EUROPEAN HEALTH and DIGITAL
EXECUTIVE AGENCY (HaDEA)

RECORD OF PERSONAL DATA PROCESSING ACTIVITY

In accordance with ***Article 31 of the Regulation (EU) 2018/1725***[1] *on the protection of natural persons with regards to the processing of personal data by the Union Institutions, bodies, offices and agencies and on the free movement of such data, individuals whose personal data are processed by the Executive Agency in any context whatsoever are to be protected with regard to the processing of personal data and the Executive Agency has to keep records of their processing operations.*

Therefore, each responsible HaDEA data controller has to maintain a record of the processing activities under his/her responsibility.

In accordance with Article 31 of the data protection regulation, this record covers two aspects:
1. Mandatory records under Art 31 of the data protection regulation (recommendation: make the header and part 1 publicly available)
2. Compliance check and risk screening (initial; part 2 is internal only to the Agency, not published)
The ground for the record is (tick the relevant one):

Record No: - FIN - 02 **Initial approval by Data Controller**: n/a

Update (s) *(if applicable):* n/a

NAME OF THE PROCESSING ACTIVITY

Use of the Early Detection and Exclusion System (EDES)

IDENTIFICATION OF THE DATA CONTROLLER

European Health and Digital Executive Agency (HaDEA): Head of Units of C1 – Operational Finance and of C2 Financial support and control

GROUND FOR THIS RECORD (*select relevant ground*)

□ Record of a new type of processing activity of personal data (before its implementation)
X Record of a processing activity of personal data that is already in place
□ **Change/Amendment/ Update of an already existing previous record**

[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 L 295/39 of 21.11.2018).

1. INFORMATION ON THE PROCESSING ACTIVITY
of the use of the Early Detection and Exclusion System (EDES)

This processing activity is performed in accordance with **Regulation (EU) No 2018/1725** on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

1.1. The Data Controller is:
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-C1-SECRETARIAT@ec.europa.eu / HADEA-C2-SECRETARIAT@ec.europa.eu

1.2 The contact details of the Data Portection Officer (DPO)

HADEA-DPO@ec.europa.eu

1.3 Joint controller: Not applicable.

1.4 The following entity(ies) is/are acting as Processor(s): Not Applicable

1.5 Description and purpose(s) of this processing :

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 Regulation[2], 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).

1.6 The legal basis for the processing based on Article 5(1) of Regulation (EU) 2018/1725 is/are:

☒ **(a)** the processing is necessary for the **performance of a task carried out in the public interest** or in the exercise of official authority vested in the Union Institution or body[3] laid down in Union law;

[2] 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).
[3] Commission Implementing Decision (EU) 2021/173 of 12 February 2021 establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council European Health and Digital Executive Agency (HaDEA), B-1049 Brussels, BELGIUM

☐ **(a2)** the processing is necessary for the **management and functioning** of the Union Institutions, bodies or agencies (Recital (22) of Regulation (EU) 2018/1725) laid down in Union law;

☒ **(b)** the processing is necessary for **compliance with a legal obligation** to which the controller is subject, which are …[4] laid down in Union law;

☐ **(c)** the processing is necessary for the **performance of a contract** to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

☐ **(d)** the data subject has given **consent** to the processing of his or her personal data for one or more specific purposes[5];

☐ **(e)** the processing is necessary in order to protect the **vital interests** of the data subject or of another natural person.

1.7 The categories of data subjects

☒ Agency staff (Contractual and temporary staff in active position)

☐ Visitors to the Agency

☒ Applicants

☒ Relatives of the data subject

☒ Complainants, correspondents and enquirers

☒ Witnesses

☒ Beneficiaries

☒ External experts

☒ Contractors

☐ Other, please specify:

1.8 Categories of personal data

a) Categories of personal data:

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;

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and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU, 2013/776/EU and 2013/770/EU [*and reference to relevant legal basis of the programme (do not forget to consider legacy), Staff Regulation, Financial Regulations or other*].

[4] *Please indicate the specific legal obligations you are referring to (i.e. Articles of the Staff Regulation).*

[5] *The type of personal data concerned by the consent has to be clearly identified!*

· 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 perosn 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 teh 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 <u>specific risks:</u>

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) outline above.

c) Categories of personal data whose processing is <u>prohibited</u>, with exceptions (art. 10):

not relevant

d) Specify any additional data or explanatory information on the data being processed, if any: -
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1.9 Retention period (maximum time limit for keeping the 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.

Is any further processing for historical, statistical or scientific purposes envisaged?
☐ yes ☒ no

1.10 The recipient(s) of the data

The recipients[6] to whom the personal data will or might be disclosed are:

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:

[6] *Consider if any of the recipients processes personal data **outside of the EU** e.g. do non EU-based entities have access to this personal data i.e. via **remote access** for maintenance services. Check with DPO the existence of an Adequacy Decision by the Commission or the suitable safeguards and the means by which to obtain a copy of them or where they have been made available.*

-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
(vi) bodies governed by private law with a public service mission, including Member State organisations, to the extent that they are provided with adequate financial guarantees; (vii) 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;
(vii) bodies or 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).

1.11 Transfers of personal data to third countries or international organisations

Authorized persons in entities implementing the budget under indirect management (Articles 144(5) and Article 62(1)(c) FR) will have access to the information on exclusion decisions also for the part of the database that is not open to the public:

(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.

All international organisations that implement EU funds are bound by Agreements with the EU (contribution agreements, delegation agreements, financial framework partnership agreements, etc.) subject to appropriate safeguards (Article 48(2) and (3) of Regulation (EU) 2018/1725), a legally binding and enforceable instrument between public authorities or bodies or a transfer based on an International agreement (Article 49 of Regulation (EU) 2018/1725; derogation(s) for specific situations in accordance with Article 50(1) (a) - (g) Regulation (EU) 2018/1725) apply.

In the absence of an adequacy decision, or of appropriate safeguards, transfer of personal data to a third country or an international organisation is based on the derogation for specific situations in accordance with Article 50(1) (d) Regulation (EU) 2018/1725.

Entities implementing the budget under indirect management (Articles 144(5) and 62(1)(c) FR) will have access to the information on exclusion decisions, to enable them to verify whether there is an exclusion in the system with a view to taking this information into account, as appropriate and on their own responsibility, when awarding contracts in budget implementation. This qualifies as an important reason of public interest, since the ultimate purpose of EDES it the protection of the Union's financial interests. No natural persons are currently excluded in the EDES Database, so for the moment there are no international transfers of personal data outside the EU.

1.12 The processing of this personal data **will not include** automated decision-making (such as profiling). N/A

1.13 Description of security measures

The following technical and organisational security measures are in place to safeguard the processing of this personal data: All personal data are stored on the servers of the European Commission. All processing operations are carried out pursuant to the Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission.

In order to protect personal data, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

1.14 Data protection Notice

Data Subjects are informed on the processing of their personal data via a **data protection notice on their rights :**

- to access their personal data held by a controller;
- to request their personal data held by a controller to be corrected;
- to obtain in some situations erasure of their personal data held by a controller, e.g. when data are held unlawfully (right to be forgotten);
- to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;

- of recourse at any time to the **HaDEA Data Protection Officer** at HADEA-DPO@ec.europa.eu Click here to enter text.and to the **European Data Protection Supervisor** at https://edps.europa.eu.

Request from a data subject to exercise a right will be dealt within **one month**.

Your right to information, access, rectification, erasure, restriction or objection to processing, communication of a personal data breach or confidentiality of electronic communications may be restricted only under certain specific conditions as set out in the **applicable Restriction Decision** in accordance with Article 25 of Regulation (EU) 2018/1725.

Electronically signed on 11/03/2025 12:32 (UTC+01) in accordance with Article 11 of Commission Decision (EU) 2021/2121