

PRIVACY STATEMENT

PROTECTION OF YOUR PERSONAL DATA

Table of Contents

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

1. Introduction

This privacy statement explains the reasons for processing, the way we collect, handle and ensure protection of all personal data provided, how that information is used, as well as what rights you may exercise in relation to your data (the right to access, rectify, block etc.).

The European institutions are committed to protecting and respecting your privacy. As this service/application collects and further processes personal data, Regulation (EC) N°45/2001¹ of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data is applicable.

¹ Regulation (EC) 45/2001 (OJ L8 of 12/01/2001).

***EU Common Entry Gate
for reporting of information on tobacco products and notification of
information on electronic cigarettes and refill containers***

This statement concerns the EU Common electronic Entry Gate for submission of information on ingredients and emissions of tobacco products and electronic cigarettes (EU-CEG) undertaken by DG SANTE.

The EU-CEG is a secure IT infrastructure essential to ensure uniform application of the electronic reporting/notification obligations set out in Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products². The reporting/notification process is articulated in several stages: submissions are made by manufactures and importers (or third parties on their behalf) of tobacco products and e-cigarettes and they concern ingredients, emissions and other information on each product, including studies on market research and preferences of various consumers group related to ingredients and emissions. Each submission contains basic information on the company that is sending the submission.

2. Why do we process your data?

Purpose of the processing operation:

DG SANTE (referred to hereafter as Data Controller) collects and uses your personal information in order to verify the identity and the contact details of the manufacturer of the product and, in case the submission is done by an importer, of the importer of the product. The purpose is also to relate a particular product submission to the relevant manufacturer/importer.

No further processing in a way incompatible with those purposes is foreseen.

The legal basis of the processing is Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. More specifically,

- for the reporting of tobacco ingredient and emissions the legal basis is Article 5;
- for the notification of e-cigarettes and refill containers the legal basis is Article 20.

² Directive 2014/40/EU (JO L 127 of 29.4.2014).

***EU Common Entry Gate
for reporting of information on tobacco products and notification of
information on electronic cigarettes and refill containers***

The information required to be submitted are defined in Commission Implementing Decisions (EU) 2015/2186 of 25 November 2015 and 2015/2183 of 24 November.

Data processing can be considered legitimate under Article 5 (a) and (b) of Regulation (EC) N° 45/2001. The set of information is limited to the company and processing is essential in order to allow Member States and the Commission to carry out their regulatory tasks and to comply with the legal obligations set out in Directive 2014/40/EU.

The processing of personal data does not fall under Article 27 of Regulation (EC) N° 45/2001.

3. Which data do we collect and process?

The following data which is collected and further processed might constitute personal data:

1) Personal Data of USERS

a) Data which are part of the product submission

The following data sets are part of the product submission and are related to the manufacturer's or importer's company, or the third party that is submitting data on their behalf:

- Official name
- Address
- Business phone
- Functional business email.

b) Data used to verify the identity of the company and to assign a "submitter ID"

In order to assign a "submitter ID", the Commission needs to verify the identity and authenticity of the company. Therefore, prior to the assignment manufacturers and importers send a request to the Commission and submit the data listed below.

The fields that could contain personal data are (mandatory data fields are marked with an asterisk):

- Company registered name (*)
- Company alternative/abridged name (if exists)
- Company postal address
- Corporate e-mail address (*)

***EU Common Entry Gate
for reporting of information on tobacco products and notification of
information on electronic cigarettes and refill containers***

- Corporate fax number
- Corporate phone number (*).

2) Personal Data of NON-USERS:

If the submission is drafted by an importer, or by a third party acting only behalf of the importer/manufacture, in addition to the data referring to its own company, the submitter has to indicate the following information, that might potentially include personal data, in relation to the manufacturer/importer:

- Official name
- Address
- Business phone
- Functional business email address.

If manufacturers or importers have a "parent" or "affiliate" company, they should as well indicate this information in relation to "parent" or "affiliate" company.

4. How long do we keep your data?

Data are kept for 20 years, which is the time necessary to fulfil the purposes of collecting and processing the data.

5. How do we protect your data?

All data in electronic format (e-mails, documents, uploaded batches of data etc.) are stored either on the servers of the European Commission or of its contractors; the operations of which abide by the European Commission's security decision of 16 August 2006 [C(2006) 3602] concerning the security of information systems used by the European Commission.

At the level of the EU-CEG, security measures applied contain:

- Encryption: All data transferred from the manufacturers and importers will be encrypted with the EU-CEG public certificate.
- Secure transfer: HTTPS protocol will be used for secure transfer.
- Authentication: ECAS.
- Network security: For Member State access a secure private network (TestaNG) will be used. Hosting: The application will be hosted in DIGIT secure hosting facilities.

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

Access to data is provided to Member State users (which include EEAs countries) and Commission users (policy units and support staff). Transfers to third party countries not subject to Directive 95/46/EC is not foreseen.

EU Common Entry Gate
for reporting of information on tobacco products and notification of
information on electronic cigarettes and refill containers

Member States will be able to see the entire product submission. The personal data that might be present in the product submission are listed in point 3.1 a). With respect to the product submission, only the Member State in which the products will be placed on the market receive the submission and will be able to view its information, but not to modify it (read-only access). The Commission will be able to see ECAS and SAAS information, the entire product submissions as well as the data used to verify the identity of the company and assign a "submitter ID" (point 3.1.b).

According to article 5(4) of Directive 2014/40/EU, Member States shall ensure that the information submitted through the EU-CEG is made publicly available on a website. The Member States shall take into account the need to protect trade secrets when making that information publicly available. Therefore, when submitting information, manufacturers and importers (*and third parties*) can specify which information they consider confidential.

What are your rights and how can you exercise them?

According to Regulation (EC) n°45/2001, you are entitled to access your personal data and rectify and/or block it in case the data is inaccurate or incomplete. You can exercise your rights by contacting the data controller or, in case of conflict, the Data Protection Officer, and, if necessary, the European Data Protection Supervisor using the contact information provided under point 8 below.

In all cases, the Commission can block, modify or erase personal data submitted. Data subjects can send their justified legitimate requests for the modification or removal of their personal data via an e-mail to SANTE-EU-CEG@ec.europa.eu.

Personal data will be removed from the data subject within 30 days following the receipt of a legitimate request.

With regards to **data which are part of the product submission**, manufacturers, importers and third parties will be able to verify their personal data through the checksum of the data submitted. Such a checksum is contained in the success message that they receive each time a new submission has been successfully sent.

In order to modify their data, manufacturers and importers can send in a new submission containing new or updated company data.

7. Contact information

EU Common Entry Gate
for reporting of information on tobacco products and notification of
information on electronic cigarettes and refill containers

If case of comments, questions, as well as concerns or complaints regarding the collection and use of your personal data, please feel free to contact the Data Controller using the following contact information: SANTE-EU-CEG@ec.europa.eu.

The Data Controller:
DG SANTE, Unit B2
SANTE-EU-CEG@ec.europa.eu

The Data Protection Officer (DPO) of the Commission: DATA-PROTECTION-OFFICER@ec.europa.eu

The European Data Protection Supervisor (EDPS): edps@edps.europa.eu.

8. Where to find more detailed information?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link: <http://ec.europa.eu/dpo-register>

