





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





## **IUCLID** 6

Version 5.15.0 (April 2021) release webinar

12<sup>th</sup> May 2021





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





### Agenda for today

| Introduction   |
|--|
| The web interface and REACH users                      |
| Adaptations of IUCLID for EU Plant Protection Products |
| Demo of key features included in the new release       |
| Conclusions and what's next                            |

Slido

#### Question and answers session

- This time, the Q&A session is organised using Slido
- The Slido session will last until 5pm (EET) on the webinar day
- You can decide to keep your questions anonymous
- We will answer your questions during the day



https://www.sli.do/





### Recordings

- This webinar will also be published on the IUCLID 6 website
  - The recording of the webinar (and presentation)
  - Questions and answers



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

## Introducing the April 2021 IUCLID release

IUCLID version 5.15.0



### Highlights

- IUCLID 6 v5.15.0
  - Published on 28<sup>th</sup> of April to all IUCLID users
  - ECHA Cloud Services instances updated starting from 26<sup>th</sup> of April
- High level scope items
  - Fixes and improvements (see demo later on)



- Guided dossier approach decommissioned
- Web interface finalisation
- More information in the release notes

https://iuclid6.echa.europa.eu/documents/21812392/22308511/IUCLID 6 Rel ease Notes.pdf/



#### **IUCLID** news

#### 28/04/2021

#### IUCLID 6 April 2021 Service Release

#### A new service release of IUCLID is made available to all users. The release contain

The IUCLID software is continuously undergoing new development for different user 🖞 made available regularly. Twice a year, in April (Service Release) and October (Major made available to all users on the IUCLID website. This new version contains fixes and new tab, and to reorder elements in tables and repeatable sets

The Guided dossier approach, introduced some years ago, has now been superseded available from the IUCLID Dashboard, from where you can continue to prepare your do

In addition, this release provides the latest configuration for preparing dossiers under El Products and the Waste Framework Directive (SCIP notifications). For example, update reports.

With this release we also pursue the transition from the classic interface to the web int Users and Reports management. We have kept the classic interface available only to available from the IUCLID website after answering a short survey that will help us ident

A webinar will be held on the 12th of May to present this new release, its features, and to the event.

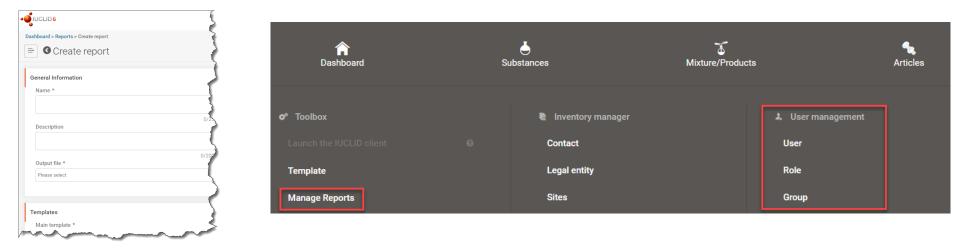
You can access the full release notes and download the new version from the IUCLID automatically upgraded during the week of the release

Additional information



### Finalising the web interface

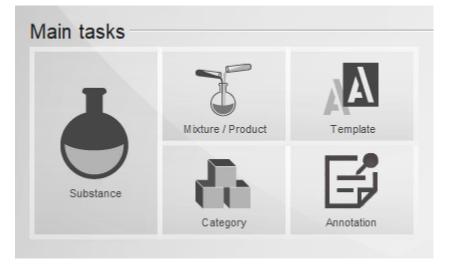
- Important features have been added to the April release to finalise the web interface
  - Report manager (see also <u>https://iuclid6.echa.europa.eu/reports</u>)
  - User and Role management (including Group management with Instance-Based Security enabled)



• Additional improvements are also making the web interface easier to use



### April release and the availability of the classic interface



- The Classic interface is still be available with the April release this year:
  - To give users time to become familiar with the user management
  - To allow more time for ECHA to improve aspects of performance with the web interface

### Transition to the web interface



#### IUCLID6 IUCLID 6 version 5.1 Latest version of its second IUCLID is 6. What is not Go to the IUCLID Get the 111 100 installed and website and instructions on how to start the access to the answer a short Classic interface **Classic interface** survey needed

### How to access the classic interface with IUCLID 6.5.15?

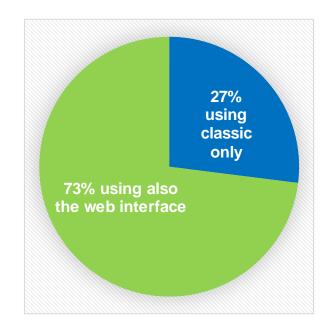
https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface

## Transition to the web interface



#### Information collected with the survey so far

- Users who needed to access the classic interface are also using the web interface already (73%)
- We also collected useful feedback to further improve the user interface (some already available in the April release)
  - Make the navigation tree easier to use
  - Improve the way references are made between documents
  - Allow changing the Working Legal entity for Desktop version users
  - More training needed, manuals
  - Please make the survey shorter ©

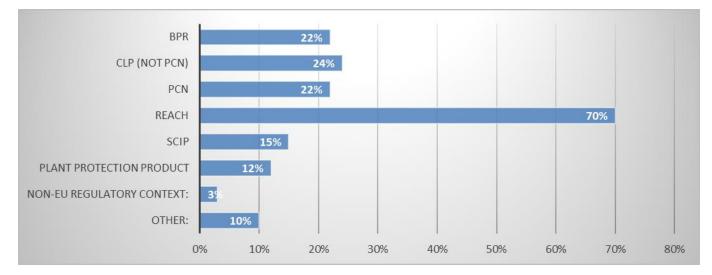


| Why you are not using the web interface only |     |
|--|-----|
| Not trained and lacking time                 | 32% |
| Missing small but important features         | 35% |
| Missing large and essential features         | 33% |



### Area of work

• With the survey we also collected information about the area of work



- Understandably there is an inverse correlation between the time a user has been using IUCLID and the acceptance of the web interface: the longer you have used the classic interface, the more difficult it is to transition to the web interface
- Demo will follow for REACH users



# The web interface and REACH users

- Presentation of the material currently available for supporting the use of IUCLID web user interface.
- Demonstration on useful features for create REACH dossier with IUCLID web user interface.



## Support material for the use of IUCLID web UI

### Tools and guidance

- REACH Manuals www.echa.europa.eu/manuals
- 'Learn to use the new interface' webpage https://iuclid6.echa.europa.eu/learn-to-use-the-new-interface)
- Manual 'Functionalities of IUCLID in the web interface'
   Access through button in IUCLID web user interface



PROPER PARTY AND IN CONSISTENCE

-

00000 4

RECHA

Doursel Subvectoriel Texts

Manuals

IUCLID 6



### HOW TO CREATE A REACH DOSSIER WITH IUCLID WEB UI



### Scope of the demo

- Overview of some useful features of the IUCLID web interface
- Presentation of the improvements in the web interface vs classic IUCLID

| Dashboard |                 |   | To the other and the series in the                                  | 0 |
|-----------|-----------------|---|---|---|
|           | Substances<br>1 | 2 | Import RICLID file(s) Q (paraets settings: 11 more free setting (2) |   |
|           | Matures<br>0    | 2 | Coop file to import = Browse<br>Advanced import                     |   |
|           | Articles 0      |   |   |   |



# **IUCLID Cloud services**

- Easy to set up
- Maintained by ECHA (always use the latest version)
- Dossiers can easily be retrieved for submission

Further info at https://iuclid6.echa.europa.eu/faq





### **Background information**

- New regulation on the transparency and sustainability of the EU risk assessment in the food chain (EFSA)
  - Make studies available to the public
  - Notification of studies
  - EFSA can commission additional studies
- EFSA and ECHA worked on providing IT tools to support this regulation, in the context of Plant Protection Products, around IUCLID



• The Regulation applies since the 27<sup>th</sup> of March 2021

More information: <u>https://www.efsa.europa.eu/en/news/transparency-risk-assessment-new-era-begins</u>

### How the latest version of IUCLID is adapted for Pesticides

- All pesticides **dossier types** supported
  - Substance authorisation (initial and renewal), including for micro-organisms
  - Maximum Residue Levels (in food) applications
  - Basic substance
  - (Product authorisation, although no agreement to be used at MSCA level)

| Article 7  |   |
|--|---|
| Format and software for the submission of the  | e application for renewal   |
| 1. The Authority shall establish and make available online a central submissi<br>submission system facilitates the verification of admissibility performed by Ma | 2   |
| 2. The standard data formats proposed by the Authority as part of the Regulation (EC) No $178/2002 \ are hereby adopted.$  | IUCLID software package pursuant to Article 39f of                |
| 3. The application for renewal shall be submitted via the central submission s   | ystem using the IUCLID software package.                          |
| 4. The applicant, when requesting certain information to be kent confider Regulation (EC) No 1107/2009, shall ind  | ntial in accordance with Article 63(1). (2) and (2a) of Article 2 |
| The Authority shall assess such a requirequirequirequirequirequirequirequi   | Adoption of standard data formats                                 |

The standard data formats for the approval of an active substance and those for the amendment to the conditions of such an approval, as proposed by the Authority, based on the IUCLID software package and linked with the central submission system to be established in accordance with Article 7(1) of Commission Implementing Regulation (EU) 2020/1740 (\*), are hereby adopted.

|            | D6  |         |                    |      |               |
|------------|---|---------|--------------------|------|---------------|
| Dashboard  | d > Mixtures / Products > Test product                      |         |                    | Ne   | ew working    |
| ⇒ 3        | Test product<br>c3a49870-ce15-49bf-8cb7-13f76d87cf50        |         |                    | 5    | Select workin |
| Workin     | g context: EU PPP Active substance                          | applica | ition (produc      |      | BPR Activ     |
|            |   |         |                    |      | BPR Active    |
| 1          | EU PPP Active substance application<br>(product)            |         |                    |      | BPR Basic     |
| <b>~</b> 🏅 | Test product  |         | UUID: c3a<br>Mixtu | 14   | BPR Bioci     |
| >          | 1 Identity of the plant protection                          |         | Test               |      | BPR Sumr      |
|            | product and applicant<br>2 Physical, chemical and technical |         | Public             |      | CLP Interc    |
|            | properties of the plant protection<br>product               | +       | None               |      | CLP PCN       |
|            |   |         | Legal              |      | CLP Poiso     |
|            | 3 Data on application                                       |         | Third              |      | CLP Poiso     |
|            | 4 Further information on the plant protection product       |         | None               |      | Complete      |
|            | 5 Analytical methods  | +       |                    |      |               |
|            | 6 Efficacy data   | +       | Other id           |      | EU PPP B      |
|            | 7 Toxicological studies on the plant                        |         | #                  |      | EU PPP M      |
|            | protection product  | 1       |                    |      | EU PPP M      |
| >          | 8 Residues in or on treated products<br>food and feed       | s,      | Contact            |      | EU PPP M      |
|            | 9 Fate and behaviour in the                                 | +       | Role in t          | None | EU PPP O      |
|            | environment   |         |                    |      | EU PPP P      |
|            | 10 Ecotoxicological studies                                 | +       |                    |      | HSNO App      |
| >          | 11 Literature data and change log                           |         |                    |      | HSNO Ful      |
|            | 12 Classification and labelling                             | +       |                    |      | HSNO Lim      |
|            | 13 Summary and evaluation                                   | +       |                    |      | OECD har      |
|            | Inherited templates   |         |                    |      |               |



| lew working context  |
|--|
| Select working context   |
| BPR Active substance application (representative product)        |
| BPR Active substance application (representative product)        |
| BPR Basic information (mixture)                                  |
| BPR Biocidal product authorisation                               |
| BPR Summary of product characteristics (SPC)                     |
| CLP Interchangeable Component Group (ICG)                        |
| CLP PCN Standard formula component                               |
| CLP Poison centres notification                                  |
| CLP Poison centres notification (mixture in mixture)             |
| Complete table of contents                                       |
| EU PPP Active substance application (product)                    |
| EU PPP Basic substance application                               |
| EU PPP Microorganisms - active substance application (production |
| EU PPP Microorganisms - plant protection product authorisation   |
| EU PPP MRL application   |
| EU PPP Other mixture   |
| EU PPP Plant protection product authorisation                    |
| HSNO Applicant full assessment                                   |
| HSNO Full assessment   |
| HSNO Limited assessment  |
| OECD harmonised templates - mixture                              |
|  |



SuperUs

### How the latest version of IUCLID is adapted for Pesticides

- All pesticides dossier types supported
- Validation assistant configured to support data entry

|  | FLG I   |
|--|---|
| Validation assistant report  | Ø Re-validate 	✓ Edit draft dossier header  |
| Submission checks 💿 🕈 Quality checks 96  |   |
| Quality concerns have been detected for this substance dataset / c<br>circumstances in which some of the warnings can be ignored. The use  | ting inconsistencies in the information provided, there may be special  |
| 1.4 Detailed quantitative and qualitative information on the com<br>Mixture composition is incomplete. At least one Mixture completed and the second secon | Quality check (QLT_PPP_021  |
| 2 Physical, chemical and technical properties of the plant proto<br>Section 2 Physical, chemical and technical properties of the plant   | Quality check (QLT_PPP_014  |
| <ul> <li>2.1 Appearance</li> <li>Section 2.1 Appearance: At least one endpoint study record into<br/>they cannot be used to fulfil the information requirement.</li> <li>To indicate an endpoint study record as a key study or as par-<br/>methods, and Results and discussion for this endpoint. Other</li> <li>To indicate an endpoint study record as data waiving, make a</li> </ul>  | Quality check (QLT_PPP_013<br>relate, as additional endpoint study records, but<br>inistrative data', 'Data source', 'Materials and |
| 2.1 Appearance<br>Section 2.1 Appearance: At least one endpoint study summary  | Quality check (QLT_PPP_014  |
| 2.4 Acidity / alkalinity and pH value<br>Section 2.4 Acidity / alkalinity and pH value: At least one endpositudy records, but they cannot be used to fulfil the information<br>- To indicate an endpoint study record as a key study or as par<br>methods, and Results and discussion' for this endpoint. Other<br>- To indicate an endpoint study record as data waiving, make a  | Quality check (QLT_PPP_013)<br>provided as appropriate, as additional endpoint<br>inistrative data', 'Data source', 'Materials and  |
| <ul> <li>2.4 Acidity / alkalinity and pH value</li> <li>Section 2.4 Acidity / alkalinity and pH value: At least one endpoint</li> </ul>  | Quality check (QLT_PPP_014  |
| 2.6 Relative density and bulk density  | Quality check (QLT_PPP_013  |



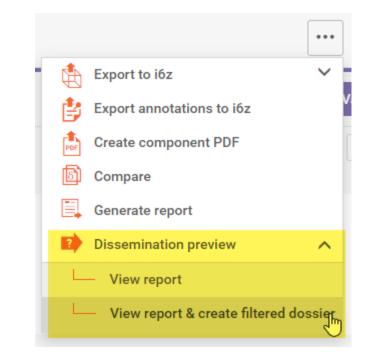
### How the latest version of IUCLID is adapted for Pesticides

- All pesticides dossier types supported
- Validation assistant configured to support data entry
- First reports are available to support the evaluation work

| Select the ty | pe of report  | ×     |
|---------------|---|-------|
| POF           | Documents D (GAP)                                     | [PDF] |
| RIF           | Documents D (GAP)                                     | [RTF] |
| 5             | Documents D (GAP) - CSV                               | [CSV] |
| POF           | Documents M (Active Substance) - Section 2 (PhysChem) | [PDF] |
| RTF           | Documents M (Active Substance) - Section 2 (PhysChem) | [RTF] |
| PDF           | Documents M (Active Substance) - Section 5 (Tox)      | [PDF] |
| RTF           | Documents M (Active Substance) - Section 5 (Tox)      | [RTF] |
| PDF           | Documents M (Product) - Section 2 (PhysChem)          | [PDF] |
| RTF           | Documents M (Product) - Section 2 (PhysChem)          | [RTF] |
| PDF           | Documents M (Product) - Section 7 (Tox)               | [PDF] |
| RTF           | Documents M (Product) - Section 7 (Tox)               | [RTF] |

### How the latest version of IUCLID is adapted for Pesticides

- All pesticides dossier types supported
- Validation assistant configured to support data entry
- First reports are available to support the evaluation work
- A **filtering** configuration is available to preview the information to be made publicly available (generating a filtered dossier is now also possible)





### Demo of some key features introduced in the new release



Before ending the webinar





- Non confidential data collected under REACH by ECHA are made available in IUCLID format
- The data was refreshed on the 11<sup>th</sup> of March, including 23,000 substances (full list available in an Excel file)
- ~100 new substances compared to the previous update in March
- Download from the IUCLID website as a set of IUCLID (i6z) dossiers

https://iuclid6.echa.europa.eu/reach-study-results

#### IUCLID news

11/03/2021

REACH Study Results refreshed

The REACH Study Results download file has been refreshed, with over 100 new confidential substance data submitted to ECHA under the REACH regulation.

On the ECHA website data may be viewed only one substance at a time, but REAC installation of IUCLID, and then analysed using the IUCLID 6 API, the IUCLID Data

An index is provided of the approximately 23,000 substances, which allows users to been added to help identify the substances for which data may have changed in this

More information on REACH Study Results | ECHA data on registered substances

#### Updated twice a year



### What's next?

- IUCLID 6 development will continue with the following planned releases
  - June / July 2021 Cloud release
  - October 2021 Public release, including format changes: more information on format updates will be available at <u>https://iuclid6.echa.europa.eu/format</u>
- Additional releases can be made to support specific user groups

#### Planned releases

Two IUCLID releases are made per year: a major release in October, and format is modified only in the major release in October. Releases are sch month. The IUCLID instances hosted by ECHA in the ECHA Cloud Servic functionality becomes available, but the IUCLID format it uses changes a

The information below aims at highlighting the work planned for the web development to complete the transition from the IUCLID Classic interface t is not an exhaustive list, and is subject to change.

#### Next releases

- 28<sup>th</sup> of April 2021
- June or July 2021 (ECHA Cloud Services)
- 27<sup>th</sup> of October 2021

#### Features planned for the next IUCLID releases

- Bulk delete of IUCLID documents in a dataset.
- Full print to PDF: including all linked entities and their documents, for components.
- Report generator: advanced settings to filter datasets

https://iuclid6.echa.europa.eu/planned-releases



### Known developments

- Category advanced options: to include the full content of category members or only the substance properties
- Create a PDF for the full dossier or dataset (including all components)
- Create RTF: as an alternative to PDF creation
- Single Sign On solution: permitting users who have central account management systems to integrate with IUCLID



## Before ending the webinar



https://www.sli.do/





### slido

### Joining as a participant?

# iuclidapril2021



You can also join our LinkedIn group: <u>https://www.linkedin.com/groups/12043483/</u>



Thank you for your participation

