

DG SANTE rules and procedures

Registration of requests

1. Requests arrive:
 - directly from the Secretariat General in Unit A4.001 **SANTE ACCESS TO DOCUMENTS** mailbox (75% of cases) with a GESTDEM number (GESTDEM is the corporate SG database for the monitoring of requests for access to documents);
 - by post at CAD (Cellule Administration des Documents/Document Management Team - Incoming mail);
 - by post, fax or e-mail in the Units: these must be saved in ARES by the Units like any other important document and assigned to **SANTE ACCESS TO DOCUMENTS** (EXP task for ve_sante.accdoc) for further registration in ARES and GESTDEM and appropriate monitoring.
2. Requests are registered by the CAD and assigned to the relevant Unit or Directorate (the Directorate is then responsible for assigning to a Unit). The requests are scanned (when on paper) and attached to the ARES document.
3. The CAD adds the deadline fixed by the Secretariat General and specific instructions for the processing of the request.
4. Coordinator in Unit A4.001: [redacted] (tel. [redacted]).

Acknowledgement of receipt


The Secretariat General sends an automatic acknowledgment of receipt for all requests arriving in their mailbox or via the electronic form posted on the Europa website.

For requests arriving directly in DG SANTE the Unit in assignment must send the acknowledgement of receipt unless a reply can be sent immediately.

Please choose the appropriate "Receipt" standard letter available in all languages.

Contact: [redacted] (tel. [redacted]) or [redacted] (tel. [redacted]).

Preparation of reply - Code of Good Administrative Behaviour

According to the Code of Good Administrative Behaviour and to Regulation 1049/2001  a reply to the request should be sent in the language of the applicant **within 15 working days** as from the registration date (see date in deadline in ARES).

Failure to reply within 15 working days is equivalent to **refusing access** to the requested document **without giving a reason** which constitutes grounds for the applicant to send a confirmatory application to the Secretary General (on the basis of Regulation 1049/2001) and/or to make a complaint to the Ombudsman (on the basis of the Code of Good Administrative Behaviour).

Units have four possible replies to draft for signature:

1. Holding letter (in case the deadline cannot be matched)
2. Positive reply = release of the requested document
3. Negative reply = refusal to release the requested document
4. **Partial access reply** = access to part(s) of the requested document

Contact: [redacted] (tel. [redacted]) or [redacted] (tel. [redacted]).

Holding letter

- Should a final reply take more time than the specified deadline, a holding reply must be sent. This can happen due to longer search through archives, coordination with another DG, absence of person in charge of the reply, translation, etc.
- The holding reply is prepared by the Unit in attribution, using the appropriate template (See model of holding reply in **standard letters**).
- Compulsory e-Signatory workflow in ARES:
RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: ve_sante.accdoc
SIGN: Head of Unit
EXP: ve_sante.cad.out
- The letter is drafted in ARES using "Answer" option, with an e-signature including ve_sante.accdoc "visa", prior to the Head of Unit's signature and then sent off according to the procedure for outgoing mail.
 - The new deadline of 15 working days will start next day after end of first deadline.
 - You are entitled to only one holding reply. In some very exceptional cases, when searching for the requested documents might take months, subsequent extensions have to be justified and negotiated with the requestor (always informing SANTE A4.001 "Access to documents").
 - A holding reply must be registered in ARES in link with initial request. Should the holding reply be sent by e-mail, the sent e-mail must be scanned into ARES (as legal proof).



Contact: [redacted] (tel. [redacted] [redacted] or [redacted] (tel. [redacted] [redacted])).

Positive reply

- The Unit in attribution is responsible for preparing a draft reply using the appropriate template. See: **standard letters**. The Unit in attribution is also responsible for finding the requested documents.
Attention: in case of electronic document(s), **always send the PDF or TIF read-only format** of the document(s).
- Compulsory e-Signatory workflow in ARES:
RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: ve_sante.accdoc
SIGN: Head of Unit
EXP: ve_sante.cad.out
- The reply is drafted in ARES using the "Answer" option with an e-signature including ve_sante.accdoc "visa", prior to the Head of Unit's in attribution signature and then sent off according to the procedure for outgoing mail.
 - Positive replies once signed must be duly registered in ARES in link with the initial request.
 - Should the reply be sent as attachment **by e-mail**, the sent e-mail must be scanned into ARES (as legal proof) in link with initial request.



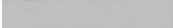
Contact: [redacted] (tel. [redacted] [redacted] or [redacted] (tel. [redacted] [redacted])).

Negative reply

- SG Quality chart for negative or partial access replies
- List of documents 
- The Unit prepares a draft **justifying its negative reply** with arguments and the corresponding paragraph of **Article 4 of Regulation 1049/2001** . See: **standard letters**.
- The negative reply is drafted in ARES with an e-signature including A4.001 (**ve_sante.accdoc**), Unit A2 ([redacted]), the Head of Unit A2 and the Head of Unit A4 before the signature of the Director General.
- Compulsory e-Signatory workflow in ARES:
RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: Head of Unit
VISA: ve_sante.accdoc
VISA: [redacted] - A2
VISA: Head of Unit A2
VISA: Head of Unit A4
VISA: ASSIST DIR (relevant Dir.)
VISA: Director
VISA: Assistant to the DDG (relevant DDG)
VISA: DDG
VISA: ve_sante.dg.ast
SIGN: Director General
EXP: ve_sante.cad.out
- The signed negative reply will be registered in ARES.
- **The negative reply must be sent by registered post with acknowledgement of receipt.**
- **Never send a negative reply without approval of A2 and A4.001 and signature of the Director General.**

Contact: [redacted] (tel. [redacted] [redacted] or [redacted] (tel. [redacted] [redacted])).

Partial access reply

- List of documents 
- The Unit in attribution prepares a draft justifying its partial access based on one or more exception(s) in Article 4, of Regulation 1049/2001. See: [standard letters](#).
Attention: **Never send the electronic version of a document in which you have erased data! Please use Adobe Acrobat Pro to ensure correct erasing of data.** Otherwise please take good care to send to the requestor a scanned copy of the document on which data that cannot be communicated have been erased.
- The partial access reply is drafted in ARES with an e-signature including A4.001 (**ve_sante.accdoc**), Unit A2 () , the Head of Unit A2 and the Head of Unit A4 before the signature of the Director General.
- Compulsory e-Signatory workflow in ARES:
RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: Head of Unit
VISA: **ve_sante.accdoc**
VISA:  - A2
VISA: Head of Unit A2
VISA: Head of Unit A4
VISA: ASSIST DIR (relevant Dir.)
VISA: Director
VISA: Assistant to the DDG (relevant DDG)
VISA: DDG
VISA: **ve_sante.dg.ast**
SIGN: Director General
EXP: **ve_sante.cad.out**
- The signed partial access reply will be registered in ARES.
- **Partial access replies must be sent by registered post with acknowledgement of receipt.**
- **Never send a partial access reply without approval of A2 and A4.001 and signature of the Director General.**

Contact:  (tel.  ) or  (tel.  ).

Confirmatory application

The requestor may not agree with DG SANTE refusal or partial access and has a right to send a confirmatory application to the Secretary General.

According to the rules of procedure the Secretary General will have to reply to the applicant and will therefore ask DG SANTE to provide the refused document and a note with arguments to justify the initial refusal/partial access.

The deadline will then be **5 working days** and the relevant documents and notes to the Secretary General will be sent by e-mail to the following mailbox: SG DOSSIERS ACCES, copy to: SANTE ACCESS TO DOCUMENTS.

Contact:  (tel.  ) or  (tel.  .

Partial access / negative replies and devoid of purpose replies are to be sent by registered post with acknowledgement of receipt

Compulsory E-signatory workflow in ARES:

Holding / Positive Reply / Partial access reply (personal data expunged)

RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: ve_sante.accdoc
SIGN: Head of Unit
EXP: **ve_sante.cad.out**

Devoid of purpose reply

RED: Case handler in Unit Chef de File
(CONTRIB: the Unit(s))
VISA: Head of Unit
VISA: ve_sante.accdoc
VISA: Head of Unit A4
VISA: ASSIST DIR (relevant Dir.)
VISA: Director
VISA: **ve_sante.dg.ast**
SIGN: Director General
EXP: **ve_sante.cad.out**

Partial access / Negative Reply

RED: Case handler in Unit Chef de File

(CONTRIB: the Unit(s))

VISA: Head of Unit

VISA: **ve_sante.accdoc**

VISA: [REDACTED] - **A2**

VISA: Head of Unit A2

VISA: Head of Unit A4

VISA: ASSIST DIR (relevant Dir.)

VISA: Director

VISA: ve_sante.dg-ast

SIGN: Director General

EXP: ve_sante.cad.out

Contact

- Coordination of requests: Unit A4.001 - [REDACTED] (tel. [REDACTED] - [REDACTED]) or [REDACTED] (tel. [REDACTED] - [REDACTED]) - [REDACTED] (tel. [REDACTED] - [REDACTED])
- Legal advice (for negative or partial answers): Unit A2 - [REDACTED] (tel. [REDACTED] or [REDACTED] (tel. [REDACTED] - [REDACTED])
- Partial answers with only personal data expunged: [REDACTED] (tel. [REDACTED] - [REDACTED]), [REDACTED] (tel. [REDACTED] - [REDACTED]) or [REDACTED] tel. [REDACTED] - [REDACTED]