



Data Protection Notice – EFSA use of IUCLID (International Uniform Chemical Information Database)

IUCLID (International Uniform Chemical Information Database) is a software application developed by the European Chemicals Agency (ECHA) to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. It is a key software application for regulatory authorities such as EFSA and for the chemical industry, aligned with the OECD Harmonized Templates and used in the implementation of various regulatory programmes.

Commission Regulation (EU) 2020/1740 prescribes the use of IUCLID as the e-submission tool for the renewal process for applications for plant protection products' (PPP) active substances.

Since the use of IUCLID entails the processing of certain personal data, EFSA informs you on the following in accordance with Article 15 of Regulation (EU) 2018/1725¹ on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies:

1. Information on the controller and the data protection officer:

The EFSA Unit on Evidence Management (IUCLID Team) is the controller of EFSA's implementation of IUCLID. The controller can be contacted writing to DATA.Admin@efsa.europa.eu

EFSA's data protection officer can be contacted writing to DataProtectionOfficer@efsa.europa.eu

2. Purpose of the personal data processing:

The personal data processing is supporting the functioning of the IUCLID e-submission builder for application dossiers in the context of EFSA authorisation processes in the area of pesticides, i.e. the initial and renewal applications for plant protection products' (PPP) active substances and Maximum Residue Levels.

¹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ 21.11.2018, L 295/39.

3. Legal basis:

The personal data processing is necessary for the performance of a task carried out in the public interest and for the management and functioning of EFSA as mandated by its Founding Regulation (EC) No 178/2002², more specifically by Article 39f thereof. This provision charges EFSA to adopt standard data formats to allow documents to be submitted, searched, copied and printed while ensuring regulatory requirements set out in Union law. Commission Regulation (EU) 2020/1740 laying down the provisions necessary for the implementation of the renewal procedure for active substances prescribes in Article 7 the use of IUCLID as the e-submission tool for applications of PPP active substances and Maximum Residue Levels (MRLs).

EFSA and ECHA have concluded a Service Level Agreement with regard to the deployment of IUCLID in the context of authorisation processes EFSA is in charge of in the area of pesticides.

4. Categories of data subjects whose data are processed in IUCLID:

The following categories of data subjects are concerned:

- ✓ Representatives of the applicants for plant protection products' active substances and Maximum Residue Levels, including registered users of the IUCLID tool or representatives of applicants having user rights granted through the ECHA Cloud Services and in accordance with ECHA's account user management solution
- ✓ Study authors referenced in applications for PPP active substances and/or their annexes

5. Categories of personal data processed:

It concerns the following personal data:

- ✓ Identification & contact data of representatives of applicants for PPP active substances and Maximum Residue Levels: their name, job title, affiliation, work address, work contact details incl. email & phone number
- ✓ Identification data of study authors: their name and any other of their personal details referenced in the dossier application and/or its annexes.

6. Recipients of personal data:

The data are available to the stakeholders involved in the authorization process for PPP active substances, namely:

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24 as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain and amending *inter alia* Regulation (EC) No 178/2002, OJ L 231, 6.9.2019, p. 1-28.

- ✓ Representatives of EU Member States National Competent Authorities (NCAs) involved in the authorisation process of PPP active substances as rapporteur Member State (RMS) or otherwise, pursuant to Regulation (EC) No 1107/2009 as amended by Regulation (EU) 2019/1381,
- ✓ The staff of EFSA, i.e. the IUCLID Team within the DATA Unit and the staff of the PRES and PREV Units in charge of the authorisation process of PPP active substances and Maximum Residue Levels (MRLs), as well as any consultants assisting EFSA, subject to contractually warranted confidentiality duties
- ✓ Services in charge at the European Commission, i.e. DG SANTE
- ✓ ECHA staff in charge of providing technical user support on IUCLID
- ✓ Pursuant to Article 39e(1) of EFSA's Founding Regulation (EC) No 178/2002, the name and address of the applicant as well as names of authors of published or publicly available studies are made available online by means of EFSA's dissemination portal.

7. What are your rights as a data subject in relation to data collected and processed on you?

As a data subject, you can exercise your right of access, rectification or erasure of your personal data stored in IUCLID and related rights laid down in Chapter III of Regulation (EU) 2018/1725, by sending a request by email to the Data Controller at the functional mailbox indicated in point 1 above.

8. Basic information concerning the IUCLID tool:

As a system developed by the European Chemicals Agency, IUCLID is hosted in the ECHA Cloud Services, a secure online platform used to distribute ECHA's IT applications into a private cloud environment. The service is built within ECHA's IT infrastructure and the use of encrypted communication, regular security audits and updates of all the components make sure that your data hosted in the ECHA Cloud is safe and cannot be accessed by anyone else. For more information on ECHA Cloud Services and IUCLID cloud, please check out the online Q&A: <https://ecs.echa.europa.eu/cloud/q-and-a.html>

EFSA's connection to IUCLID is supported by additional cloud resources by Microsoft Azure for which the data centres are located in The Netherlands and France.

To access IUCLID, users need firstly to create an account with an associated legal entity in the ECHA Cloud Services web page. Once logged in with the ECHA account, the available IUCLID services can be selected.

9. Retention period of personal data:

All personal data is retained in IUCLID as long as the user account for ECHA cloud services is maintained. Inactive profiles in ECHA cloud services are automatically deleted on a periodical basis.



10. Right to lodge a complaint:

Data subjects have the right to lodge a complaint on the processing of their personal data in the context of EFSA's use of IUCLID with the European Data Protection Supervisor - edps@edps.europa.eu