



Data Protection Notice for the use of the Early Detection and Exclusion System (EDES)

The European Health and Digital Executive Agency (HaDEA) processes your personal data¹ in line with [Regulation \(EU\) 2018/1725 of the European Parliament and of the Council of 23 October 2018](#)² on the protection of personal data by the European Union's institutions, bodies and agencies and on the free movement of such data.

What is the purpose(s) of this processing activity?

The purpose of the processing operation is the protection of the Union's financial interests by means of detection of risks and imposition of administrative sanctions. Pursuant to article 137 (1) of the Financial Regulation³, in order to protect the financial interests of the Union, the Commission shall set up and operate an early-detection and exclusion system. The purpose of such a system shall be to facilitate:

- 1.the early detection of risks threatening the Union's financial interests;
- 2.the exclusion of persons or entities which are in one of the exclusion situations listed in Article 138(1) of the FR;
- 3.the imposition of a financial penalty on a recipient of EU funds pursuant to Article 140 of the FR;
- 4.the publication on the Commission's internet site of information related to the exclusion and where applicable the financial penalty, in order to reinforce their deterrent effect (Article 142 of the FR).

Who is the data controller?

The Heads of Units in C1 (Operational Finance) and C2 (Financial Support and Control) of the European Health and Digital Executive Agency (HaDEA), Place Charles Rogier 16, B-1049 Brussels, BELGIUM and can be contacted via HADEA-C.1-SECRETARIAT@ec.europa.eu / HADEA-C2-SECRETARIAT@ec.europa.eu

¹ **Personal data** shall mean any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

² 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 L295/39 of 21.11.2018).

³ [Regulation](#) (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union, (OJ L, 2024/2509, 26.9.2024).

Which personal data is collected?

Categories of personal data that will be processed in EDES are the following:

- 1) For natural persons who fall under the meaning of Article 137(2) of the Financial Regulation:
 - Identification data: Name, surname, address, country, identity card number/passport number/driving license (or other document proving identity), issuing country, date of birth, place of birth;
 - Data on the link (if existing) with a legal entity file kept in the accounting system of the Commission;
 - Data on exclusion or early detection or financial penalty; · Ground (in the case of exclusion): the grounds of the exclusion are mentioned under article 138 (1) of the Financial Regulation, such as final judgement that the data subject is guilty of fraud, corruption, etc.
 - Data on the duration of the exclusion or early detection: starting end, ending date, extension;
 - Data on the panel (article 145 FR): if the case is submitted to the panel, date of the panel, if observations were submitted by the data subject, if the recommendation of the panel was taken into account, revision of the panel's recommendation, etc.
 - Data on the financial penalty: amount, if the amount was paid; · Authorising officer responsible for the case; · Contact person responsible for the case.
- 2) For natural persons who are members of the administrative, management or supervisory body of the person or entity referred to in Article 137(2), or who have powers of representation, decision or control with regard to that person or entity and who are in a situation listed in article 138(1) points (c) to (h) of the Financial Regulation, pursuant to article 138(5)(a) of the Financial Regulation;
 - Identification data: Name, surname, address, country, identity card number/passport number/driving license (or other document proving identity), issuing country, date of birth, place of birth;
 - Data on the link with an excluded entity or person: identification of the linked excluded person or entity, and if the natural person is a person with power of representation, decision making or control or if the person is a member of the administrative, management or supervisory body of the person or entity.
- 3) For natural persons who assume unlimited liability for the debts of the person or entity referred to in Article 137(2) and who are in a situation listed in article 138 (1) point (a) or (b) of the Financial Regulation, pursuant to article 138, paragraph 5 of the Financial Regulation.
 - Identification data: Name, surname, address, country, identity card number/passport number/driving license (or other document proving identity), issuing country, date of birth, place of birth;
 - Data on the link with an excluded person or entity: identification of the linked excluded person or entity, and if the natural person is a person who assumes unlimited liability for the debts of that person or entity
- 4) For natural persons who are essential for the award or for the implementation of the legal commitment and who are in one or more of the situations referred to in article 138 (1) points (c) to (h) of the Financial Regulation, pursuant to article 138(5)(c) of the Financial Regulation.

- Identification data: Name, surname, address, country, identity card number/passport number/driving license (or other document proving identity), issuing country, date of birth, place of birth;
- Data on the link with an excluded person or entity: identification of the linked excluded person or entity, and if the natural person was essential for the award or the implementation of the legal commitment.
- Pursuant to article 142 FR, the following data may be published subject to the decision of the authorising officer:
 - Identification data: name of the data subject;
 - Data on exclusion and grounds of exclusion (article 138 (1) of the FR); · Duration of exclusion;
 - Data on financial penalty: amount and if it was paid;

Where the decision on the exclusion and/or financial penalty has been taken on the basis of a preliminary classification as referred to in Article 138 (3) FR, the publication shall indicate that there is no final judgment or, where applicable, final administrative decision. In those cases, information about any appeals, their status and their outcome, as well as any revised decision of the authorising officer, shall be published without delay.

Where a financial penalty has been imposed, the publication shall also indicate whether that penalty has been paid.

b) Categories of personal data processing likely to present specific risks: not relevant

Some data processed contains sensitive data under Article 11 of Regulation (EU) 2018/1725 'criminal convictions and offences', which may be processed, pursuant to Article 138 (1) FR:

- data relating to insolvency or winding-up procedures, or an analogous situation.
- data relating to the non-payment of taxes or social security contributions.
- data relating to grave professional misconduct (fraudulent misrepresentation of information, distortion of competition, violation of intellectual property rights, attempt to influence the decision-making process of the contracting authority during a procurement procedure, etc.).
- Data relating to fraud, corruption, participation in criminal organisation, money laundering, offences linked to terrorist activities, child labor or other forms of trafficking in human beings.
- Data relating to significant deficiencies in complying with main obligations in the performance of a contract.
- Data relating to an irregularity.
- Data relating to the creation of an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office.

Such data may be processed only on the basis of the relevant provisions of the EU Financial Regulation (Articles 137 to 147 FR). The rights of defence of the person or entity are strictly respected in line with Article 145(5) FR. Other provisions relevant to personal data and providing for appropriate safeguards for the rights and freedoms of data subjects are Article 142(1), 5th subparagraph FR, Article 142(2)(c) FR and Article 145(6), 2nd subparagraph FR.

The above-mentioned personal data are mandatory for the purpose(s) outlined above.

Who has access to the personal data of data subjects and to whom can they be disclosed?

1) Within the EU organisations:

- competent persons within the Agency, including in particular the Director, relevant staff members involved in the EDES file, like Financial or Project officer/advisor, competent Head of Department/ Head of Unit/Head of Sector, HaDEA EDES Central point, Legal Advisors, Anti-fraud Team, DPO

- authorised persons within the Commission and other Executive Agencies for information concerning early detection, exclusion and financial penalty

- authorised persons within all other Institutions, bodies, European offices and agencies for information concerning early detection, exclusion and financial penalty

- members of the EDES Panel referred to in Article 145 FR

- authorised persons from all entities participating in the implementation of the budget in accordance with Articles 62 FR (see article 144 (5) FR) only for exclusion decisions:

(a) authorised persons from the Member States, managing funds under shared management

(b) authorised persons from entities managing funds under indirect management:

-the European Investment Bank ('the EIB') or the European Investment Fund ('the EIF') or both of them acting as a group ('the EIB group');

-Union bodies referred to in Articles 70 and 71 FR; -public law bodies; 5/7 -bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

-bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;

-persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act. The Specific clauses will be inserted by the European Commission in the delegation agreements.

2) Outside the EU organisation:

Authorised persons in entities implementing the budget under indirect management (Articles 144(5) and Article 62(1)(c) FR):

- (i) third countries or the bodies they have designated;
- (ii) international organisations and their agencies;
- (iii) public law bodies;
- (iv) bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
- (v) persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

- 3) the Public for cases which are made public on the website of the EDES related to exclusion and where applicable, the financial penalty (Article 142 FR). According to Article 142, 5th subparagraph FR, where personal data is concerned the authorising officer shall inform the economic operator of its rights under the applicable data protection rules and of the procedures available to exercise those rights. Pursuant to Article 142 (2) (c) FR where a natural person is concerned, personal data shall not be published, unless the publication of personal data is exceptionally justified, inter-alia, by the seriousness of the act or its impact on the Union's financial interests. In such cases, the decision to publish the information shall duly take into consideration the right to privacy and other rights provided for in Regulation (EU) 2018/1725.
- 4) As well as bodies in charge of monitoring and inspection tasks in application of Union or national law (eg internal audits, Court of Auditors, European Anti-Fraud office (OLAF), European Public Prosecutor's Office (EPPO), European Court of Justice and national courts, law enforcement bodies, national authorities).

How long do we keep your personal data?

For Early detection:

Pursuant to Article 144 (4), 3rd subparagraph FR, information is registered for a maximum duration of 1 year from the validation by the Commission and automatically removed at the end of this period.

If, during this period, the Authorising Officer requests the Panel referred to in Article 145 FR to issue a recommendation in an exclusion case, the retention period may be extended until the Authorising Officer has taken a decision (Art 144(4) FR).

In other cases, as soon as it is no longer justified, the information on early detection is closed by the authorising officer.

For Exclusion the duration of the exclusion shall not exceed:

- a) Five years for cases referred to in Article 138 (1) (d) FR (in cases of fraud, corruption, participation in criminal organisation, money laundering, offences linked to terrorist activities, child labour or other forms of trafficking in human beings);
- b) Three years for the cases referred to in Article 138(1) (c), (e) to (h) FR (grave professional misconduct, significant deficiencies in complying with main obligations in the performance of a contract and irregularity);
- c) The duration, if any, set by the final judgement or the final administrative decision of a Member State;

In the cases of Article 138(1) (a) and (b) FR, the duration of the exclusion will correspond with the period in which the exclusion ground is valid (bankruptcy, insolvency or winding-up procedures, or an analogous situation, non-payment of taxes or social security contributions).

Any decision of the authorising officer or any recommendation of the panel referred to in Article 145 FR on the proposed duration of the exclusion shall be made in compliance with the principle of proportionality (Article 138 (4) FR). A published information on exclusion will be removed as soon as the exclusion has come to an end (see Article 142, 4th subparagraph FR).

For Financial Penalty, if the relevant information has been published, the publication shall be removed six months after payment of that penalty (Article 142, 4th subparagraph FR).

The information on early detection and/or exclusion will be removed (automatically) as soon as the time period has elapsed if the authorising officer has not removed it before the end of its duration.

Removed information on early detection, exclusion and/or financial penalty shall be accessible for audit, investigation purposes and for the purposes of the preliminary classification in law due to the fact that the "recurrence" is a criterion to be taken into consideration for the recommendation of the Panel referred to in article 145 (pursuant to article 138 (4) of the FR). The removed information shall not be visible for the users of the EDES database. The additional period that this information will remain in the EDES-DB shall not exceed five years after the removal of the information, in line with Article 75 FR.

What are your rights regarding your personal data?

You have the right to access your personal data and to request your personal data to be rectified, if the data is inaccurate or incomplete; where applicable, you have the right to request restriction or to object to processing, to request a copy or erasure of your personal data held by the data controller. If processing is based on your consent, you have the right to withdraw your consent at any time, without affecting the lawfulness of the processing based on your consent before its withdrawal.

Your request to exercise one of the above rights will be dealt with without undue delay and within **one month**.

If you have **any queries** concerning the processing of your personal data or wish to exercise any of the rights described above, you contact *the Heads of Units in C1 (Operational Finance) and C2 (Financial Support and Control) of the European Health and Digital Executive Agency (HaDEA)*, Place Charles Rogier 16, B-1049 Brussels, BELGIUM and can be contacted via HADEA-C.1-SECRETARIAT@ec.europa.eu / HADEA-C2-SECRETARIAT@ec.europa.eu and HaDEA DPO HADEA-DPO@ec.europa.eu

You shall have right of recourse at any time to the European Data Protection Supervisor at EDPS@edps.europa.eu.

