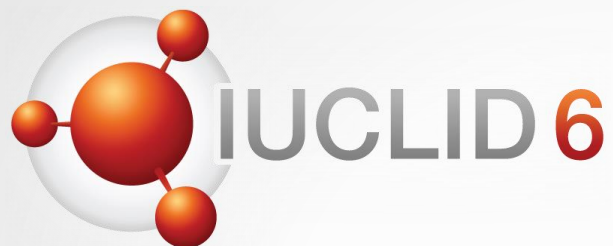


IUCLID 6





IUCLID 6

Version 5.1.2 (October 2020) release webinar

11th November 2020



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



Agenda for today

What?	Who?
<ul style="list-style-type: none">• Introduction to the October 2020 release• Format changes• Transition to the web interface	François Le Goff
<ul style="list-style-type: none">• Demo of key features included in the new release	Mark Roberts
<ul style="list-style-type: none">• ECHA Cloud Services• Additional information• Conclusions	Tommy Hägg

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

slido
**Joining as a
participant?**

No account needed.

iuclidoctober2020



By using Slido you accept our [Policy](#).

<https://www.sli.do/>

Recordings

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

[IUCLID](#) > [Support](#) > [Documentation](#) > [Webinars](#)



Documentation

- [System requirements](#)
- [Videotutorials](#)
- [Training material](#)
- **Webinars**
- [Verification of downloads](#)
- [Learn to use the new interface](#)

Webinars

What's new in IUCLID 6.4? (8th November 2019)

Registration to the webinar can be made on [this page](#).

Using the IUCLID web interface for biocides submissions (15th May 2019)



Agenda:

- The webinar introduces you to the latest IUCLID web interface improvements in IUCLID 6 (v3.16.1) for biocides submissions, including the creation and navigation of a BPR dossier, the comparison tool, and the report generator.

<https://iuclid6.echa.europa.eu/webinars>

Introducing the October 2020 IUCLID release

IUCLID version 5.1.2



Highlights

- Format update to support
 - The latest OECD harmonised templates
 - SCIP and Poison Centres formats
 - The use of IUCLID in Australia and New Zealand
 - The latest updates of the CLP regulation and the Globally Harmonised System
- New features and a move towards the web interface
- More information in the release notes

https://iuclid6.echa.europa.eu/documents/21812392/22308511/IUCLID_6_Release_Notes.pdf/

IUCLID news

28/10/2020

IUCLID 6.5 is available

Every October, a new major release of IUCLID is published and made available to all users. It brings improvements but also changes to the IUCLID format.

The IUCLID team has implemented, in the new version of the IUCLID format, the latest changes of the Classification and Labelling format in accordance with the latest updates of the CLP regulation and, in addition, the relevant modifications have been made to the SCIP and PCN formats in order to comply with submissions to the SCIP database and the Poison Centres in Europe. Updates specified by Australia support the implementation of IUCLID in both OECD member countries. Finally, the 2019 prototype of the submissions in Europe has evolved into a first official version of IUCLID for these dossier types, under the name of IUCLID 6.5.

On the software features side, some evolutions can be noted too, particularly the move towards the web interface with the abandonment of the classic interface availability by default. There will still be a possibility to use the classic interface in the next months though, following the instructions published on the IUCLID website. This move is aimed at reducing the gap between the two interfaces, for example by proposing a more efficient way of managing data.

You can access the full release notes and download the new version from the IUCLID website. ECHA will automatically upgrade the week of the release. We will hold a webinar, on the 11th of November, to discuss the new version.

Additional information

[Download IUCLID 6.5 release notes \(5 formats\)](#) | [Webinar](#) | [LinkedIn group](#)

Additional information

- Migration: as with previous IUCLID releases
 - Forward migration from older IUCLID 6 releases to 6.5
 - Backward migration to the previous major version (from 6.5 to 6.4)
- Validation assistant
 - Small updates relevant for REACH
 - New rules for Poison Centres
 - Update of the configuration for Australia
 - First set of rules for EU Plant Protection Products
- Filtering / dissemination preview extended to pesticides dossiers (prototype)
- Public API: REST resource for working contexts replacing the one for submission types

Format changes



IUCLID 6.5 release



Format changes

- October releases of IUCLID include format changes
- The new format has been published on the IUCLID website
<https://iuclid6.echa.europa.eu/format>
- The documentation includes
 - The list of fields
 - The IUCLID documents in .doc and .xsd format
 - A comparison with the previous format
 - The migration rules between IUCLID 6.4 and 6.5
 - Dynamic content rules implemented in the web interface

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:

- IUCLID 6.5, published on 28th of October 2020 (zip | 24.7 MB)
- IUCLID 6.4, published on 30th of October 2019 (zip | 20.2 MB)
- IUCLID 6.3, published on 24th of October 2018 (zip | 16.1 MB)
- IUCLID 6.2, published on 15th of November 2017 (zip | 15.0 MB)
- IUCLID 6.1, published on 29th 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 (.dot).

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:

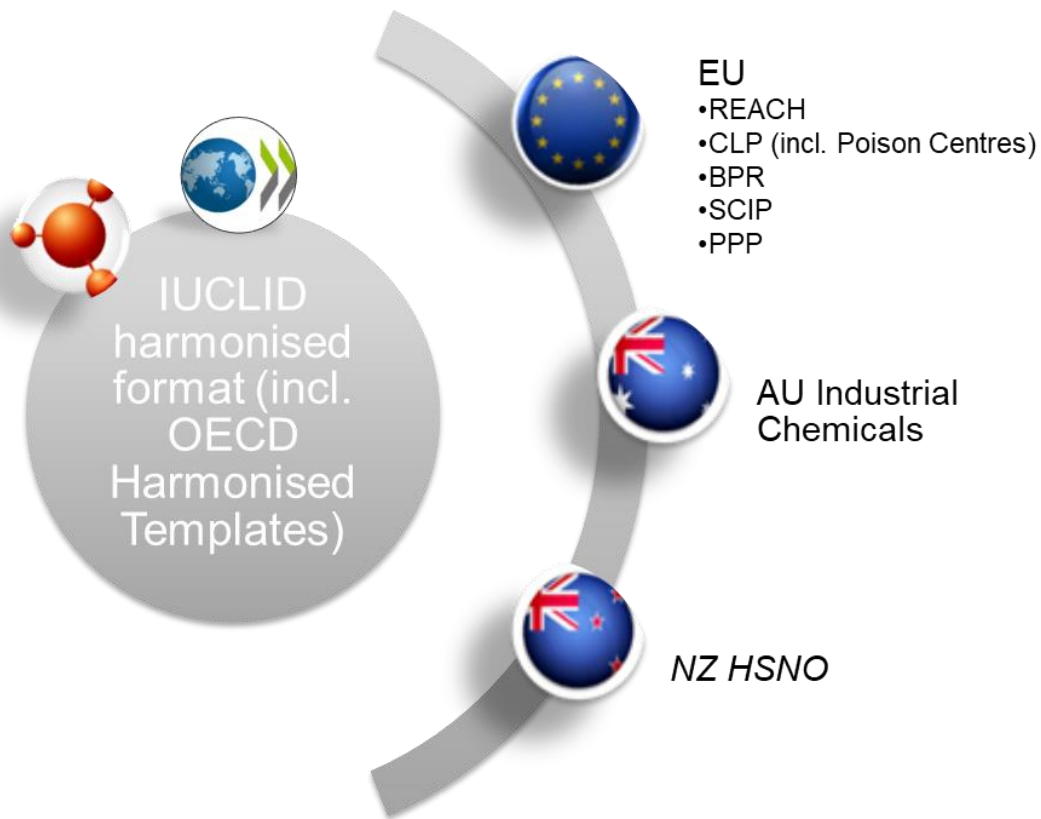
- Developers' Guide to the IUCLID i6z Format (.pdf | 1.1 MB)

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

The screenshot shows a file explorer window with two panes. The left pane shows a directory structure with folders: lau_ind_chem, bpr, clp, core, domain, nz_hsno, oecd, ppp, reach, scip, xsd_platform, DCRs_of_IUCLID6_5.xml, Full_Comparison_Application_Tag_IUCLID6_4_6-IUCLID6, IUCLID6_5_2020-10-27_10-59-03.xlsx, and migration_IUCLID6_5.zip. The right pane shows a list of files, including various .xsd files for endpoint summaries (e.g., ToxicityToSoilMacroorganismsExceptArthropods, ToxicityToSoilMicroorganisms, ToxicityToTerrestrialArthropods, ToxicityToTerrestrialPlants, Toxicokinetics, TransportAndDistribution, Vapour, Viscosity, WaterSolubility, ZetaPotential) and .doc files for additional information on environmental fate, residues in food, and toxicological information.

Structure of the format



Highlights of key format changes



- Maintenance update to all OECD Harmonised Templates
- New template 'Phototoxicity in vitro'
- More important updates for
 - #58 Basic toxicokinetics
 - #29 Biodegradation in water and sediment: simulation tests
 - #30 Biodegradation in soil
 - #41 Short-term toxicity to fish
 - #48-2 Endocrine disrupter testing in aquatic vertebrates – in vivo
 - #58 Basic toxicokinetics
 - #65 Eye irritation
 - #66-1 Skin sensitisation
 - #67 Repeated dose toxicity: oral
 - # 74 Developmental toxicity / teratogenicity
 - #85-2 Metabolism of residues in livestock
 - #85-3 Metabolism of residues in crops and in rotational crops
 - #85-5 Residues in crops (field trials) and in rotational crops (limited field studies)
 - # 88 Effectiveness against target organisms and intended uses - general information
 - #89 Efficacy data
 - #201 Intermediate effects – mechanistic information

Highlights of key format changes



- Regulatory purposes extension
 - AU: AICIS - [Australian Industrial Chemicals Introduction Scheme]
 - EU: BPR
 - NZ: HSNO - [Hazardous Substances and New Organisms Act]
- Category: add the possibility to include mixtures (in addition to substances)
- Literature reference: new fields
 - Attached documents (multiple)
 - Attached (sanitised) documents for publication (multiple)
 - Other study identifier(s), repeatable block containing
 - Study ID
 - Remarks
- Reference substance: reorganisation of fields leading to change of paths

Highlights of key format changes



- GHS (Classification and Labelling information)
 - New fields for Chemicals under pressure: HazardCategory, HazardStatement, ReasonForNoClassification
 - Reproductive toxicity, Germ cell mutagenicity, Carcinogenicity
 - Hazard Category 1 added
 - Route of exposure changed to multi-select picklist
 - Specific target organ toxicity - single (STOT-SE) and Specific target organ toxicity - repeated (STOT-RE)
 - System, picklist added
 - Affected organs, picklist added
 - Route of exposure changed to multi-select picklist
- Specific concentration limits, phrase groups updated to take into account latest GHS revision + alignment with phrases used in hazard section
 - Hazard categories
 - Hazard statement
 - Precautionary statement
- Additional non-GHS hazard statement: region of application added to the phrase (additional text)
- Note, phrase group updated

Highlights of key format changes



- Guidance on safe use
 - Help texts and labels updates
 - Class or division (phrases from the UN Recommendations on the Transport of Dangerous Goods)
 - Compatibility group, new field
 - Classification code, removed
 - Subsidiary hazard(s), new field
 - Packing group, from Text to Picklist (phrases from the UN RTDG)
 - Special provisions, new field
 - Language, new field
 - EmS code, from Text to Picklist (phrases from the UN RTDG)

Changes to the IUCLID harmonised format



Highlights of key format changes



- Mixture composition
 - Country from Picklist to Multi-select
 - Formulation type, phrase group updated
 - Function, phrase group updated
 - Impurities and additives removed (merged with components)
 - Interchangeable component group (ICG) and Standard Formula, checkbox added
- Updates of endpoint summaries to allow the provision of attachments
- 'Technical characteristics of the product' and 'Measures to protect humans, animals and the environment' moved from BPR to IUCLID
- New endpoint summary for Phototoxicity

Highlights of key format changes

- REACH regulation
 - New update reasons for registrations
 - New text templates for opt-out justifications
- Biocidal Product Regulation
 - New dossier type 'BPR Technical Equivalence'
- Classification Labelling and Packaging regulation
 - Interchangeable Component Group (ICG) and Standard formula component for Poison Centres
- SCIP: update of the dossier header and article document for SCIP notifications
- Plant Protection Products
 - Submission types for
 - EU PPP Active substance application
 - EU PPP Microorganisms - active substance application
 - EU PPP MRL application
 - EU PPP Basic substance application
 - 53 new documents created to comply with the information requirements



EU
•REACH
•CLP (incl. Poison Centres)
•BPR
•SCIP
•PPP

Changes to the IUCLID harmonised format



Highlights of key format changes



AU Industrial
Chemicals



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

- AICIS replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on 1 July 2020.
- There are 5 types of certificate applications that an applicant can apply for based on how they categorised their introduction. Information requirements checked by the Validation Assistant
- New document for AICIS statements

▼ AU Industrial Chemicals

Commercial Evaluation Authorisation

PBT assessment - AU

Pre-introduction report

AICIS Statement

Changes to the IUCLID harmonised format



Highlights of key format changes



NZ HSNO



**Environmental
Protection Authority**
Te Mana Rauhi Taiao

- Under the HSNO Act all hazardous substances (this includes mixtures) must have an approval to be imported, manufactured or used in NZ.
- New documents designed
 - first set implemented in the October 2019 release
 - second set came in October 2020
- A set of six submission types for substances and mixtures

▼	NZ Hazardous Substances and New Organisms (HSNO)
^	Regulatory history
^	HSNO Classification
	HSNO controls
^	HSW requirements
	Intended general uses
	Intended pesticide uses
	Intended veterinary uses
	Intended exclusive economic zone uses
^	Human health risk assessment
^	Environmental risk assessment

Transition to the web interface



Transition to the web interface



Web interface for **basic** chemical management

- IUCLID web user interface initially available only in the ECHA Cloud Services, then, in **October 2018**, to all IUCLID users (IUCLID v6.3).

Web interface for **advanced** chemical management

- From the October 2019 release (v6.4), the web interface started to gain more advanced functionality.
- With the October 2020 release, the web interface is now considered to be comparable to the classic interface for users to perform chemical information management.
- The classic interface will remain available for the leftover advanced features until **April 2021** and to help industry train their staff in preparation for working with only one interface



Transition to the web user interface



Remaining scope

Finalisation of main features

Remaining advanced features

October 2020 release

- **Advanced search for Dossiers**
- **Bulk deletion and export**
- **Inbound references**
(to view which entities and documents are linked to the selected one)
- **PNEC calculator**
- **Advanced import options**

Additional improvements

- **New navigation tree for datasets**
- **Print dossier advanced settings**

April 2021 release

- **Inventory manager**
- **Report manager**
- **User and role management**

Additional improvements

- **Report generator advanced settings**
- **Validation assistant advanced settings**
- **Transfer annotations between dossiers**
- **Simplified Classification and Labelling document for all submission types**

Continuing to monitor user feedback

- To check how well the web interface is being adopted, we have re-launched the survey we did at the end of 2019.
- The main conclusions of the last survey were that:
 - authorities are using the web interface predominantly
 - data editors are still missing features
 - promotion of the web interface should be increased
- The new survey re-opened on 30th September



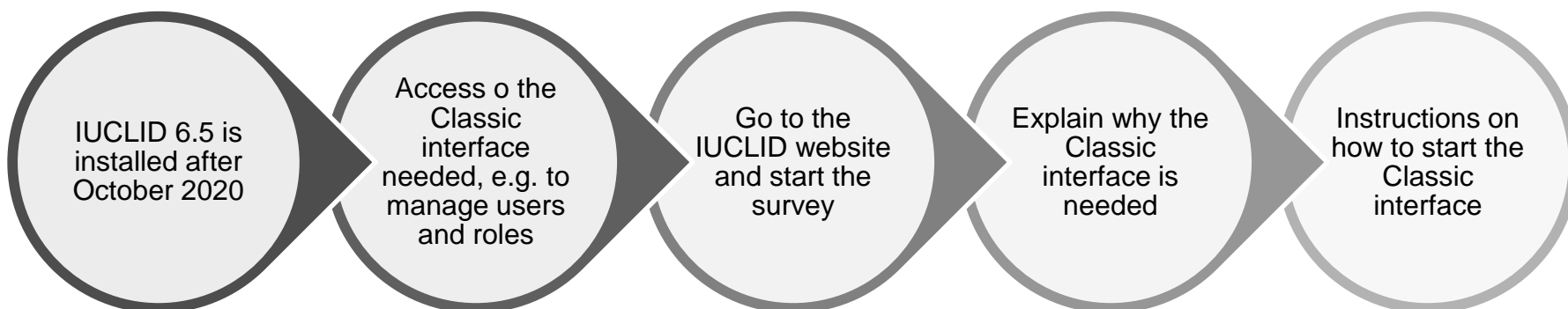
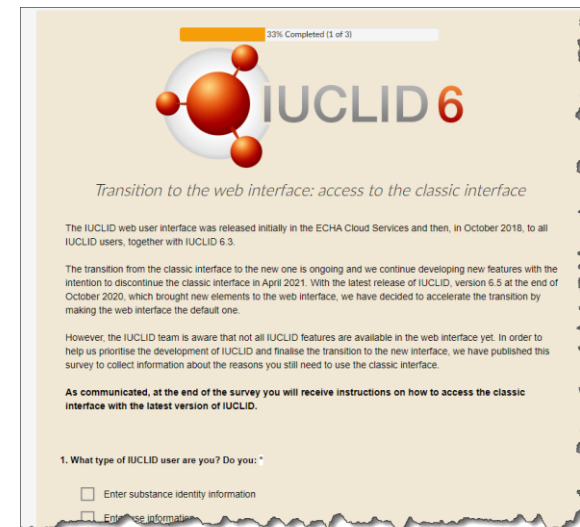
Phased transition to the web interface



How to access the classic interface with IUCLID 6.5?

Access the Classic interface of IUCLID

If you need to use the classic interface to carry out some specific task that you cannot do via the web interface, get instructions on how to open it from the link below. You will be asked to answer a short survey before getting the [instructions](#).

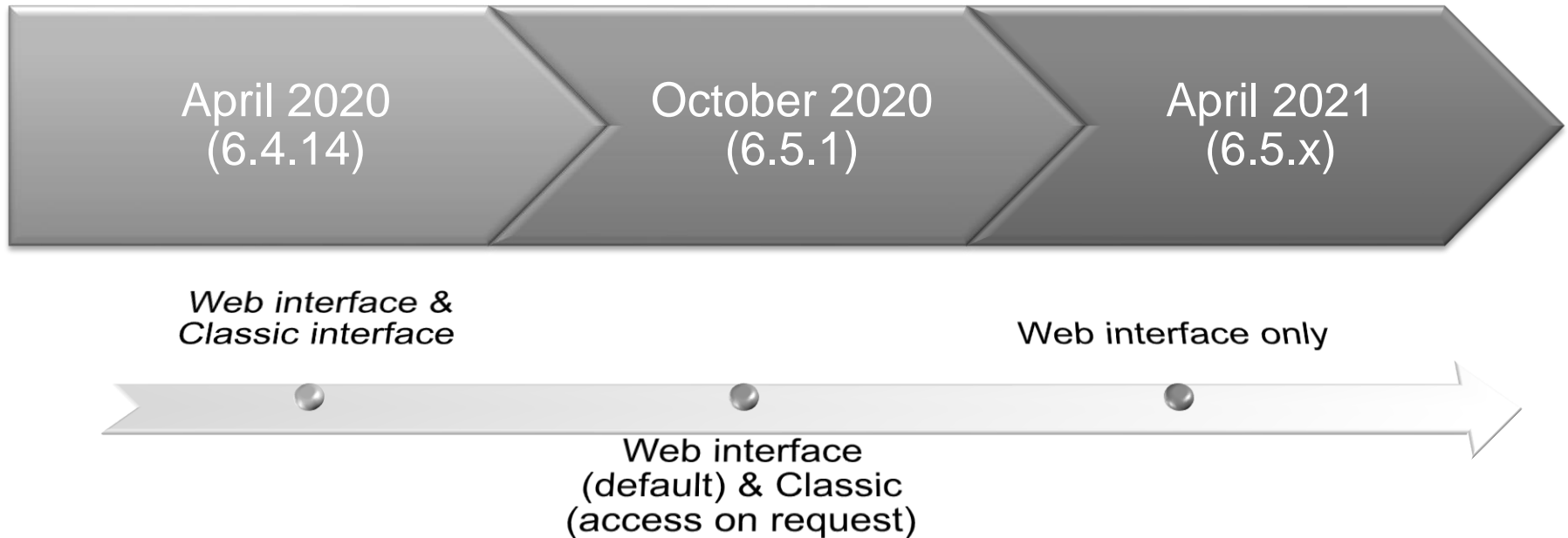


<https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface>

Phased transition to the web interface



Timeline



Continuing the support for the transition

- Continue to provide support material on the dedicated webpage:
<https://iuclid6.echa.europa.eu/learn-to-use-the-new-interface>



- Add video tutorials, e.g. for new features introduced since April 2020
- Add training material to help larger companies train staff
- Update the web interface functionalities manual
- Other ideas? Please share them with us!

Demo of some key features introduced in
the new release



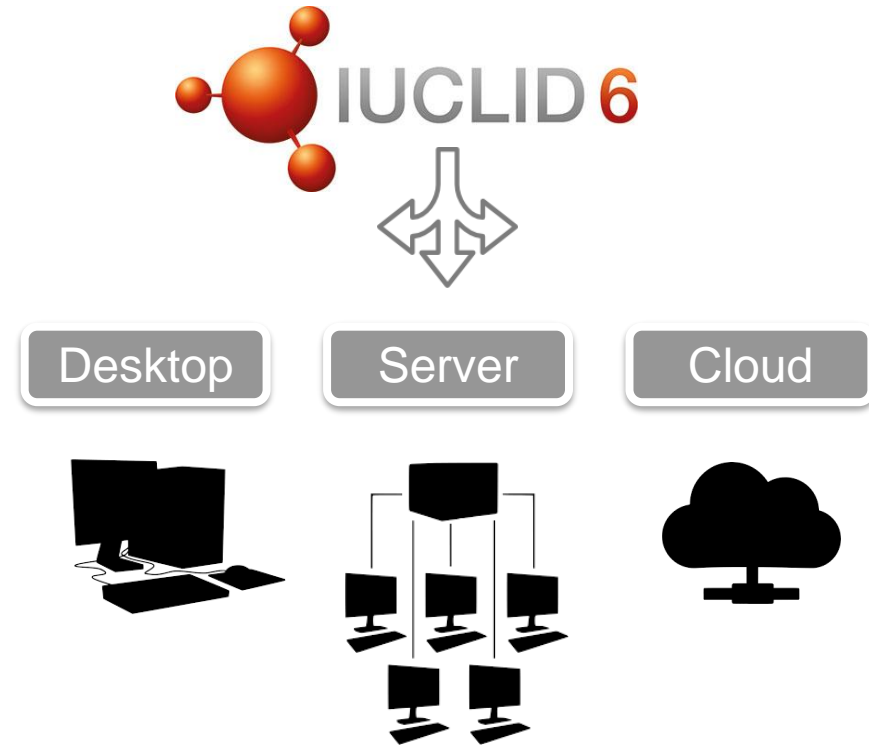
ECHA Cloud Services



Different distributions of IUCLID

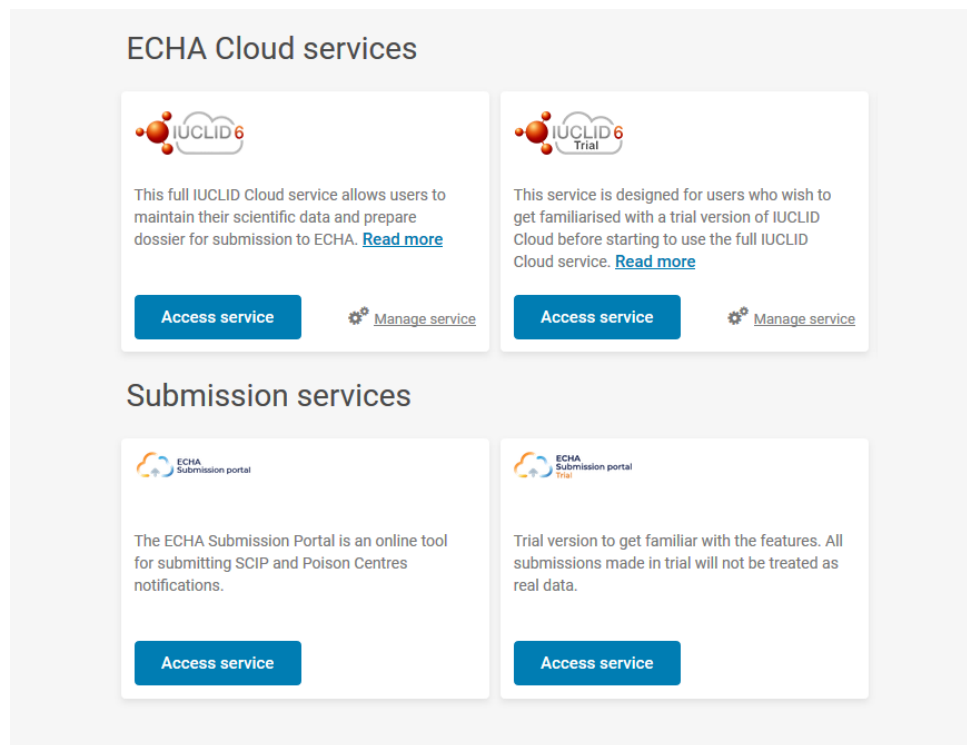


- One IUCLID software, different ways of distributing it
 - Desktop: for single user, on his/her own computer
 - Server: hosted on a server, shared with multiple users
 - Cloud: ECHA Cloud Services, hosted by ECHA, for REACH, CLP and SCIP users




IUCLID Cloud services

- IUCLID Cloud
 - Free to use, back-up, 24/7, 1 GB
 - Existing instances upgraded to new version on 28/10/
 - Seamless submission of PCN and SCIP dossier
 - Legal entity synchronised with login
 - Foreign users concept allows for giving access to users from other companies
- IUCLID Cloud Trial
 - Free to use, no back-up, 100 MB
 - Existing instances upgraded to new version on 28/10/
 - Can be used for testing and training of the web user interface





The screenshot displays a user interface for ECHA Cloud services. It is organized into two main sections: 'ECHA Cloud services' and 'Submission services'. Each section contains two service cards. The 'ECHA Cloud services' section features 'IUCLID 6' and 'IUCLID 6 Trial'. The 'Submission services' section features 'ECHA Submission portal' and 'ECHA Submission portal Trial'. Each card includes a description, an 'Access service' button, and a 'Manage service' button with a gear icon.

ECHA Cloud services




This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. [Read more](#)


[Access service](#)  [Manage service](#)



This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the full IUCLID Cloud service. [Read more](#)


[Access service](#)  [Manage service](#)

Submission services



The ECHA Submission Portal is an online tool for submitting SCIP and Poison Centres notifications.

[Access service](#)

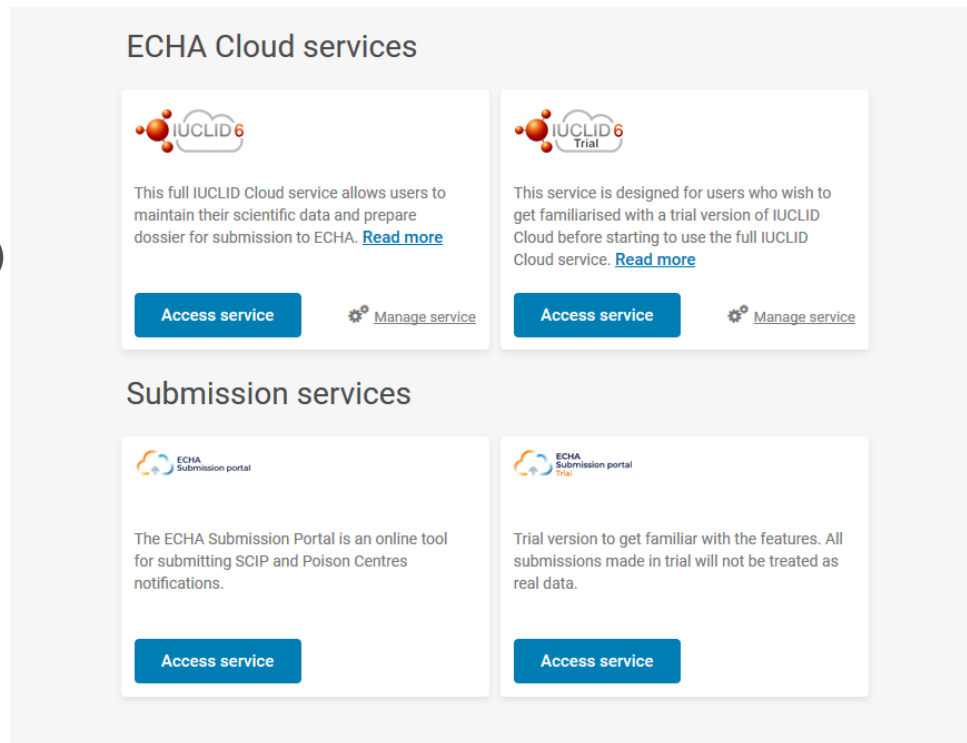


Trial version to get familiar with the features. All submissions made in trial will not be treated as real data.

[Access service](#)

ECHA Submission portal

- Used to submit and follow-up PCN and SCIP dossiers
- Allows dossiers to be submitted from other systems (System to System (S2S))
- Trial service can be used to test both manual and System to system submissions
- More information about the usage from the PCN and SCIP websites
- Will integrate the submission of EFSA PPP dossiers in 2021



The screenshot displays a user interface for ECHA services, organized into two main sections: "ECHA Cloud services" and "Submission services".

ECHA Cloud services

- IUCLID 6**: This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. [Read more](#)
Buttons: [Access service](#), [Manage service](#)
- IUCLID 6 Trial**: This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the full IUCLID Cloud service. [Read more](#)
Buttons: [Access service](#), [Manage service](#)

Submission services

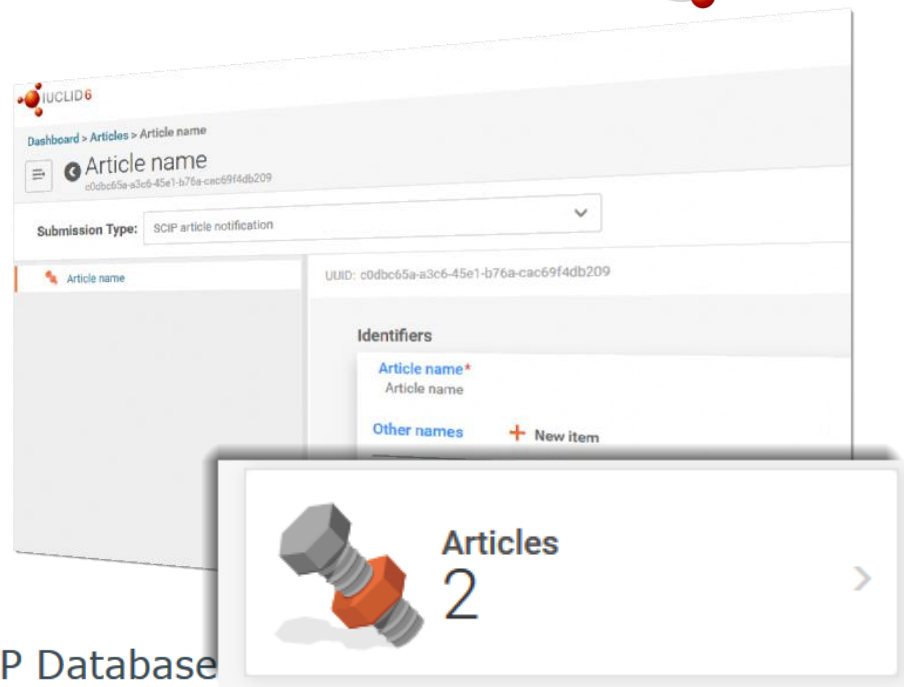
- ECHA Submission portal**: The ECHA Submission Portal is an online tool for submitting SCIP and Poison Centres notifications.
Button: [Access service](#)
- ECHA Submission portal Trial**: Trial version to get familiar with the features. All submissions made in trial will not be treated as real data.
Button: [Access service](#)

Before ending the webinar



IUCLID support for SCIP

- The SCIP format was updated with minor changes
- The SCIP notifications can now be submitted to the production submission portal
- Obligation to notify starts 5/1/2021
- SCIP webinar 19/11/2020
- For more information, consult the SCIP webpage (<https://echa.europa.eu/scip>)



SCIP is the database for information on **Substances of Concern In** articles as such or in complex objects (**Products**) established under the Waste Framework Directive (WFD).

Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021. The SCIP database ensures that the information on articles containing Candidate List substances is available throughout the whole lifecycle of products and materials, including at the waste stage. The information in the database is then made available to waste operators and consumers.

▪ [Go to SCIP Prototype](#)

Poison Centres Notifications



IUCLID support for PCN

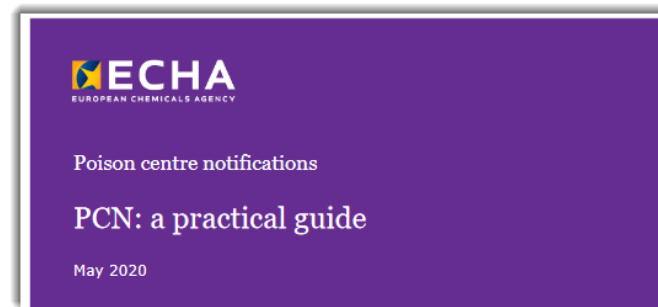
- Format updated to comply with amendments to Annex VIII
- The standard IUCLID user interface improved to support the creation of PCN dossiers (in addition to the guided dossier approach)
- PCN Webinar held 4/11/2020 – Recording available on ECHA YouTube Channel
- For more information
 - Poison Centres website (<https://poisoncentres.echa.europa.eu/>)
 - Join the LinkedIn group (<https://www.linkedin.com/groups/12364138/>)



A new customised way to prepare your poison centre notifications

4 May 2020

Companies can now choose a tailor-made dataset mode to help them prepare their poison centre notifications in IUCLID.



Support to dossier creation from own system



Relevant for PCN and SCIP data preparation – S2S submission

- Option 1: Building a custom script/application that generates i6z files according to the format
 - Independent i6z files are generated that represent full datasets/dossiers
 - I6z file generation can feel a bit complex (e.g. due to additional administrative technical data like manifest.xml)
 - Inventory documents (like ReferenceSubstance) that are reused must be linked in different i6z files
 - Manual verification is complex and it is recommended to manually import the files to a local IUCLID installation to validate the format and the validation rules
- Option 2: Building a custom script/application that writes to a IUCLID instance via the Public REST API
 - Easier to reuse inventory documents (like ReferenceSubstance)
 - Easier to test, as data is generated directly in a IUCLID instance
 - Individual IUCLID documents are created/filled during one transaction. It could be harder to ensure the business consistency of a full dataset/dossier
- How to create IUCLID dossiers without IUCLID
 - i6z documentation: [Developers' Guide to the IUCLID i6z Format](#) (.pdf | 1.1 MB)
 - API, documentation updated: <https://iuclid6.echa.europa.eu/public-api>

Update of REACH Study Results



- Non confidential data collected under REACH by ECHA are made available in IUCLID format
- The data was refreshed on the 3rd of September, including 23,000 substances (full list available in an Excel file)
- ~250 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

03/09/2020

REACH Study Results updated

A new version of REACH Study Results is available, with 250 new substances added since March 2020. It contains data in IUCLID format, that were submitted to ECHA under the REACH regulation.

REACH Study Results contain results from studies that relate to: *physical-chemical properties, environmental fate, toxicological information*. REACH Study Results is an alternative way of delivering substance data already published on the ECHA website.

[ECHA > Information on Chemicals > Registered substances](#)

On the ECHA website data may be viewed only one substance at a time, but REACH Study Results allows data to be downloaded in bulk, after the installation of IUCLID, and then analysed using the [IUCLID 6 REST Public API](#), the [IUCLID Data Extractor](#) or, an [add-on for Excel](#). This allows access to the approximately 23,000 substances, which allows users to identify and import only the substances of interest.

REACH registrations are continually updated and submitted to ECHA. Therefore, we plan to update the Reach Study Results on 3rd of September. This will allow you to have access to the latest REACH data.

[More information on REACH Study Results](#)

Updated twice a year

What's next?

- IUCLID 6 development will continue with two main releases next year
 - April 2021 (with the objective to decommission the classic interface)
 - October 2021 (including format changes)
- Additional releases will be made in the Cloud Services, as needed, to support PCN, SCIP and EFSA users

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

Planned releases

Two IUCLID releases are made per year: a major release in October, and a service format is modified only in the major release in October. Releases are scheduled for every month. The IUCLID instances hosted by ECHA in the [ECHA Cloud Services](#) are updated as new functionality becomes available, but the IUCLID format it uses changes only once a year.

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

Features planned for the next IUCLID releases

Key development to complete the move to the web interface

- Bulk delete of IUCLID documents in a dataset.
- Full print to PDF: including all linked entities and their documents, for example, components.
- Import: advanced options for content control and document filtering. Currently, there are settings to filter out section documents and confidential fields.
- Inventory Manager to replace duplicate entities with a single entity, for example, components.
- Report Manager to upload custom report templates for use with the Report Generator.
- More features to be added to the management of Users and Roles.

Additional web interface improvements

- Annotation transferring between dossiers.
- Creation in IUCLID of a Summary of Product Characteristics (SPC).
- Report generator: advanced settings to filter datasets and Dossiers.
- Validation Assistant: advanced settings to filter datasets and Dossiers.

Before ending the webinar



Q&A session with Slido



<https://www.sli.do/>

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participant?**

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



Thank you for your participation

echa.eu

iuclid6.echa.europa.eu

oecd.org/ehs/templates



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

