APIS
APPLIED INSECT SCIENCE

Feedback on the EFSA approach to the use of IUCLID for microbials.

- General food law Regulation 178/2002
- Regulation (EU) 2019/1381 ‘ transparency regulation’
- Risk communication
  - Strengthen citizens' trust that the risk analysis is underpinned by the objective of ensuring a high level of protection of human health and consumers' interests.
  - explaining not only risk assessment findings themselves but also how such findings are used to help risk management decisions
  - The general plan on risk communication should also identify the tools and channels to be used and should establish appropriate mechanisms of coordination and cooperation between the risk assessors and risk managers at Union and national level

What does it mean for dossiers

- Notification of studies
- Pre-notification of renewal dossiers
- Pre-submission advice

- Public access to information
- to make the full dossier available to the public
- (except information granted confidentiallity)

International Uniform ChemicaL Information Database

- Stores and records on substance, product and use data in a structured format
- Provides a user interface and additional functionalities to manage data
- Provides a means to exchange data
- Has reporting functionalities

Why IUCLID

IUCLID interface and maintenance centralized

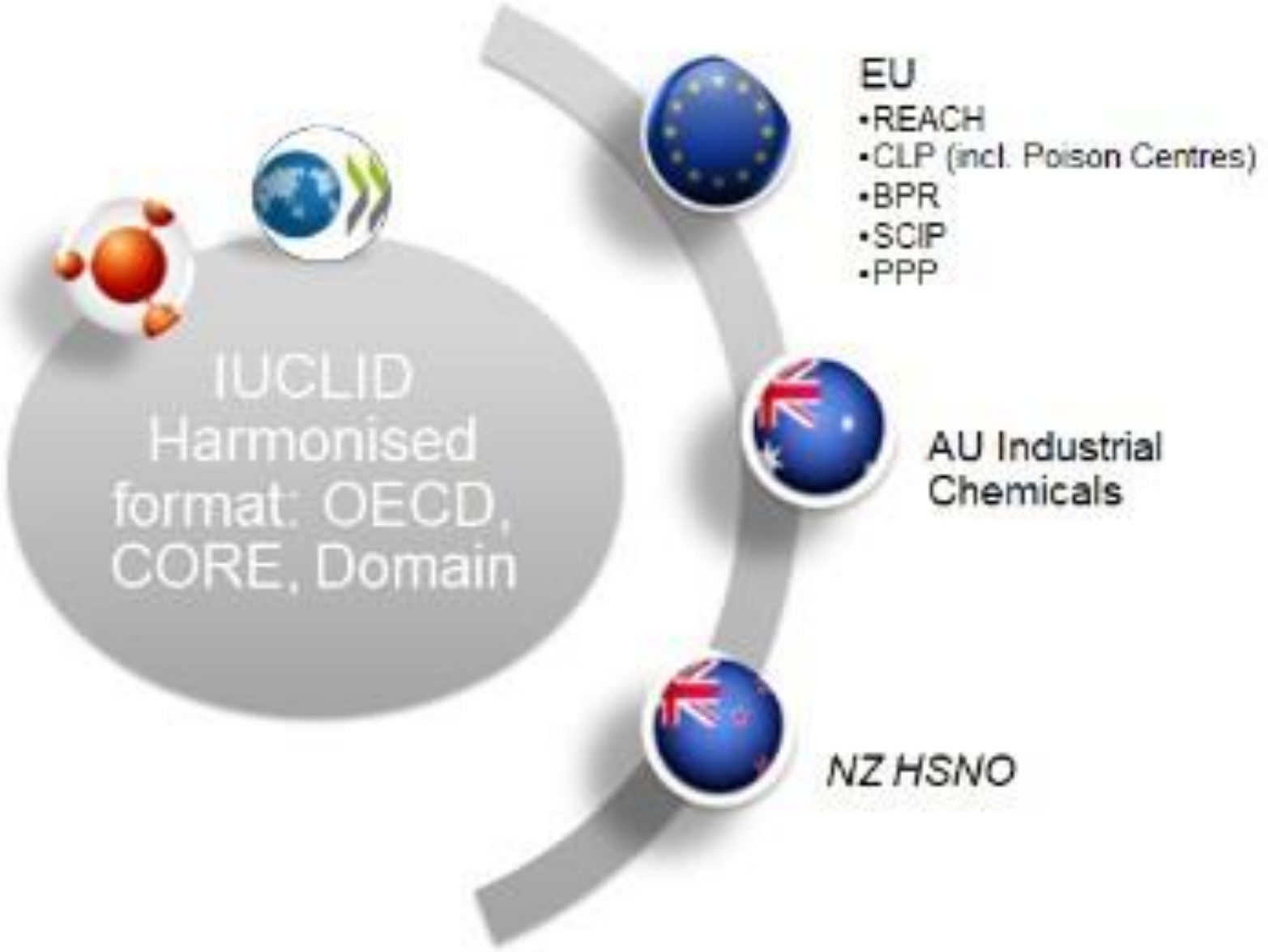
Standard format for data

- OECD harmonised template (OHT) for regulatory lab studies
- Harmonising data between systems
- Screening data (validation)
- publishing

IUCLID is used by various regulations

- REACH industrial chemicals
- BPR biocides
- CLP
- Etc

Harmonisation between regulations


IUCLID
Harmonised
format: OECD,
CORE, Domain
EU
•REACH
•CLP (incl. Poison Centres)
•BPR
•SCIP
•PPP
AU Industrial
Chemicals
NZ HSNO

ECHA EFSA project to develop IUCLID for PPP submissions

Further important information on the project

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

IUCLID for PPP submission

Submission types

EU PPP Active substance application
EU PPP Basic substance application
EU PPP MRL application
EU PPP Microorganisms –active substance application
EU PPP Plant protection product authorisation
EU PPP Plant protection product authorisation (microorganisms)

Active substance core dossier

- Data requirements according to 283/2013 Part B

Product dossier

- Data requirements according to 284/2013 Part B

GLP laboratory studies → OECD harmonised templates (OHT)

- Current text description is from chemicals (BPR)
- OHT are from chemicals
- Many points in study summaries are not relevant – lots of confusion
- Microbial guidelines included (require deeper search)
- Picklist options provide right information sometimes
- Mostly however the option other is to be choosen
- Free text is possible

Please refer to the work by Knoell proof of concept dossier

https://zenodo.org/record/4040679#.X4Q5WdAzZPZ

Literature references

- Type of information – choose other and specify. No picklist option available
- Templates as for study summary
- Text boxes available for summary – free text

- Terminology in IUCLID from chemicals (headers, template points)

Validation assistent

- Technical validation – generate validation report

Reporting

- Generate pdf
- print IUCLID documents selected study records or the selected dataset.
- DAR report generator (under development)

Reporting options available – different format

Currently no options for risk assessment report (like e.g. Chesar) on top.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