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Item 7 - IUCLID format updates

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IUCLID format updates plan (2022-2023)

- **Endpoint Study Record (OHTs):**

OHT n./Name	IUCLID Backlog (#)
50-2 Toxicity to terrestrial arthropods	Splitting of the OHT into 3 sub-templates (#2284)
85-2 Metabolism of residues in livestock	Update to support integration with **METAPATH** (#2075, #2089,#1768)
85-3 Metabolism of residues in crops and in rotational crops	Update to support integration with **METAPATH** (#2075, #2089,#1787, #1790)
85-4 Residues in livestock	Small fix - animal number (#2375)
85-5 Residues in crops (field trials)/rotational crops	Inclusion of revised TG 509; updates to support integration with **RUEDIS** and **PRIMo 4** + identification of key results (#2079, #2089, #2094)
85-8 Nature of residues in processed commodities	Update to support integration with **METAPATH** (#2075, #2089,#2147)
85-9 Magnitude of residues in processed commodities	Updates to support integration with **RUEDIS** and **PRIMo 4** (#2147,#1786, #2073)
87 Analytical methods	Full revision including comments from the OHT Expert Group (July 2021) and SANTE/2020/12830 rev. 1. (Residues methods) (#1855, #2144, #2354)

- **Other IUCLID documents:**

Endpoint Summary **Magnitude of residues in plants**	Updates to support integration with **RUEDIS** and **PRIMo 4** (#2155 #2292).
Endpoint Study Record **Magnitude of residues in processed commodities** (including pollen and bee products)	Update needed for processing factors and **REUDIS** alignment; identification of key results (#2067, #2073, #2292 #2128).
Endpoint Summary **Nature and magnitude of residues in processed commodities**	Update needed for processing factors and **REUDIS** alignment (#2067, #2073, #2292). Integration with **PRIMo 4** also to be considered.
Flexible Summary **Residues in livestock, feeding studies**	Updates to support integration with **RUEDIS** and **PRIMo 4** (#2376)

Open backlog (IUCLID user requirements)

Inventory of IUCLID documents (OECD)

OHT 50-2: project plan

- Jan 2022, **ECHA/EFSA/OECD/NZ EPA/Industry** held the kick-off meeting and established the Working Group (ECHA-EFSA core team).
- **Objective(s)**
  - i. **Splitting** the OHT 50-2 "Toxicity to terrestrial arthropods" into relevant **sub-templates** in time for the next major IUCLID release (April 2023) as requested by BIAC;
  - ii. Addressing **reporting needs** for different type of studies/arthropods:
    - Bees and other **pollinators**;
    - Extended **laboratory studies**, **semi-field studies** and **field studies**.
  - iii. Considering ECHA/EFSA **Guidance Documents** and EU PPP **data requirements** for **microorganisms.**

***NB**: work is restricted to OHT 50-2 and related TGs only; no other restructuring of the terrestrial compartment!*

OHT 50-2: analysis of relevant TGs - bees

Feb 22 — Analysis of relevant test guidelines – conclusions on the number of sub-templates

- Bees (honeybee, bumblebee, solitary bees)

Test Guideline(TG)/Guidance Document (GD)	Topic of TG/GD	Organism	Type of study	Endpoint
OECD GD No 239	Larval Toxicity Test following Repeated Exposure	Honeybee	Laboratory	bee larval toxicity - chronic
OECD TG 245	10-d oral exposure in lab	Honeybee	Laboratory	toxicity to bees: chronic oral
OECD TG 246	Acute Contact Toxicity Test	Bumblebee	Laboratory	toxicity to bees: acute contact
OECD GD No 332	Homing flight test, using single oral exposure to sublethal doses of test chemical	Honeybee	Semi-field	toxicity to bees: sublethal effects (reproduction, homing flight activity)
OECD GD No 75	Brood test Under Semi-field Conditions	Honeybee	Semi-field	toxicity to bees: cage and tunnel tests
Eeraerts et al. (2020) & Claus et al. (2021)	Oral toxicity test protocol for larvae of solitary bees	Solitary bee	Laboratory	bee larval toxicity - chronic
ICPPR by Roessink et al. (2017 & 2019)	Acute oral toxicity	Solitary bee	Laboratory	toxicity to bees: acute oral
EPA OPPTS 850.3040	Field Testing	Pollinators	Field	toxicity to bees: field tests
Luckmann et al. (2019)	Brood test under semi-field conditions - new considerations	Honeybee	Semi-field	toxicity to bees: cage and tunnel tests

OHT 50-2: analysis of relevant TGs – arthropods other than bees

- Terrestrial arthropods other than bees

Test Guideline(TG)/Guidance Document (GD)	Topic of TG/GD	Organism	Type of study	Endpoint
IOBC: pages 57-70	Guidelines to evaluate side-effects of plant protection products to non-target arthropods	Predatory bug	Laboratory	Toxicity to non-target arthropods on inert substrate (NTA other than pollinators)
IOBC: pages 87-106	Guidelines to evaluate side-effects of plant protection products to non-target arthropods	Carabid beetle	Laboratory	
IOBC: pages 121-144	Guidelines to evaluate side-effects of plant protection products to non-target arthropods	Predatory mite	Laboratory	
Mead-Briggs M.A. et al. (2010)	Extended laboratory test for evaluating the effects of plant protection products	Parasitic wasp	Laboratory - extended	

- Soil arthropods

Test Guideline(TG)/Guidance Document (GD)	Topic of TG/GD	Organism	Type of study	Endpoint
ISO 11267	Inhibition of Reproduction by Soil Pollutants	Collembola	Laboratory	toxicity to terrestrial arthropods: long-term
OECD TG 226	Reproduction Test in Soil	Predatory Mite	Laboratory	

OHT 50-2: results of TG analysis

Apr 22 — Drafting of the revised templates based on the relevant test guidelines

- The current OHT 50-2 "Toxicity to terrestrial arthropods" planned to be split into **three** separate **templates**
  - *i. Toxicity to bees (OHT 50-x)*
  - *ii. Toxicity to terrestrial arthropods other than bees (OHT 50-y)*
  - *iii. Toxicity to soil arthropods (OHT 50-z)*
- No need for a separate template for honeybees nor field studies
- Proposal for **Dynamic Content Rule (DCR)** i.e., "conditional formatting" for bee template (lab Vs field studies):
  - Ad-hoc fields (e.g., "*place of the test*", "*GPS coordinates)* to be displayed only for field studies

OHT 50-2: conclusions and next steps

- New OHT 50-x **sub-templates** to harmonise the reporting of **sublethal**, **semi-** and **field studies** on i) **bees**, ii) **terrestrial arthropods** other than bees and iii) **soil arthropods**;
- Proposal for **changes/improvements** to all OHTs (e.g., attachment field, results section);
- Reflecting **Microorganism** data requirements (EC, 2020) into **OHTs sub-templates** (e.g., pathogenicity, infectivity).

May 22	**Technical review by the IUCLID team and encoding in ITEM format**
Jun 22	Review of the draft templates by participating agencies
Aug 22	Finalisation of drafting work – templates ready for consultation
Oct 22	OECD consultation & modifications based on feedback from consultation
Mar 23	IUCLID adaptations – beta testing of the new format
Apr 23	Implementation in IUCLID & publication on the OECD website

Save the date!

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