

### Major release of IUCLID 6 with format changes

### **IUCLID 6 Version 8.0.1**

16<sup>th</sup> May 2024





IUCLID 6 is developed by the European Chemicals Agency in association with the OECD



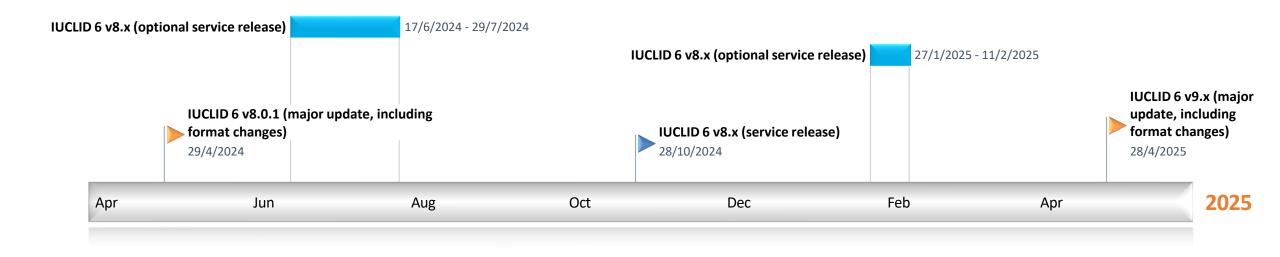
### Introduction to IUCLID 6 version 8

**IUCLID** version 8.0.1





Release plan





#### Release notes

- Details about the releases are maintained in the Release notes\* published on the IUCLID website
- Release notes are updated each time a IUCLID release is shared with (a group of) users

\* https://iuclid6.echa.europa.eu/documents/1387205/1809509/IUCLID\_6\_Release\_Notes.pdf

#### IUCLID 6

### Release notes

Version 8.0.1

29/04/2024



## 

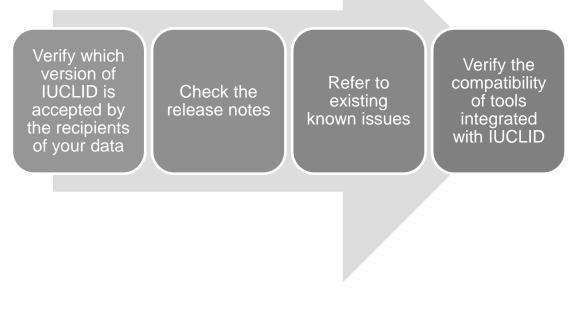
#### Overview of the release scope

- This is a major IUCLID release, with format changes
- It also includes fixes and improvements
  - Display of documents in the correct order in different places of the interface
  - Show pictograms in the Classification records retrieved from ECHA's inventory
  - Improve the display of additional texts linked to picklist entries
  - Update of report templates and validation assistant rules (mainly to adapt to the new format)
  - Fix for Known issue #116: data migrated as attachments instead of to the relevant field





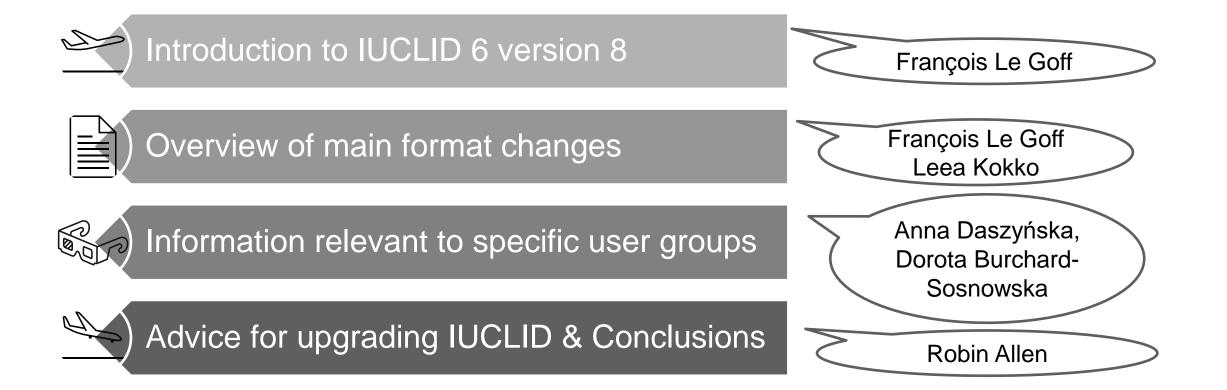
#### Deciding to upgrade





https://iuclid6.echa.europa.eu/faq#known\_issues

Agenda for today





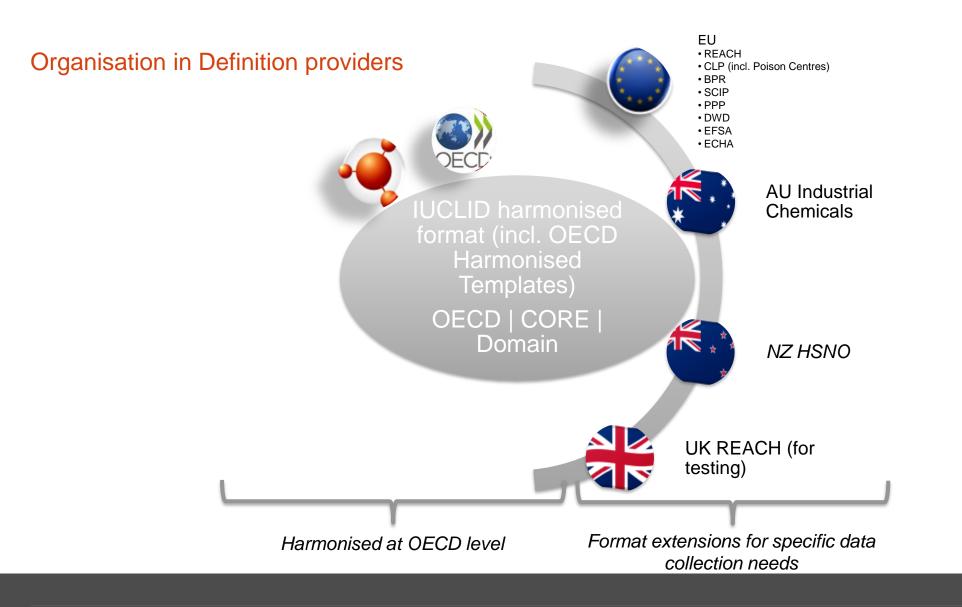
## Overview of main format changes

**IUCLID** version 8.0.1

- Francois Le Goff
- Leea Kokko



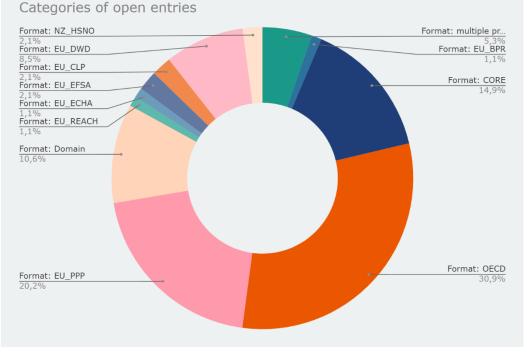






#### Requirements

- IUCLID users, including organisations that have implemented IUCLID, are regularly providing feedback and requirements, this includes changes to the IUCLID format
- These requirements are collected all year long
- For the preparation of the format changes published in April 2024, requirements have been collected, reviewed, prioritised and 94 of them have been implemented

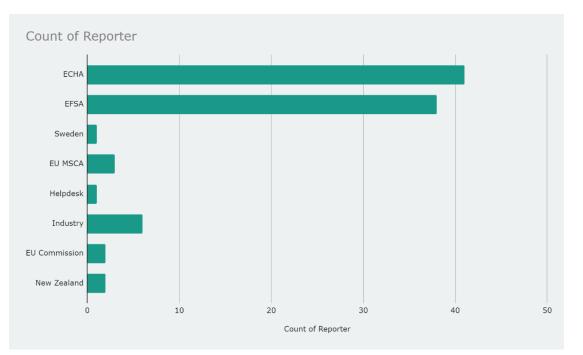


Repartition, by definition providers, of format changes requests for the April 2024 release of IUCLID



#### Main drivers of the 2024 update

- Apart from the standard maintenance of the format based on IUCLID users feedback, the main drivers for this format updates are:
  - EU Classification, Labelling and Packaging regulation updates
  - EU Drinking Water Directive implementation
  - Improvement of data collection and processes in:
    - ECHA: REACH, BPR
    - EFSA: PPP
  - New and updated OECD test guidelines



Origin of prioritised requirements

#### https://iuclid6.echa.europa.eu/format

#### Format documentation package

- All XML Shema Definitions files (.xsd)
- User-readable IUCLID documents representation (.doc)
- Lists of all IUCLID fields (.xls)
- Comparison files showing the differences compared to the previous version of the format, i.e. v8 compared to v7
- Migration rules implemented in IUCLID
- Dynamic content rules, to describe the conditional display rules linked to specific IUCLID fields in the IUCLID 6 web interface

Name
Comparison with v7
DOCs
List of fields
XSDs
DCRs_of_IUCLID6_8.xml
Z migration_IUCLID6_8_batch10.zip
Z PhraseGroupMappings_IUCLID6_8_batch10.zip
🔐 Phrases.xml
TOCs.zip

#### **IUCLID** format

From this page you can download information related to the IUCLID 6 format for the major versions of IUCLID 6 that have been published to date. The archives per major version are:

	<ul> <li>IUCLID 6 v8, published on 29<sup>th</sup> of April 2024</li> <li>IUCLID 6 v7, published on 19<sup>th</sup> of May 2023</li> <li>IUCLID 6 v6, published on 17<sup>th</sup> of October 2021</li> <li>IUCLID 6 v5, published on 28<sup>th</sup> of October 2020</li> <li>IUCLID 6 v4, published on 30<sup>th</sup> of October 2019</li> </ul>	<ul> <li>✿ (.zip   37.1 MB)</li> <li>✿ (.zip   31.8 MB)</li> <li>✿ (.zip   25.1 MB) - (updated on 16.12.2021)</li> <li>✿ (.zip   24.7 MB)</li> <li>✿ (.zip   20.2 MB)</li> </ul>
l		
l	<ul> <li>IUCLID 6 v4, published on 30<sup>th</sup> of October 2019</li> </ul>	(.zip   20.2 MB)
l	<ul> <li>IUCLID 6 v3, published on 24<sup>th</sup> of October 2018</li> </ul>	🏠 (.zip   16.1 MB)
l	<ul> <li>IUCLID 6 v2, published on 15<sup>th</sup> of November 2017</li> </ul>	🏠 (.zip   15.0 MB)
l	IUCLID 6 v1, published on 29 <sup>th</sup> of April 2016	🏠 (.zip   14.7 MB)

The format is expressed for all IUCLID 6 entities and documents in the general-purpose mark-up language XML, and XML Schema definition files (.xsd). In addition, the format is made available in a more readable version (.doc).

IUCLID 6 is built as a platform and is a modular system. The IUCLID 6 format is divided up in to different groups ('definition providers') depending on its source identified in the section below. To allow data to be exchanged, it can be exported and imported in the IUCLID i6z format. The following document explains the structure of IUCLID i6z files:

Developers' Guide to the IUCLID i6z Format (.pdf | 1.1 MB) - updated on 19/05/2023

More information on how the IUCLID format is used in specific contexts can be found on the following pages:

- EU Poison Centres Notification format
- SCIP database format

### **IUCLID** format



#### Example of changes to specific definition providers



- Australia
  - Update of relevant table of Contents to refer to the new version of the OHTs on Use and Exposure information



- New Zealand
  - Update of phrase groups in several documents

More information communicated by the relevant authorities to the relevant user groups

### **IUCLID** format



### Example of changes to specific definition providers

- EFSA and EU PPP
  - Introduction of the 'Contributor' role in the dossier header (e.g. for data submitted with a Letter of Access)
  - New flexible summary on 'Impurities' to comply with Commission Regulation (EU) No 283/2013
  - New flexible summary for 'Definition residues biomonitoring'
  - Update of the flexible summary 'Summary of evaluation': new field 'Complementary information' to distinguish the type of bibliography or supporting documentation to support Basic substance applications
  - Micro-organisms: changes to support the assessment of secondary metabolites in accordance with new data requirements on microorganisms and SANCO/2020/12258 metabolite guidance
  - New section "Endocrine disrupting properties" (for active substances) to report in vivo and in vitro/in chemico endocrine disrupting test results
  - GAP document has two new fields: "Concentration of target a.s. in dilution" and "Concentration of other a.s. in dilution"
  - Validation rules and filtering logic updated

More information communicated by the relevant authorities to the relevant user groups

### **IUCLID** format



### Example of changes to specific definition providers

- EU CLP (Poison Centres Notification)
  - Possibility to link several mixtures for group submissions
  - New update justification added
- EU ECHA
  - For dissemination of information under ECHA CHEM, there will be an indication whether a dossier was filtered according to the pre-REACH legislation (cf. filtered as NONS)
- Changes relevant to EU Biocides (BPR) and EU Drinking Water Directive covered in this webinar

More information communicated by the relevant authorities to the relevant user groups



#### Harmonisation of the 'Use and Exposure' Templates

- Use and exposure information OECD Harmonised Templates have been created in 2016 (OHTs 301 to 306)
- Use and Exposure information 'REACH templates' were still in use until now
- In 2023 a proposal was sent by ECHA for further harmonisation
- In April 2024, only one set of templates exist for storing Use and Exposure information

#### CORE

- > 1 General information
- > 2 Classification & Labelling and PBT assessment
  - 3 Manufacture, use and exposure
    - 3.2 Estimated quantities

3.3 Sites

3.4 Information on mixtures

3.5 Use and exposure information

3.5.0 Use and exposure information relevant for all uses

#### 3.5.1 Manufacture

- 3.5.2 Formulation or re-packing
- 3.5.3 Uses at industrial sites
- 3.5.4 Widespread uses by professional workers
- 3.5.5 Consumer uses

3.5.6 Service life

#### OECD

- A Physico-chemical properties
- > B Degradation and accumulation
- > C Effects on biotic systems
- > D Health Effects
- > E Analytical methods
- > F Pesticide residue chemistry
- > G Efficacy
- > H Emissions from treated articles
- I Intermediate effects mechanistic information
  - J Use and Exposure information

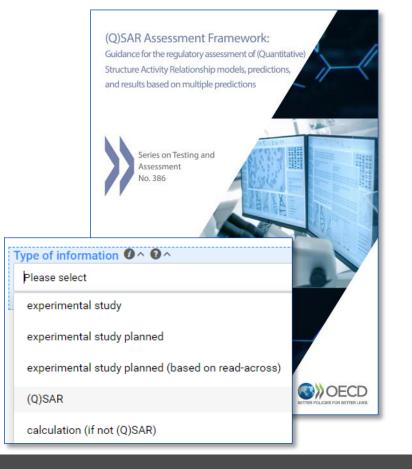
#### 301 Manufacture

- 302 Formulation or re-packing
- 303 Uses at industrial sites
- 304 Widespread uses by professional workers
- 305 Consumer uses
- 306 Service life



### (Q)SAR Assessment Framework 1/2

- Changes have been made to all study summaries to improve the reporting of (Q)SAR studies in IUCLID
  - 18 new fields added regarding (Q)SAR models, their validation and applicability
    - The new fields are visible to the user only if **Type of information** of the study is specified as **(Q)SAR**
  - Changes to picklist values in field "Rationale for reliability incl. deficiencies"
  - Adjustments to (Q)SAR-related text templates and help texts in several fields
- To implement the (Q)SAR assessment framework, adopted by the OECD in 2023
  - Helps regulators assess (Q)SAR studies, supports alternatives to animal testing

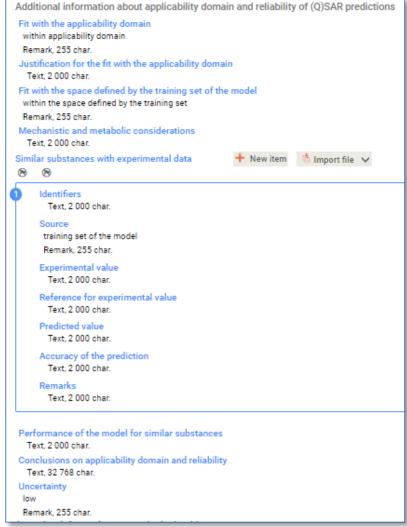




### (Q)SAR Assessment Framework 2/2

- 3 new fields under section Materials & Methods
  - To describe the model and software used
- 15 new fields under section **Results & Discussion**, to structure information on:
  - Applicability domain
  - Reliability of (Q)SAR predictions
  - Analogues ("Similar substances with experimental data")
  - Uncertainty

#### Model and software Model name and version Text, 2 000 char. Software name and version Text, 2 000 char. Remarks Rich text area





#### Alignment of result reporting in environmental fate study summaries

- The result reporting in selected environmental fate templates was better aligned by introducing the result sections Material (mass) balance and Disappearance time (DT) of parent compound to the following documents, as applicable:
  - OHT 25 Hydrolysis
  - OHT 26 Phototransformation in water
  - OHT 27 Phototransformation in soil
- The result sections were already used in:
  - OHT 29 Biodegradation in water and sediment: simulation tests
  - OHT 30 Biodegradation in soil

	Material	(mass) balance	e +	• New item	t Import	t file 🗸					
	#	Key result	Samplin	g ti Sar	npling c	% Tota	al ext	% Minerali	% Other vol	% Recovery	St. dev.
	1		2.5 h		diated nple	> 75 < 85	-	> 8 - < 10	> 1 - < 2	> 85 - < 86	2
sappea #	arance time (DT) Key result	of parent comp Parameter	ound Value	+ New iter St. dev.		rt file ∨ of ki	Type of va	Temp.	Chi-squar	p-value (t	Kinetic pa.
1		DT50 Remark	> 12 - < 12.5 h	0.5		lo-)first = half-	degradation time		0.2	> 0.05 - < 0.07	Free text (e.g. alpha = 0,5)



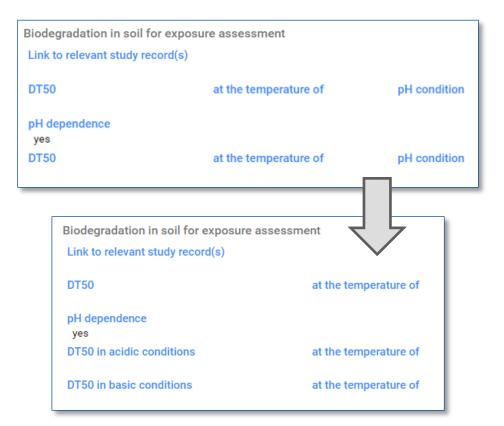
### Revision of OECD Harmonised Templates by the OECD Secretariat

- To take into account the evolution of OECD Test Guidelines, the OECD Secretariat has proposed revisions to the following OHTs:
  - OHT 29 Biodegradation in water and sediment: simulation tests (new TG 320)
  - OHT 48-2 Endocrine disrupter testing in aquatic vertebrates in vivo/embryo (TG 240, new TG 251)
  - OHT 49 Sediment toxicity (TG 218, TG 219)
  - OHT 65 Eye Irritation (new TG 467, new TG 492B, TG 496)
  - OHT 71 Genetic toxicity in vivo (new TG 470, TG 488)
  - OHT 105 Nanomaterial specific surface area → Nanomaterial specific surface area and skeletal density (new TG 124)
  - OHT 107 Nanomaterial surface chemistry (new TG 126)



#### Endpoint summaries

- OHT 30 S Biodegradation in soil & OHT 39 S Field studies
  - Changes to how pH dependent key values are reported
- OHT 34 S Adsorption/desorption
  - Enabling the reporting of pH dependent key values
- OHT 39 S Field studies
  - Correction of referenced document
- OHT 67 to 69-2 S Repeated dose toxicity
  - Fields "Experimental exposure time per week (hours/week)"
    - Units "days/week" and "hours/week" introduced in the oral and dermal/inhalation route fields, respectively
- Flexible record OHT 201 Intermediate effects mechanistic information
  - Changes to how attachments can be provided in the Materials and methods and Results and discussion sections



## Information relevant to specific user groups

- EU Classification, Labelling and Packaging regulation (CLP)
- EU Biocidal Products Regulation (BPR)
- Drinking Water Directive (DWD)

IUCLID version 8.0.1



## Information relevant to specific user groups

• EU Classification, Labelling and Packaging regulation (CLP)

**IUCLID** version 8.0.1

Anna Daszyńska





#### Amendments to EU CLP regulation: key information

- EU CLP regulation implements UN Globally harmonised system for classification and labelling (GHS).
- Recently, EU Commission amended the CLP regulation with new hazard classes that are not covered by GHS. The change entered into force in April 2023.
- Information on new hazard classes can be submitted to ECHA in dossiers under the CLP, REACH and Biocidal Products regulations.
- Different transition periods apply for substances and mixtures (New hazard classes 2023 ECHA (europa.eu)).
- No changes to the completeness check of REACH registrations in relation to the new hazard classes, but the IUCLID Validation assistant will remind companies to start entering this data whenever available.
- Manuals on dossier preparation updated accordingly (<u>Manuals ECHA (europa.eu</u>))



#### New fields for reporting new hazard classes

#### Health hazards:

Endocrine disruption for human health (EU CLP)

Hazard category ED HH 1 Hazard statement EUH380: May cause endocrine disruption in humans. European Union

#### Environmental hazards:

Endocrine disruption for the environment (EU CLP)

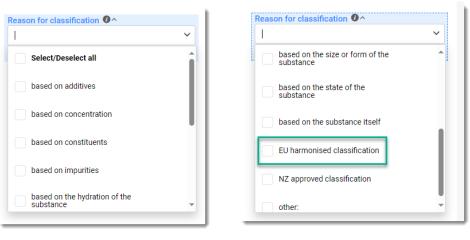
Hazard category	Hazard statement
ED ENV 1	EUH430: May cause endocrine disruption in the
	environment. European Union
Persistent, Bioaccumulative and Toxic or	Very Persistent, Very Bioaccumulative properties (EU CLP)
Hazard category	Hazard statement
PBT	EUH440: Accumulates in the environment and living
	organisms including in humans. European Union
Persistent, Mobile and Toxic or Very Pers	istent, Very Mobile properties (EU CLP)
Hazard category	Hazard statement
PMT	EUH450: Can cause long-lasting and diffuse
	contamination of water resources. European Union

Hazard class and category code	Hazard statement code	Hazard statement
ED HH 1	EUH380	May cause endocrine disruption in humans
ED HH 2	EUH381	Suspected of causing endocrine disruption in humans
ED ENV 1	EUH430	May cause endocrine disruption in the environment
ED ENV 2	EUH431	Suspected of causing endocrine disruption in the environment
РВТ	EUH440	Accumulates in the environment and living organisms including in humans
vPvB	EUH441	Strongly accumulates in the environment and living organisms including in humans
РМТ	EUH450	Can cause long-lasting and diffuse contamination of water resources
vPvM	EUH451	Can cause very long-lasting and diffuse contamination of water resources

## 

#### Additional new fields

#### Reason for classification:



#### Acute Toxicity Estimates (ATE):

Acute Toxicity Estimates (ATE)	1
Oral	
Dermal	
Inhalation	J

### Information relevant to specific user groups

• EU Biocidal Products Regulation (BPR)

**IUCLID** version 8

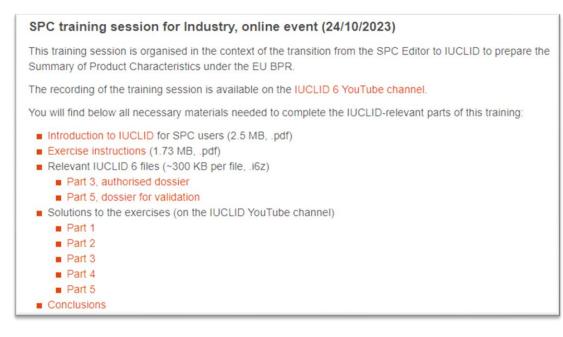
Dorota Burchard-Sosnowska





#### BPR Summary of product characteristics (SPC): key information

- Since February 2024, the SPC Editor was discontinued and replaced with SPC in IUCLID
  - Dedicated webinar 'Get ready for the transition of SPC into IUCLID' took place 15.02
  - Training material from SPC training session for Industry (24/10/2023) available on the <u>IUCLID website</u>





- 'Product'
  - Header 'Specific composition of each biocidal product' replaced by 'Composition of the product' (v.8.0.1)

1			
5-dc2a-432b-895d-6	7eb3573f64d		
rmation Specif	c composition o	of each biocidal prod	uct
nposition of eac	ch biocidal pro	oduct	
ew item 🛛 👌 Impo	ort file 🗸		
Common n	Function	Generated i	Content (%)
📥 Iodine   EC 231-442-4	active substance		1 % (w/w)
r	S-dc2a-432b-895d-63 mation Specifi position of eac w item the Impo Common n      Iodine   EC	dc2a-432b-895d-67eb3573f64d  mation Specific composition of position of each biocidal pr witem the Import file ↓ Common n Function      lodine   EC 231-442-4   active	dc2a-432b-895d-67eb3573f64d  mation Specific composition of each biocidal prod  position of each biocidal product  w item ⓑ Import file ↓  Common n Function Generated i      lodine   EC 231-442-4



- 'Product'
  - both Content (%) and Content range (%) allowed to be reported for an active substance generated in situ, but if one option is selected, the other is blocked (v.8.0.1)

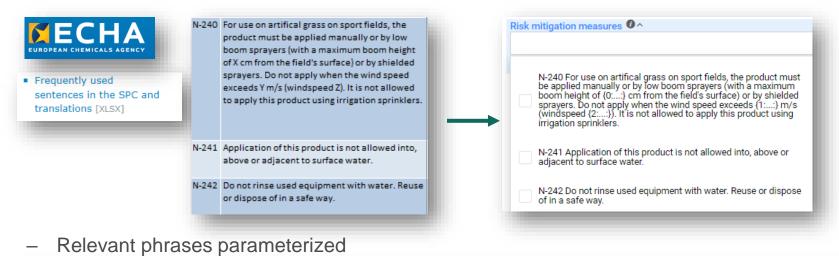
Set values Common name Hydrogen peroxide   EC 231-765-0   7722-84-1 Function		Set values Common name Argen peroxide   EC 231-765-0   7722-84-1 Function
active substance Generated in situ Content (%)	OR	active substance Generated in situ Content (%)
1 % (w/w) Content range (%)		Content range (%)         ● ^ ● ^           ✓         1         ✓         3         % (w/w)         ✓



- 'Hazard and precautionary statements'
  - Hazard pictograms added (v.8.0.1)

Hazard and precautionary statements
Hazard pictogram
🕂 New item 🖄 Import file 🗸
1 Code
GHS08: health hazard
Hazard Statements
+ New item tile
Hazard statement
H319: Causes serious eye irritation.
Additional labelling requirements
+ New item 👌 Import file 🗸
Additional non-GHS hazard statement EUH070: Toxic by eye contact. European Union
Precautionary statements
+ New item 🐁 Import file 🗸
Precautionary statement
P337+P313: If eye irritation persists: Get medical advice.

- 'General directions for use' and 'Use-specific directions for use' (v.8.0.1)
  - 'Frequently used sentences in the SPC' (PT 1-5, 8 and 18) available in form of a picklist in addition to a free text field. Translations will be progressively added.
  - Content of both fields retrieved in an rtf / pdf SPC



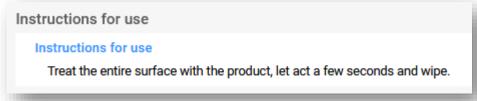


#### BPR Biocidal product authorisation: format changes

- Sections 7 and 11 (v.8.0.1)
  - Similar structure of section 7 in BPR Biocidal product authorisation dataset and BPR Summary of product characteristics (SPC)
  - Use-specific instruction for use should be reported in section 7.9 Proposed instructions for use (new document)

```
Use-specific instructions for use
Treat the entire surface with the product, let act a few seconds and wipe.
```

 Instruction for use relevant to the whole meta SPC or to the whole single product, should be reported in section 11 'Measures to protect humans, animals and the environment' (existing document)



 - 'Frequently used sentences in the SPC and translations' (PT 1-5, 8 and 18) available in form of a picklist in both documents



# Reuse of existing BPR Biocidal product authorisation datasets to create an SPC (v.8.0.2)

- BPR Biocidal product authorisation  $\rightarrow$  BPR Summary of product characteristics (SPC):
  - only documents relevant to the SPC are displayed in the table of contents

Working context		Working context
BPR Biocidal product authorisation		BPR Summary of product characteristics (SPC)
C Type at least 3 characters X		Q Type at least 3 characters
BPR Biocidal product authorisation		
Y 🏅 Rodenticide example		BPR Summary of product characteristics (SPC)
> 1 Applicant*	4	✓ T Rodenticide example
> 2 Identity of the biocidal product*	2	> Manufacturers of the product
ightarrow 3 Physical, chemical and technical properties*		<ul> <li>Product information</li> </ul>
> 4 Physical hazards and respective characteristics*	$\rightarrow$	
5 Methods of detection and identification*		> Hazard and precautionary statements
> 6 Effectiveness against target organisms*	1	> Authorised uses
> 7 Intended uses and exposure*	6	> General directions for use
> 8 Toxicological profile for humans and animals*	4	Other information
> 9 Ecotoxicological studies*	3	
> 10 Environmental fate and behaviour*		
> 11 Measures to protect humans, animals and the environment*	1	
> 12 Classification & Labelling*	2	
> 13 Summary and evaluation	1	

2



# Reuse of existing BPR Biocidal product authorisation datasets to create an SPC (v.8.0.2)

- BPR Biocidal product authorisation  $\rightarrow$  BPR Summary of product characteristics (SPC):
  - in documents used by both working contexts, fields relevant only to BPR Biocidal product authorisation, are hidden, but can be displayed if working context is changed again

S.001	GHS.001
): 9e7f8479-76f6-34be-8786-2ff4a78d91d2	UUID: 9e7f8479-76f6-34be-8786-2ff4a78d91d2
0	Hazard and precautionary statements
eneral Information Classification Labelling Note	es (EU CLP)
	Hazard and precautionary statements
	Hazard pictogram
eral Information	+ New item 🛛 🖕 Import file 🗸
lame	
Not classified	
mplementation	GHS09: environment
ype of classification	
ype of classification	
Remarks	Code GHS06: skull and crossbones
elated composition	GHSU6, skull and crossbores
Related composition 0 ^ 0 ^	Hazard Statements
Felect	+ New item 🔹 Import file 🗸
ssification	
hysical Hazards	1 Hazard statement
Explosives	H280: Contains gas under pressure; may explode if heated.
Hazard category Hazard statement	
Expl. Div. 1.1 H200: Unstable exp ammable gases and chemically unstable gases	Jiusives.
Hazard category Hazard statement	
Flam. Gas 1A H220: Extremely fla	ammable gas. H400: Very toxic to aquatic life.



# Reuse of existing BPR Biocidal product authorisation datasets to create an SPC (v.8.0.2)

- BPR Biocidal product authorisation → BPR Summary of product characteristics (SPC):
  - only substances relevant to the SPC (active substance, substances of concern, releasers, other substance(s) knowledge of which is essential for proper use of biocidal products) included in the SPC dossier and report
  - not relevant substances should be flagged in the BPR biocidal product authorisation dataset accordingly to instructions provided in <u>BSM Technical guide: How to prepare a biocides dossier</u>

Please select	Flags for regulatory programme Select information to be included*	~ )
Justification @ < A Insert existing templates Components + New item time time time time time time time	No regulatory purposes AU: AICIS	×
0/32768 # Component flag Name Function	US: FIFRA	×
Use restricted to selected regulatory programmes @ solvent ii 1 @ Pnot SPC 7732-18-5 solvent	US: TSCA other:	×
other: X not SPC 7/255	Other	0/255 press facto close



# Reuse of existing BPR Biocidal product authorisation datasets to create an SPC (v.8.0.2)

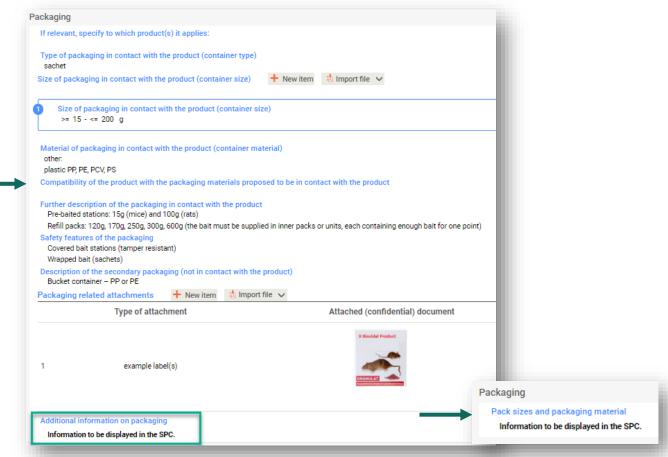
- BPR Biocidal product authorisation  $\rightarrow$  BPR Summary of product characteristics (SPC):
  - substances other than an active substance are allowed in an SPC as a dataset (rtf / pdf SPC will retrieve a reference substance)

nposition of	the product		Working context					
+ New it	em 🎂 Import file 🗸	BPR Summary of product characteristics (SPC)						
	Common name	Function	Generated in situ	Content (%)	Content range (%)	Substance of concern	Type at least 3 characters	
🗄 1 🍐 Broo	lifacoum   3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]-4-hydroxy-2H-chromen-2-one   EC 259-980-5   56073-10-0	active substance		50 ppm			<< 🝹 Rodenticide example 🕚 Product composition.	01
2 🔥 Py	e substance   oryzalin   4-(dipropylamino)-3,5-dinitrobenzenesulfonamide   EC 242-777-0   19044-88-3	dye		9 % (w/w)		☑ .	🖌 🤞 Dye substance	
<b>ii</b> 3	Solvent substance   triphenylene   EC 205-922-9   217-59-4	solvent		90 % (w/w)			<ul> <li>Identity of the substance</li> <li>Dye substance</li> </ul>	



# Reuse of existing BPR Biocidal product authorisation datasets to create an SPC (v.8.0.2)

- What are the differences that require manual adaptation:
  - mixture component reported in a biocidal product composition needs to be manually adapted, as only substances are allowed in the SPC
  - content of the field 'Additional information on packaging' in the biocidal product authorisation dataset is transferred to the field 'Pack size and packaging material' in the SPC; if this field is left empty, information about packaging needs to be provided from scratch in the SPC
  - Other information' is an original document not mapped to BPR Biocidal product dataset



### SPC Reports (Single product and Family) (v.8.0.1)

#### Improvements

- The table of contents has been removed
- The reference substance name in the active substance is taken from 'Manufacturer(s) of the active substance(s)' table
- The reference substance name is now displayed for components indicated as substances of concern
- The Family and Product name in the cover page is taken from the 'Family or meta SPC identifier' or 'Product name' fields respectively
- The translated name of a reference substance is displayed for the reference substance component if this reference substance has been selected from ECHA BPR Active Substances

#### **Fixes**

- '&' correctly displayed
- cover page and header details in the Maltese version of the SPC correctly displayed
- composition tables for Meta SPCs and Products include all the relevant components (unless they are 0-0%)



## Information relevant to specific user groups

• Drinking Water Directive (DWD)

**IUCLID** version 8.0.1

Dorota Burchard-Sosnowska



#### Drinking Water Directive: IUCLID format

- Minimum Viable Product format prepared based on:
  - development of the legal framework in 2023
  - requirements and feedback from experts
- Three working contexts:
  - DWD Notification of intention (dossier)
  - DWD application (dossier)
  - DWD Data for relevant chemical species (sub tree in DWD application, in section 1.5)
- If you are interested in joining the Drinking Water Directive IT tools user group which focuses on testing and providing feedback to ECHA, please contact ECHA by e-mail at <u>ECHA\_DWD@echa.europa.eu</u>



## Advice for upgrading IUCLID

- Checklist and tips
- Export to previous major version

**IUCLID** version 8.0.1

• Robin Allen



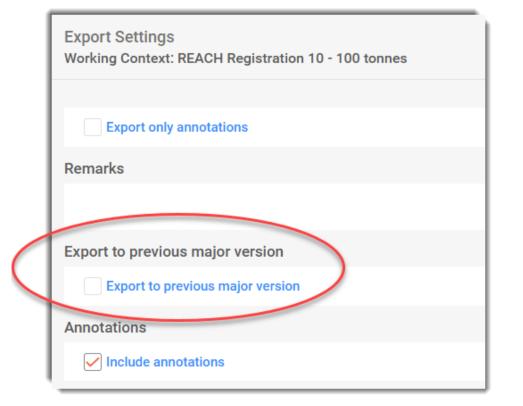
### Before upgrading: Compatibility of data

- **Upgrade:** IUCLID data are converted to the latest version.
- **Import:** All IUCLID 6 files can be imported into the latest version. Import converts the data into version 8.
- **Export:** IUCLID data are exported in the current version.



#### Before upgrading: Recommendations

- Upgrade to the latest version as soon as possible
- Ensure that you, and any users of the instance of IUCLID know what effects the upgrade will have
- Follow recommendations from the relevant authorities in terms of data submission:
  - Some authorities can accept dossiers in several versions of IUCLID
  - Some authorities can accept only the latest version of IUCLID
  - Some authorities can reject the latest version of IUCLID until they have updated their systems to the new version



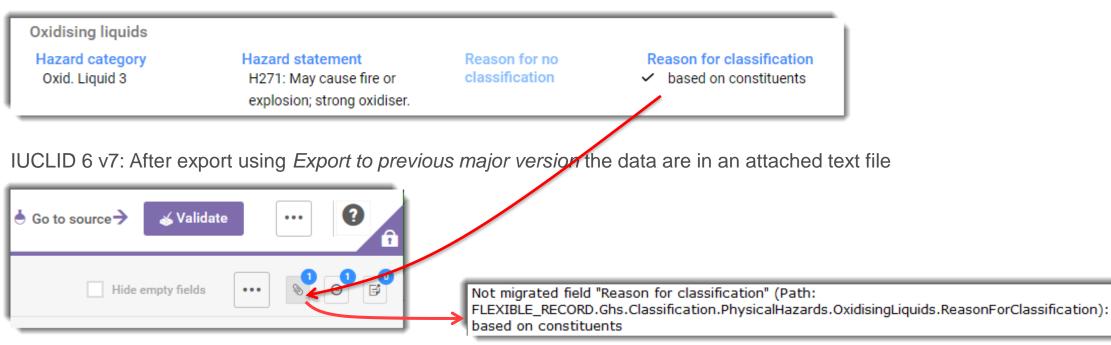


## IUCLID new functionalities 2024 webinar

Export to previous major version Example 1: New field

•

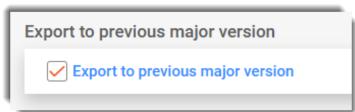
- Export to previous major version
- IUCLID 6 v8: Data in the new field Reason for classification





## IUCLID new functionalities 2024 webinar

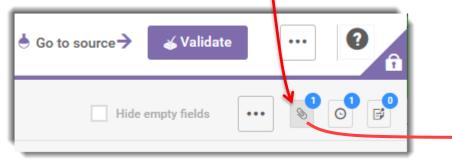
Export to previous major version Example 2: New subsection and values



• IUCLID 6 v8: Data in new subsection Endocrine disruption for the environment (EU CLP) in section 2.1 GHS under REACH

Endocrine disruption for	the environment (EU CLP)		
Hazard category ED ENV 1	Hazard statement EUH430: May cause endocrine disruption in the environment. [European Union]	Reason for no classification	Reason for classification ✓ based on additives

• IUCLID 6 v7: After export using *Export to previous major version* the data are in an attached text file.



6.8-to-6.7_migration_dataloss_26 Apr 2024 131239.txt - Notepad	-		×		
File Edit Format View Help					
Not migrated field "Hazard statement" (Path: FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.EDENV.HazardStatement EUH430: May cause endocrine disruption in the environment.					





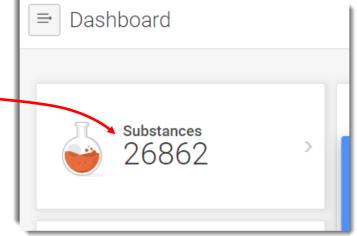
### Before upgrading: Backup IUCLID data

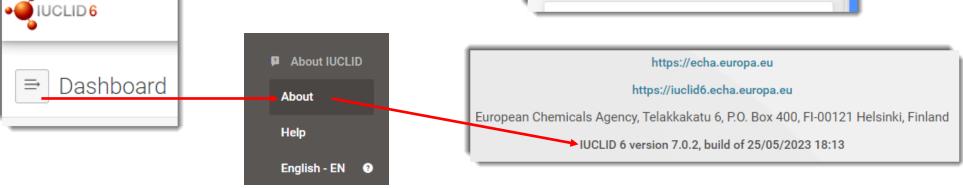
- Verify the backup process
- Backup by installation type:
  - IUCLID 6 Desktop: a backup is made automatically during the upgrade
  - ECHA Cloud: data is managed as part of the service
  - IUCLID 6 Server: if an external database is used, the database must be backed up separately before the upgrade, as described by the database vendor:
     Derby Network Server
     PostgreSQL
     Oracle



### Before upgrading: Health check

- An update of IUCLID does not require an increase in the system resources. For comparison with the situation after the upgrade, you can do the following:
  - Note the counts of entities on the Dashboard
  - Check the response times in the interface
  - The version of the IUCLID application is visible under: *About > Dashboard*.







### Upgrading: The IUCLID Updater Tool

- Download from the IUCLID website free of charge for: Windows, Linux, and macOS
- Works with all versions of IUCLID 6 of types Desktop and Server
- Migrates all types of supported databases to version 8
- Backs up IUCLID data for the IUCLID Desktop, but not all Server installations.

Manual for update and installation: https://iuclid6.echa.europa.eu/documentation



#### 🝕 IUCLID 6 Updater Tool

#### Welcome to the IUCLID 6 Updater tool (8.0.1).

In the first field below, enter and/or verify the installation directory directory contains a folder named *glassfish4* or *payara5*. Then, ch restore to a previous version of the application and its data.

#### IUCLID 6 installation directory

C:\iuclid6-desktop-7.12.4

#### Details of installation

Type: Desktop

Version: 7.12.4

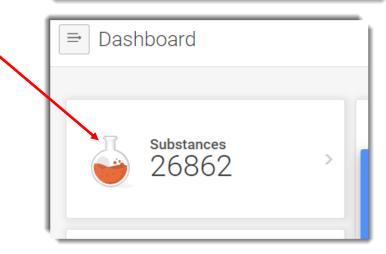
#### Select the action to perform

- Opdate IUCLID 6 installation to version 8.0.1
- C Restore IUCLID 6 to a previous version

### After upgrading: Health check

- For comparison with the situation before the upgrade, you can do the following:
  - Before trying to access the interface, clear the browser cache. Shortcuts for this are: *Ctrl F5* or *Shift F5*.
  - Check that the version of the IUCLID application from About is 8.0.1.
  - Check that the data you expect to see are accessible, including the counts on the Dashboard;
  - If you have data that are affected by the migration to the new format, check a few examples to see what has happened;
  - Try out new features that are described in the release notes.

IUCLID 6 version 8.0.1, build of 12/04/2024 16:02

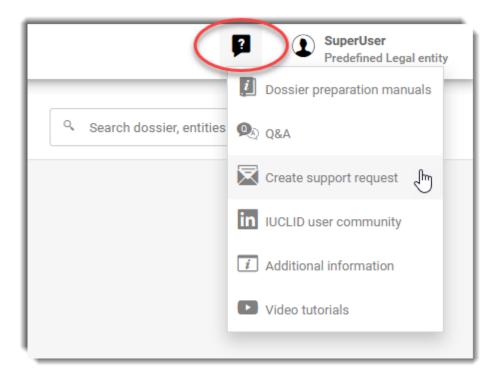




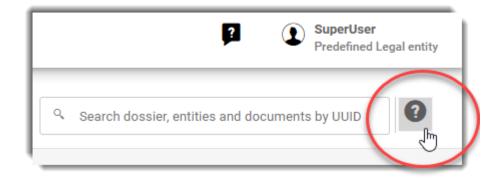


### After upgrading: Sources of help

• Links to more info and help



• User manual



### Conclusions

Robin Allen





- The new release is available from our website at: <u>https://iuclid6.echa.europa.eu/</u>
- It includes:
  - Format changes, applied automatically during the upgrade
  - Fixes
  - Improvements
- Check the release notes for further details

Question and answers session

- Q&A using Slido open until 16:00 (EET)
- You can keep your questions anonymous
- All Q&As will be published on the webinar pages in the upcoming days at <u>https://echa.europa.eu/webinars</u>





### Information and news about IUCLID





### IUCLID website

- Documentation
- Downloads
- Product information



# YouTube channel

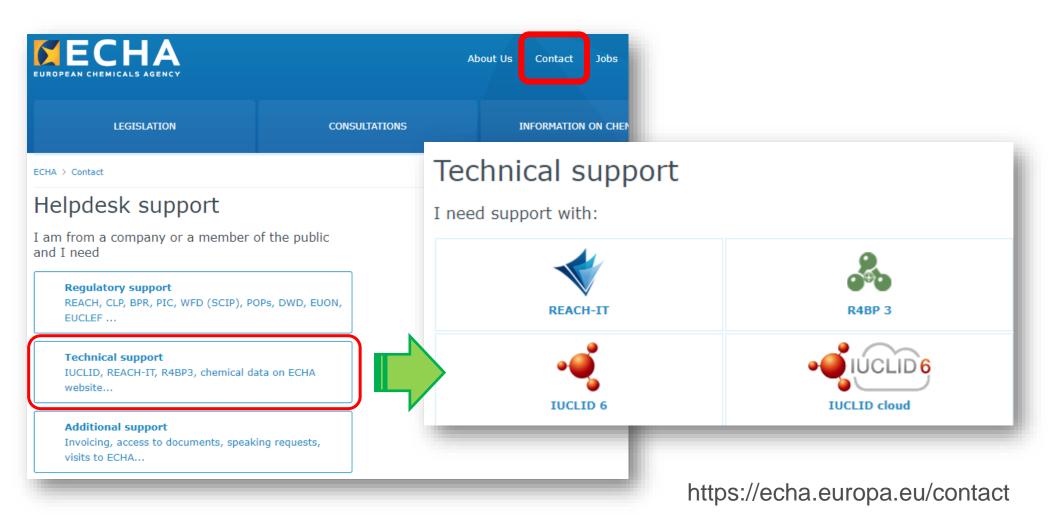
- Video tutorials
- Trainings
- Webinars



### LinkedIn group

- News
- Discussion topics







Thank you for your participation

