

TERMS AND CONDITIONS OF USE AND SERVICE OF <u>IUCLID CLOUD</u> (Version 4.2 – 10/02/2024)

PLEASE READ THE FOLLOWING TERMS AND CONDITIONS GOVERNING THE USE OF IUCLID CLOUD CAREFULLY BEFORE USING IUCLID CLOUD. TO AGREE TO THE TERMS OF SERVICE TICK THE BOX THAT YOU HAVE READ AND ACCEPTED THE TERMS OF SERVICE. ACCESS TO IUCLID CLOUD IS SUBJECT TO PRIOR ACCEPTANCE OF THESE TERMS AND CONDITIONS.

1. Definitions

(a) Unless otherwise expressly stated to the contrary, terms used herein shall bear the following meanings:

BPR means Regulation (EU) No 528/2012 of the European Parliament and

of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products and related legislation which has

the Biocidal Products Regulation as the legal basis;

CLP Regulation means Regulation (EC) No 1272/2008 on classification,

labelling and packaging of substances and mixtures;

Consent means any freely given, specific, informed and unambiguous

indication of the Data Subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him

or her;

Covered legislation the system aims to provide the possibility to prepare IUCLID

dossiers for the following legislation: (i) REACH Regulation, (ii) CLP Regulation, (iii) the WFD, (iv) the BPR, as well as the requirements set out in (v) the Regulation EC No 1107/2009;

Data means any data placed on IUCLID Cloud by the Party;

Data Subject means an identified or identifiable natural person;

ECHA means the European Chemicals Agency established in Helsinki,

Finland;

ECHA Account means the online platform ECHA has put in place for creating

individual user accounts, which enable Parties to create subscriptions to ECHA's IT services and applications. Within ECHA Account, the Legal Entity Manager can grant and revoke access rights to ECHA's IT services and applications for Users

from its own group;

ECHA Cloud services the platform from where the IUCLID Cloud services can be

subscribed and managed by the Legal Entity Manager;



ECHA Submission portal

means the central IT system that includes the official ECHA Submission portal web application and website, where the use of the portal is envisaged under the Covered Legislation and for access to any communication related to such submission; The ECHA Submission portal has a Trial version;

EFSA

means the European Food Safety Authority established in Parma, Italy;

IUCLID Cloud

means the ECHA IT service offering (and encompassing) IUCLID Cloud service and the IUCLID Cloud Trial service;

IUCLID Cloud service

means the IT service in the Cloud, which allows the Party to collect, store and process data in the Cloud in accordance with the International Uniform Chemical Information Database (hereinafter "IUCLID") reporting format including, by way of example, data on chemical substances, their properties, their producers or importers and related data and meta data;

IUCLID Cloud Trial Service

means the IT trial service in the Cloud, which does not contain all the features of IUCLID Cloud Service;

Legal Entity Manager

The main User of a Party that has the access rights to manage and create other Users, assign roles and subscribe to services on behalf of the Party;

Party

means any legal entity that has access rights to either (or both) of the IUCLID Cloud services;

Personal Data

means any information relating to an identified or identifiable natural person;

PPP Regulation

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market as last amended by Regulation (EU) 2019/1381;

R4BP 3

means the central online platform established and maintained by ECHA as per Article 71 and Article 79 of the Biocidal Products Regulation;

REACH-IT

means the central IT system that includes the official REACH-IT web application and website as ECHA prescribes for submission of REACH-IT data and for notification of all decisions and correspondence related to such submission under the Covered legislation;

REACH Regulation

means Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;

Responsible Agency

means either ECHA or EFSA as the Agency responsible under the relevant Covered legislation for processing the submitted information or both, where they are referred to as Responsible Agencies;



Subscription means the action performed by the Legal Entity Manager when

he/she decides to start using either of the IUCLID Cloud

services;

Terms and Conditions means these terms and conditions as amended from time to

time and in force. The personal data protection policy of the Responsible Agency forms an integral part of these terms and conditions. For this policy and more information on personal data protection, the Party shall refer to the webpage on personal data protection of the Responsible Agency, where for ECHA this is: http://echa.europa.eu/about-us/the-way-wework/personal-data-protection and for EFSA this is:

https://www.efsa.europa.eu/en/personal-data-protection;

User means the person(s) whom the Party has nominated and

authorised to have access to and use the IUCLID Cloud;

WFD Directive 2008/98/EC of the European Parliament and of the

Council of 19 November 2008 on waste and repealing certain

Directives.

(b) Headings are for ease of reference only and do not form part of these Terms and Conditions. Words denoting the singular include the plural and vice versa, words denoting one gender include all genders and words denoting persons include corporations and vice versa.

2. IUCLID Cloud services and Conditions of Use

- (a) Under the Covered legislation, concerned parties are required to provide the Responsible Agency with information on chemical substances, their properties, their producers or importers and related data and meta-data. The required information shall be provided in the International Uniform Chemical Information Database (IUCLID) format.
- (b) IUCLID Cloud provides a Party with an IT service, the IUCLID Cloud service, which enables it to collect, store and process data required by the Covered legislation, including, by way of example, data on chemical substances, their properties, their producers or importers and related data and metadata.
- (c) Each Party acknowledges that the IUCLID Cloud service is provided only as a tool enabling the Party to develop the data submissions required under the Covered legislation. IUCLID Cloud service may not and is not intended to be used for any other purposes.
- (d) Each Party further acknowledges that the use of the IUCLID Cloud service is insufficient to comply with the Covered legislation, since any dossier, notification, request and/or update prepared in the IUCLID Cloud service will not be automatically synchronised with REACH-IT, R4BP 3 or the ECHA Submission portal, and the submission of the data to the Responsible Agency for compliance purposes cannot be completed in the IUCLID Cloud Service. For the purposes of complying with the REACH Regulation and the CLP Regulation, excluding Article 45 and Annex VIII of the CLP Regulation, the Party must transfer its finalised data submission to REACH-IT in order for ECHA to formally receive the submission. For the purposes of complying with the BPR, the Party must submit its finalised data submission through R4BP 3 in order for ECHA to formally receive the submission.

Furthermore, each Party acknowledges that the use of the IUCLID Cloud service is insufficient to comply with the data submission requirements under the WFD, the PPP



Regulation and Article 45 and Annex VIII of the CLP Regulation since any submission prepared in the IUCLID Cloud service will not be automatically synchronised with the ECHA Submission Portal. The Party must transfer and subsequently submit its finalised submission to the ECHA Submission Portal in order for the Responsible Agency to formally receive the submission.

- (e) IUCLID Cloud also offers another IT service called the IUCLID Cloud Trial service. IUCLID Cloud Trial service is a trial service, enabling the Party to get acquainted with the IUCLID Cloud. IUCLID Cloud Trial service is only intended as a learning tool and it does not contain all the features of the IUCLID Cloud service, and it may not and is not intended to be used for any other purposes.
- (f) The Party acknowledges that IUCLID Cloud is not offered in all official languages of the European Union and it may not be used with all internet browsers.
- (g) For the sake of clarity, IUCLID is also offered as downloadable software subject to acceptance of a separate licence agreement.

3. Registration and Subscription

- (a) Access to and use of IUCLID Cloud is granted to the Party subject to and in accordance with these Terms and Conditions.
- (b) In order to access IUCLID Cloud, the Party shall first log into ECHA Cloud services by using its registered user ID(s) and user password(s) created in ECHA Account, by the Legal Entity Manager, for ECHA IT applications and services, such as REACH-IT. If the Party does not have a registered user ID(s) and user password(s), the Party shall create a user account in ECHA Account consisting of a user ID and user password, and it will need to provide the requisite information.

A Subscription is required for each service of IUCLID Cloud. The Party, represented by a Legal Entity Manager, shall create a unique Subscription for IUCLID Cloud Trial service and/or IUCLID Cloud service, depending on its needs. The Party acknowledges that a Subscription for IUCLID Cloud Trial service and/or IUCLID Cloud service is limited to one per Party. The User management of the Party's Subscription is managed by the Legal Entity Manager of the Party with the ECHA Account user management application. The Party is entitled to grant access rights to Users for IUCLID Cloud, and to remove User rights from Users. In accessing and using IUCLID Cloud, Users shall use the Party's registered user ID and user password.

When creating the unique Subscription(s) for IUCLID Cloud Trial service and/or IUCLID Cloud service, the Party has to read and agree to these Terms and Conditions by ticking the box stating that it has read and agreed to the Terms and Conditions. Each User is also obligated to read and accept these Terms and Conditions upon his/her first attempt to access IUCLID Cloud.

ECHA reserves the absolute right, at its sole discretion, to vary these Terms and Conditions in any way and at any time, and Users will be requested to read and accept the amended Terms and Conditions upon their first attempt to access IUCLID Cloud after the variations have been made. By accessing and/or continuing to use IUCLID Cloud, the Users (and, by extension, the Party) specifically accept these Terms and Conditions as varied.

(c) The Party agrees that any Users applying its user ID(s) and user password(s) to access IUCLID Cloud are acting on behalf of the Party and have the legal authority to act on its behalf. A reference in these Terms and Conditions to the Users of the Party logging onto IUCLID Cloud, or continuing to use IUCLID Cloud or otherwise accessing IUCLID Cloud,



- shall include any such act done by any person using the user ID(s) and/or user password(s) of the Party (whether authorised by the Party or not).
- (d) The Party agrees to keep the details of its Users up-to-date at any time. To this end, ECHA may require the Users to confirm their details on a yearly basis.

4. Technical Support, Back-up and Data Storage

- (a) The Party acknowledges that IUCLID Cloud Trial Service does not include technical support services or back-up functions, and the data storage offered in IUCLID Cloud Trial Service is limited to the extent that it can only be used as a learning tool.
- (b) Any functions offered in the IUCLID Cloud service, including, but not limited to, data storage and recovery, are subject to Section 7 of these Terms and Conditions. It is recommended that the Party keeps its own records (back-ups) of its Data.
- (c) The IUCLID Cloud service includes helpdesk and technical support services. Requests on regulatory issues may be made via the information request forms on the contact page of the Responsible Agency. For ECHA please go to ECHA's contact page. For EFSA, please go to https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request. Any information supplied by the Responsible Agency for technical support purposes may only be used by the Party for the purpose of using the IUCLID Cloud service and may not be disclosed to any third party or used for other purposes. The Responsible Agency is only responsible for providing the requested information within a reasonable timeframe, taking into account the complexity of the question and/or of the information requested by the Party. All the actions taken by the Responsible Agency will be performed according to the information delivered by the Party. To such effect, the Responsible Agencies will not accept any responsibility if such information contains errors or omissions. The Party is absolutely responsible for the data delivered in any request for information.
- (d) Without prejudice to Section 6, the Responsible Agencies will not have access to the Data placed on IUCLID Cloud by a Party or Users, unless permission has been given by the Party or User concerned. Permission will only be sought for maintenance/service related purposes and the Responsible Agencies will not review or take possession of the Data placed on IUCLID Cloud. If permission is granted, the services will be performed by the Responsible Agency, or third party service providers under appropriate confidentiality obligations.

5. Delivery of Data and Warranties

- (a) All Data shall be placed on IUCLID Cloud in a virus-free electronic format.
- (b) ECHA, EFSA and the Party acknowledge that the internet is, due to unpredictable traffic congestion, malicious third parties and other reasons, an inherently unreliable medium of communication and that such unreliability is beyond the Party's or the Responsible Agencies' control. The Responsible Agencies and the Party recognize that it is impossible to maintain flawless security. The Responsible Agencies use their utmost efforts to ensure that IUCLID Cloud will perform correctly. Neither ECHA nor EFSA shall be liable for any unauthorised access to IUCLID Cloud by any third party or for failures, errors or delays relating to a Party's internet connections.
- (c) The Party declares, warrants and undertakes to ECHA and/or EFSA that:
 - (i) any Data placed on IUCLID Cloud by means of the Party's user account shall be deemed to be placed by the Party;



- (ii) it is the owner of all intellectual property rights in the Data it has placed, including copyright, trademarks or name, or is duly authorised by the owner of such intellectual property rights for the purposes of these Terms and Conditions.
- (d) Furthermore, the Party hereby warrants to the Responsible Agency that:
 - all information provided to the Responsible Agencies in relation to its application to become a Party and all information which may subsequently be provided for the maintenance of its status as a Party from time to time is complete, correct and upto-date;
 - (ii) its use of IUCLID Cloud and its acceptance and performance of its obligations under these Terms and Conditions have been duly authorised with all necessary corporate or third party approvals obtained and do not violate the constitutive documents of the Party or any law, regulation or other agreement binding on the Party;
 - (iii) these Terms and Conditions constitute a legally binding and enforceable contract; and
 - (iv) in relation to its using IUCLID Cloud, it shall comply with all applicable laws and regulations including, without limitation, all procedures and directions notified or published by ECHA and/or, where relevant, EFSA.

6. Privacy

- (a) The Party consents (and has obtained the Consent of each Data Subject) that the Personal Data provided by it may be processed by the Responsible Agencies, other EU institutions, bodies or agencies and Member State Competent Authorities for the purpose of implementing the Covered legislation and other relevant EU legislation, and fulfilling the Party's obligations under these legislations.
- (b) The Party (and User(s)) will be requested to provide certain Personal Data such as name, mailing address, e-mail address, and other data such as country, area as well as any other information requested.
- (c) The Party must obtain the Consent of the Data Subject, or have other legal grounds, before it submits any Personal Data of that Data Subject to IUCLID Cloud as described above in Section 3 of these Terms and Conditions.
- (d) The Responsible Agencies are committed to ensure the right to privacy in accordance with Regulation (EU) 2018/1725 ('the EDPR') applicable to them in the field of data protection. For ECHA's personal data protection policy and more information on personal data protection, the Party shall refer to ECHA's webpage on personal data protection (http://echa.europa.eu/about-us/the-way-we-work/personal-data-protection). For EFSA's personal data protection policy and more information on personal data protection, the Party shall refer to EFSA's webpage on personal data protection (https://www.efsa.europa.eu/en/personal-data-protection).
- (e) For the exercise of data protection rights or for any general enquiry relating to the overall privacy policy, the Party (and User(s)) may contact ECHA via the forms on ECHA's contact page or EFSA via the email of the controller for the process (DATA.Admin@efsa.europa.eu).

7. Disclaimer and Limitation of Liability

(a) This provision is without prejudice to Article 340 of the Treaty on the Functioning of the EU, Article 101 of the REACH Regulation concerning the liability of ECHA and/or Article



47 of Regulation (EC) No 178/2002 concerning the liability of EFSA.

- (b) The Party acknowledges that any use of or reliance upon any part of IUCLID Cloud shall be at its sole risk. The Party further acknowledges that use of IUCLID Cloud is provided on an "AS IS" and "AS AVAILABLE" basis and without warranty or condition of any kind, either express or implied.
- (c) The Responsible Agencies assume no responsibility of any kind for any use of IUCLID Cloud by a Party. By accessing and/or continuing to use IUCLID Cloud and/or by providing Users with passwords to IUCLID Cloud, the Party is fully responsible for all Data placed on IUCLID Cloud. The Responsible Agencies shall not be liable or responsible jointly or individually (whether in tort, contract or otherwise) for any claim for any losses or damages of any kind (whether direct or indirect, any loss of profit, loss of revenue, loss of anticipated savings or loss of goodwill) whatsoever and howsoever arising from the use of or reliance upon IUCLID Cloud or any related system or software including any mishandling, omission, non-delivery, delay, negligent or unauthorised use of IUCLID Cloud or of the Party's registered user ID(s) and user password(s).
- (d) The Responsible Agencies accept no responsibility or liability of any kind for the accuracy, completeness or reliability of the content or format of the data submissions created in the IUCLID Cloud service, or that the data submissions fulfil the requirements of the Covered legislation. The Party acknowledges that it is the Party's obligation to ensure the accuracy, completeness and compliance of the data submissions with the Covered legislation before transferring the data submissions to REACH-IT or, where relevant, the ECHA Submission Portal.
- (e) The Responsible Agencies shall not be liable for any action taken or for any failure, hindrance or delay in the performance in whole or in part of its obligations under these Terms and Conditions if such action, failure, hindrance or delay arises out of causes beyond the reasonable control of the Responsible Agencies. Such causes may include, but shall not be limited to, acts of force majeure, labour disputes, mechanical breakdowns, computer or system failures or other failures of equipment, failures of or defects in computer or system software, computer damage due to unauthorised programming routines, unavailability of or restrictions on any communication media for whatever reason, interruptions of power supplies, any law, decree, regulation or order of any government, competent authority, supranational bodies or any court or tribunal and any other causes beyond the control of the respective Responsible Agency.
- (f) The Party irrevocably and unconditionally agrees to defend, indemnify in full and hold the Responsible Agencies, jointly or individually harmless from and against all liabilities, damages, claims, actions, costs and expenses (including legal fees) in connection with or arising out of the receipt, or transmission or publication or storage or possession of any Data through IUCLID Cloud and/or the Party's breach of these Terms and Conditions and/or its improper use of IUCLID Cloud.

8. Intellectual Property Rights and Other Proprietary Rights

- (a) Save for any intellectual property rights which the Party may have in relation to any Data, the Party acknowledges that the contents and materials of IUCLID Cloud (including its organisation and layout) are proprietary to ECHA or third parties and the copyright, database rights, catalogue rights and any other intellectual property rights in them belong to ECHA or third parties.
- (b) The Party acknowledges that IUCLID Cloud and related systems and software are proprietary to ECHA or its service providers. The Party shall not tamper with, modify, decompile, reverse engineer or otherwise alter IUCLID Cloud or any of the related software and the Party shall not attempt to gain unauthorised access to any part of



IUCLID Cloud. ECHA is entitled to deny the Party's access to all or any part of IUCLID Cloud if the Party performs any of the above acts or if ECHA at any time reasonably suspects that the Party has performed or attempted to perform any of them.

9. Modification, Discontinuance or Termination

- (a) ECHA reserves the right to modify or discontinue, temporarily or permanently, IUCLID Cloud (or any part or feature thereof) at any time after giving prior notification to the Party if it is practicable, or otherwise, without any prior notification if such notification is not practicable. ECHA (on its own, or on EFSAs behalf) may terminate or suspend the Party's access to all or part of IUCLID Cloud with effect from any time as it considers appropriate for any reason including, without limitation, breach of these Terms and Conditions or any other terms or conditions as prescribed by ECHA from time to time. If the Party's access to IUCLID Cloud is terminated or suspended, Data placed in IUCLID Cloud service will be stored for a reasonable period of time.
- (b) ECHA shall be entitled, in its sole discretion, to temporarily suspend all or part of IUCLID Cloud in order to upgrade or modify IUCLID Cloud or any related systems or software and/or to restrict the Party's access to and use of IUCLID Cloud where ECHA considers it reasonably necessary for the operation or maintenance of IUCLID Cloud or any related systems or software. ECHA shall not be liable to the Party or any third party for any claims of any kind related to such termination, restriction or suspension of IUCLID Cloud.

10. Miscellaneous Provisions

- (a) If any provision herein is held to be invalid or unenforceable to any extent, then such provision will be interpreted, construed and reformed to the extent reasonably required to render it valid, enforceable and consistent with its original intent. Each provision of these Terms and Conditions is severable, and if one or more provisions are declared invalid or unenforceable, the remaining provisions of these Terms and Conditions will remain in full force and effect.
- (b) These Terms and Conditions are not intended to contravene any mandatory requirements laid down in applicable mandatory regulations nor to exclude liability for matters, which may not be excluded under such regulations.
- (c) The Terms and Conditions shall be governed by and construed in accordance with the laws of Finland, excluding its choice of law provisions and principles.
- (d) Any dispute, controversy or claim arising out of or relating to these Terms and Conditions, or the breach or validity thereof shall be settled by the courts of Helsinki, Finland.