be provided per key value in summaries where more than one key value can be reported
  - The link displays an overview of the key information
- Key values for (eco)toxicological endpoints using a half-bounded range
  - Numerical value and operators (ca., <, <=, >, =>)
- Adjacent fields introduced in the user interface for related fields



Changes to OHTs

- Mainly small changes
  - Additions to picklist values (e.g. effect concentration units, dose descriptors)
  - Inclusion of individual fields required in accordance with the EU PPP List of Endpoints
- Biodegradation in soil and water/sediment: inclusion of several new fields, e.g.:
  - Degradation values of transformation products, when derived from the study dosed with the registered substance
  - Kinetic evaluation of DT values in accordance with FOCUS kinetics

Thank you!

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