



EUROPEAN COMMISSION

PROTECTION OF YOUR PERSONAL DATA

This privacy statement provides information about the processing and the protection of your personal data.

Processing operation: *EU Coding Platform*

Data Controller: *European Commission: Health and Food Safety (SANTE)*

Record reference: *DPR-EC-03286*

Table of Contents

- 1. Introduction**
- 2. Why and how do we process your personal data?**
- 3. On what legal ground(s) do we process your personal data?**
- 4. Which personal data do we collect and further process?**
- 5. How long do we keep your personal data?**
- 6. How do we protect and safeguard your personal data?**
- 7. Who has access to your personal data and to whom is it disclosed?**
- 8. What are your rights and how can you exercise them?**
- 9. Contact information**
- 10. Where to find more detailed information?**

1. Introduction

The European Commission (hereafter 'the Commission') is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to [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 (repealing Regulation (EC) No 45/2001).

This privacy statement explains the reason for the processing of your personal data, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to processing operation *EU Coding Platform* undertaken by *European Commission: Health and Food Safety (SANTE) Unit D2 Medical products: Quality Safety and Innovation* is presented below.

2. Why and how do we process your personal data?

Purpose of the processing operation: the *European Commission: Health and Food Safety (SANTE) Unit D2 Medical products: Quality Safety and Innovation* collects and uses your personal information exclusively to provide access to the EU Coding platform and will not be used for other compatible purposes.

EU Coding Platform users' personal data are stored and managed automatically by the European Commission through EU Login/SAAS systems. These systems assure the controlled access to EU Coding Platform.

Your personal data will not be used for an automated decision-making including profiling.

3. On what legal ground(s) do we process your personal data

We process your personal data, because:

(a) 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;

(b) processing is necessary for compliance with a legal obligation to which the controller is subject;

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

The basis for the processing referred to in points (a) and (b) of the paragraph 1 has been laid down in the following Union law.

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:294:0032:0050:EN:PDF>

Commission Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF>

This procedure covers human tissues and cells within the scope of Article 1 & 2 of Directive 2004/23/EC. The legal requirement of Article 8 of Directive 2006/86/EC on the communication of information between Competent Authorities and to the European Commission requires the Competent Authorities for human tissues and cells to:

"Communicate to each other and to the Commission, such information as is appropriate with regard to serious adverse reactions and events, in order to guarantee that adequate actions are taken."

Article 9 of the [Directive 2005/61/EC](#) on traceability requirements and notification of serious adverse reactions and events of blood and blood components, regarding communication of information between competent authorities and to the Commission provides for the Member States to ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded"

4. Which personal data do we collect and further process?

In order to carry out this processing operation the *European Commission: Health and Food Safety (SANTE) Unit D2 Medical products: Quality Safety and Innovation* collects the following categories of personal data:

- Name of the user;
- Contact details (e-mail address, telephone number, country of residence);
- Name of the Member State competent authority
- Contact details (e-mail address, telephone number*, country of residence);

The provision of personal data is mandatory with the exception of the phone number of the Member State competent authority.

The provision of personal data is mandatory to meet a technical requirement allowing access to the restricted areas of the EU Coding platform. If you do not provide your personal data, access to restricted part of the EU Coding platform will not be allowed thus preventing the performance of tasks to be carried out in the public interest.

5. How long do we keep your personal data?

The *European Commission: Health and Food Safety (SANTE) Unit D2 Medical products: Quality Safety and Innovation* only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing, namely for as long as you hold your capacity as authorised users of the system.

6. How do we protect and safeguard your personal data?

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) 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 your personal data, the Commission has put in place a number of technical and organisational measures in place. 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.

7. Who has access to your personal data and to whom is it disclosed?

Access to your personal data is provided to the Commission staff responsible for carrying out this processing operation and to authorised staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

8. What are your rights and how can you exercise them?

You have specific rights as a ‘data subject’ under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, your personal data and to rectify them in case your personal data are inaccurate or incomplete. Where applicable, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing, and the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a) on grounds relating to your particular situation.

You can exercise your rights by contacting the Data Controller, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

9. Contact information

- The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller, *European Commission: Health and Food Safety (SANTE) Unit D2 Medical products: Quality Safety and Innovation* SANTE-SoHO@ec.europa.eu.

- The Data Protection Officer (DPO) of the Commission

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

- The European Data Protection Supervisor (EDPS)

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor edps@edps.europa.eu if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.

10. Where to find more detailed information?

The Commission Data Protection Officer (DPO) publishes the register of all processing operations on personal data by the Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>.

This specific processing operation has been included in the DPO's public register with the following Record reference: *DPR-EC-03286*.