



RECORD OF A PERSONAL DATA PROCESSING ACTIVITY

according to Article 31 of [Regulation \(EU\) 2018/1725](#)

Title
EFSA use of IUCLID (International Uniform Chemical Information Database)

1) Controller(s) of data processing activity (Article 31.1(a))
EFSA unit in charge of the processing activity: Evidence Management Unit (DATA), IUCLID Team
EFSA Data Protection Officer (DPO): DataProtectionOfficer@efsa.europa.eu
Is EFSA a co-controller? No
<i>If yes</i> , indicate who is EFSA's co-controller:

2) Who is actually conducting the processing? (Article 31.1(a))
The data is processed by EFSA itself <input checked="" type="checkbox"/>
<i>Indicate the EFSA units or teams involved in the data processing:</i>
The IUCLID Team as controller can be contacted writing to DATA.Admin@efsa.europa.eu
The processing operation is conducted together with an external party <input type="checkbox"/>
<i>Please provide below details on the external involvement:</i>

3) Purpose of the processing (Article 31.1(b))
The International Uniform Chemical Information Database (IUCLID) is a software application for recording, storing, maintaining and exchanging data on intrinsic and hazard properties of chemical substances and the standard data format agreed for pesticide applications. Applicants are required to use this tool to submit their dossiers under Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005.
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.

4) Legal basis and lawfulness of the processing (Article 5(a)–(d)):

Processing necessary for:

- | | |
|---|-------------------------------------|
| (a) a task carried out in the public interest or in the exercise of official authority vested in EFSA | <input checked="" type="checkbox"/> |
| (b) compliance with a legal obligation to which EFSA is subject | <input type="checkbox"/> |
| (c) performance of a contract with the data subject or to prepare such contract | <input type="checkbox"/> |
| (d) The data subject has given consent (ex ante, explicit, informed) | <input type="checkbox"/> |

Further details on the legal basis:

In accordance with Article 39f of EFSA's Founding Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381, EFSA shall 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.

5) Description of the categories of data subjects (Article 31.1(c))

Whose personal data are processed?

- | | |
|---|-------------------------------------|
| EFSA statutory staff | <input type="checkbox"/> |
| Other individuals working for EFSA (consultants, trainees, interims, experts) | <input type="checkbox"/> |
| Stakeholders of EFSA, including Member State representatives | <input checked="" type="checkbox"/> |
| Contractors of EFSA providing goods and services | <input type="checkbox"/> |
| The general public, including visitors, correspondents, enquirers | <input type="checkbox"/> |
| Relatives of the data subject | <input type="checkbox"/> |
| Other categories of data subjects (please detail below) | <input type="checkbox"/> |

Further details concerning the data subjects whose data are processed:

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.

6) Type of personal data processed (Article 31.1(c))

a) General personal data

The personal data concerns:

- | | |
|---|-------------------------------------|
| Name, contact details and affiliation | <input checked="" type="checkbox"/> |
| Details on education, expertise, profession of the person | <input checked="" type="checkbox"/> |
| Curriculum vitae | <input type="checkbox"/> |
| Financial details | <input type="checkbox"/> |
| Family, lifestyle and social circumstances | <input type="checkbox"/> |
| Goods and services the person provides | <input type="checkbox"/> |
| Other personal data (please detail): | <input type="checkbox"/> |

b) Sensitive personal data (Article 10)

The personal data reveals:

- | | |
|---|--------------------------|
| Racial or ethnic origin of the person | <input type="checkbox"/> |
| Political opinions or trade union membership | <input type="checkbox"/> |
| Religious or philosophical beliefs | <input type="checkbox"/> |
| Health data or genetic or biometric data | <input type="checkbox"/> |
| Information regarding the person's sex life or sexual orientation | <input type="checkbox"/> |

Further details concerning the personal data processed:

- 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 their personal details referenced in the dossier application and/or its annexes

7) Recipients of the data (Article 31.1(d))

- | | |
|---|-------------------------------------|
| Line managers of the data subject | <input type="checkbox"/> |
| Designated EFSA staff members | <input checked="" type="checkbox"/> |
| Other recipients (<i>please specify</i>): | <input checked="" type="checkbox"/> |

- 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.

8) Transfers to recipients outside the EEA (Article 31.1 (e))

Data are transferred to third country recipients:

Yes No

If yes, specify to which third country:

If yes, specify under which safeguards:

- | | |
|--|--------------------------|
| Adequacy Decision of the European Commission | <input type="checkbox"/> |
| Standard Contractual Clauses | <input type="checkbox"/> |
| Binding Corporate Rules | <input type="checkbox"/> |
| Memorandum of Understanding between public authorities | <input type="checkbox"/> |

9) Technical and organisational security measures (Article 31.1(g))

How is the data stored?

- | | |
|--|-------------------------------------|
| On EFSA's Document Management System (DMS) | <input type="checkbox"/> |
| On a shared EFSA network drive or in an Outlook folder | <input type="checkbox"/> |
| In a paper file | <input type="checkbox"/> |
| Using a cloud computing solution (please detail the service provider and main characteristics of the cloud solution, e.g. public, private) | <input checked="" type="checkbox"/> |
| On servers of an external service provider | <input type="checkbox"/> |
| On servers of the European Commission or of another EU Institution | <input type="checkbox"/> |
| In another way (<i>please specify</i>): | <input type="checkbox"/> |

Please provide some general information on the security measures applied:

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.

10) Retention period (Article 4.1 (e))

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.

11) Consultation with the Information Security Officer

Was the ISO consulted on the processing operation ?

Yes No

If yes, please provide some details on the consultation with the ISO:

The ISO was consulted on the occasion of concluding the Service Level Agreement between ECHA and EFSA.

12) Information given to data subjects (Articles 15 and 16)

Has information been provided to data subjects on the way their data is processed including how they can exercise their rights (access, rectification, objection, data portability)? Usually this information is provided in a Privacy Statement, specifying the controller's contact details. As possible, please provide a link to the relevant Privacy Statement or a description.

A 'Data Protection Notice – EFSA use of IUCLID (International Uniform Chemical Information Database)' will be made available on the EFSA Toolkit webpage (<https://www.efsa.europa.eu/en/applications/toolkit>)

Last update of this record: 04/08/2021

Reference: DPO/COM/7