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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

General Affairs
Information systems

**DG SANTE INTERNAL GUIDANCE DOCUMENT ON
ACCESS TO DOCUMENTS
IMPLEMENTATION OF REGULATION (EC) No 1049/2001**

JULY 2015

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1. INTRODUCTION

Responding to requests for Access to Documents must now be seen as a normal activity. That said, it is very difficult for Units to plan for these unexpected requests, some of which are very complex and cover a wide scope and/or a large amount of documents. Good standard administrative practices can however make reacting to requests less burdensome and less disruptive of operational tasks.

Questions have been raised recently concerning **internal documents** (such as internal e-mails exchanged within SANTE and/or with Cabinet, draft texts, and handwritten notes), recordings (“tapes”) of Committee meetings, the **implementation by the Agencies** of Regulation (EC) No 1049/2001¹, and the relationship between the Regulation and SANTE sectorial legislation on the confidentiality of information contained in certain documents (dossiers).

Since the Note to the Management Team on this subject (22 September 2011, ARES(2011)1008632), there has been some improvement in SANTE with regard to respect of the procedures and the application by many Units of good practices concerning the interpretation of the different articles of the Regulation, with a view to limit the scope of the requests and/or to find a fair solution with the applicants. (*See Chapter 4.*)

Number of requests for access to documents
(figures from GESTDEM, the SG application managing requests)

	2009	2010	2011	2012	2013	2014	<i>Increase 2009-2014</i>
SANTE	249	346	449	441	539	447	+80%

The quality control of all negative and partial access replies in 2012-2013-2014 is overall positive, which is in line with the instructions of the Secretariat-General (SG).

SANTE has received more confirmatory applications, i.e. appeals to the SG against a refusal to release (parts of) the documents. In such cases, the deadline to forward the full content of (partially or totally) refused documents to the SG is 24 hours. SANTE services replied in due time (i.e. within 24 hours) and ensured full cooperation with the SG.

This guidance document focusses on **clarification concerning the above-mentioned questions and further actions to possibly limit the workload in responding to requests in the future.**

Annex 1 is a summary of the basic principles of Regulation (EC) No 1049/2001.

¹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:145:0043:0048:EN:PDF>

2. CLARIFICATIONS CONCERNING DOCUMENTS

2.1. Definition of document

The scope of the Regulation (EC) No 1049/2001 (hereafter “the Regulation”) is to give the widest possible access to documents which have not already been published or made public.

The Regulation gives a very broad definition of document. It does not provide any possibility to exclude certain categories of documents *a priori* from its scope.

Definition of document in Article 3 of the Regulation:

Article 3 – Definitions

For the purpose of this Regulation:

- (a) ‘document’ shall mean any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audio-visual recording) concerning a matter relating to the policies, activities and decisions falling within the institution’s sphere of responsibility;

Internal documents whether they are registered or not and working documents cannot systematically be excluded from the scope of the request.

Examples of internal documents include:

- preparatory documents on Commission policy decisions and initiatives, such as preliminary drafts, interim reports, draft legislative proposals or decisions;
- explanatory documents or other types of information, such as statistics, memorandums or studies, on which Commission decisions and policy measures are based;
- briefings, minutes of meetings, BTOs, mission reports, internal e-mails saved/recorded on a computer.

In order to better define the term “document”, it is useful to refer to the definition in Article 1 of the ‘e-Domec’ Decision 47/2002/EC:

- **document** shall mean any content drawn up or received by the Commission concerning a matter relating to the policies, activities and decisions falling within the institution’s competence and in the framework of its official tasks, in whatever medium (written on paper or stored in electronic form or as a sound, visual or audio-visual recording).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:021:0023:0027:EN:PDF>

Even before the migration to ARES (in May 2010) all documents (including internal documents and e-mails) which meet the ‘e-Domec’ criteria should have been duly registered. (See *Point 2.3.*)

ARES is not the only register, as specific types of documents are registered in other registers (e-Greffe, CIS-Net, Basil, MisDoc, for example) and in other electronic systems or repositories (Basis, Circa web sites, Traces, Rasff, etc.).

The identification of the relevant documents whether registered or not does not mean that all documents will be released. The opportunity to release the documents will be assessed on a case by case basis, and refusal to grant access to (parts of) documents must be reasoned based on the exceptions provided for in Article 4 of the Regulation. (*See Chapter 5.*)

2.2. E-mails

2.2.1. External e-mails (from/to outside the Commission)

All incoming and outgoing e-mails whose subject, date, sender and recipients are clearly identified and whose content fulfills the ‘e-Domec’ criteria (*See also Point 2.3.*), should be duly registered in Ares and filed in the correct file.

Any e-mail containing important information, i.e. which is not short-lived and which is likely to require action, follow-up or a reply from the Commission or one or more of its departments or to involve the responsibility of the Commission or one or more of its departments must be registered.

Guidelines for the registration of e-mails in the framework of the electronic archiving and document management policy of the European Commission (e-Domec), SEC(2006)353.

Documents NOT to be registered are described under Point 2.3.

2.2.2. Internal e-mails (within Commission services)

There is no obligation to register an internal e-mail; the decision is taken by the person sending the e-mail. *A priori* internal e-mails that do not meet the criteria for document registration (*see Point 2.3.*) do not need to be registered.

However, e-mails may be saved and filed in Ares, if this would make easier the comprehension of the relevant file.

Example: summary record of a meeting where a decision has been taken.

E-mails exchanged between two or several members of staff informally and in good faith in the “space to think” should not be registered. E-mails exchanged between two or several members of staff, and which constitute a major step in the procedure of finalising a document in the framework of the departments’ activities, must always be registered.

Guidelines for the registration of e-mails in the framework of the electronic archiving and document management policy of the European Commission (e-Domec), SEC(2006)353.

2.3. Registered documents vs. working documents

Most applicants who request access to documents are interested in “internal” documents which they cannot find easily (as opposed to published ones). The files in the Units contain both official documents and unofficial ones.

The official documents should be duly registered whereas the unofficial or working documents are saved and stored, usually on the P: drive or U: drive of the Units.

All documents **including e-mails** which meet the criteria of the provisions on the document management rules **must** be registered.

Documents to be registered

“Documents to be registered pursuant to the provisions on document management are all documents, regardless of medium, that:

- (a) are received or formally drawn up by a Commission department in the course of its activities; and**
- (b) i) are likely to require action, follow-up or a reply from the Commission or one or more of its departments; or
ii) involve the responsibility of the Commission or one or more of its departments; and**
- (c) contain important information which is not short-lived;”**

Implementing rules for Decision 2002/47/EC, ECSC, Euratom on document management and for Decision 2004/563/EC, Euratom on electronic and digitised documents, SEC(2009)1643

Documents NOT covered by the registration requirement

“Documents containing information which is unimportant and short-lived are, *in contrast*, documents:

- whose loss would not prevent the departments concerned meeting the Commission’s administrative or evidential needs; **or**
- whose value is clearly temporary and rapidly lapsing, ancillary and instrumental; **or**
- which are considered or treated as non-important and short-lived by a records schedule, a procedural regulation or routine administrative practice.”

Document registration manual, SG.B.3/MH D(2004)5794.

Commission services are asked to follow the document management rules and SG guidelines in the note from the Secretary-General Ares(2015)182108 – 16/01/2015, so as to ensure that:

- All relevant documents, including e-mails, are captured and can be easily retrieved when needed, in particular when replying to a request for access to documents.
- When processing a request for access, documents are searched only in Ares or in another document management system.
- All colleagues are aware of their responsibilities in this regard.

See Newsletter no 13 of 21/01/2015 – Document management and access to documents (note, practical registration criteria and guidelines)

<https://myintracomm.ec.europa.eu/sg/docinter/Pages/newsletter.aspx>

When processing a request for access, documents should therefore be only searched for in Ares or in another Commission document management system (such as Decide, ABAC, etc.). These systems will be integrated with Hermes/Ares/Nomcom (“IT Rationalisation” project).

2.4. Sound, visual or audio-visual recording

The definition of document includes sound, visual or audio-visual recording.

The processing of the request will be the same as for paper/electronic documents. In case of partial access, the blanking out of parts of the records should be done on the transcription of the records.

If such processing would entail a disproportionate amount of work, the access to all or part of the documents requested may be refused on the basis of the principle of proportionality. (*See also Point 4.3.3.*)

2.5. Disclosure of information from a database

Concerning applications for access to information in a database other than one already accessible to the public, as a general rule the Commission should supply the information requested on condition that it is not covered by one of the exceptions provided for in Article 4 of the Regulation and that:

- the application does not require new computer instructions to be issued in order to retrieve the data;
- the application can be processed by routine operations.

Where an application for access to information would require seeking technical assistance in order to perform a non-routine operation, access can be denied on the basis that the application does not relate to a document in an existing version and format (including electronically) and, therefore, falls out of the scope of the Regulation.

2.6. Confidential / sensitive documents

Under the rules applying in the Commission², a classified document is one marked “RESTREINT UE/EU RESTRICTED”, “CONFIDENTIEL UE/EU CONFIDENTIAL”, “SECRET UE/EU SECRET” or “TRES SECRET UE/EU TOP SECRET”.

A document is classified if it contains information whose unauthorised disclosure:

- might harm the essential interests of the European Union or one of its Member States (“top secret” – exceptional harm, “secret” – serious harm, “confidential” – harm);
- might be prejudicial to the interests of the European Union or one of the Member States (“restricted”).

² Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, OJ L 72, 17.3.2015, p. 53-88.
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D0444&qid=1438175834535&from=EN>

Because of the information it contains, such a document enjoys a special level of protection within the institution itself.

A document that is classified at least as “confidential”, and falls into the area of protection of the public interest as regards:

- public security;
- defence and military matters;
- international relations;
- the financial, monetary or economic policy of the Community or a Member State, is referred to as a “sensitive document” (Article 9 of the Regulation).

When an application for access relates to a sensitive document or another document classified under the Commission’s security rules, it will be examined by officials with authority to read the document.

Any decision refusing access to all or part of a classified document must be justified with reference to the exceptions provided for in the Regulation. (*See Chapter 5.*)

The agreement of the originating authority is required for granting access to a sensitive document (Article 9 of the Regulation; Article 6 of the internal rules)³.

3. COORDINATION ON ACCESS TO DOCUMENTS

3.1. Coordination of initial requests at Commission level

If a request covers several DGs, the coordination should be ensured by the natural lead service.

If the request is addressed to one or several DGs **and additionally the SG, the Secretary-General, the (former) President or one of the five Vice-Presidents** without a service and/or their respective Cabinets, and covers issues falling under the responsibility of one of the latter entities, then the Unit in SG responsible for the policy coordination will coordinate.

In any case, the SG.B.4 legal officers are available to provide legal and procedural support.

SANTE/A4 checks if similar requests are addressed to other DGs and informs the relevant SANTE Directorate/Unit and SG. In some very specific cases, coordination meetings may be arranged by the SG in order to find a coherent way to deal with difficult requests.

If a request covers DG SANTE documents on a topic where the natural lead service is another DG, DG SANTE will prepare the reply and the relevant documents and consult the lead DG on the draft reply in order to agree on a common position.

³ 2001/937/EC, ECSC, Euratom: Commission Decision of 5 December 2001 amending its rules of procedure – Annex : Detailed rules for the application of Regulation (EC) No 1049/2001 of 30.5.2001, OJ L 345, 29.12.2001, p. 94-98.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:345:0094:0098:EN:PDF>

Example: the same requests addressed to 5 different DGs concerning “A list of all the new members added to expert groups that were referred to in the 28th February European Commission State of Play (‘Informal Dialogue on Expert Groups; Initiatives Taken by Commission Services’)” and “Any applicant who has applied to be a member of the Commission’s expert groups but been refused, including all documents which give the justification for said unsuccessful applicants not being granted membership to the applied-for expert group” (GESTDEM [REDACTED] and [REDACTED]).

The SG organised a meeting with the relevant DGs and the Legal Service. They collected the relevant documents from the different DGs and the LS gave its interpretation of the documents covered by the request so that the DGs could answer in a coherent manner.

3.2. Coordination of requests at SANTE level

When a request addresses different Units/Directorates in SANTE, SANTE/A4 takes the lead and will draft the reply after consulting all Units/Directorates involved. Depending on the issue at stake, the relevant Director may be asked to sign the reply.

For requests which involve different Directorates/Units about an issue where there is a lead Unit, then the request is assigned to the lead Unit who will then consult other Directorates and Units on the list of documents and the draft reply in order to agree on a common position.

Example: 35 requests for “documents which contain the following information pertaining to Consultation periods opened regarding Food Safety, specifically copies (not summaries) of the original consultations (also described as opinions or comments received) SANCO received regarding the following consultation topics (titles are listed)”: 35 different consultations listed on Europa and concerning 10 Units in 4 Directorates in SANCO (GESTDEM [REDACTED]). SANCO/A4 had to take the lead and drafted the replies in different batches. In this specific case, a meeting has been arranged with the SG in order to clarify the notion of “disproportionate amount of work”. (*See also Point 4.3.3.*)

3.2.1. Role of SANTE/A2

Unit A2 is involved in the process of the assessment and validation of negative and partial access replies, as well as providing legal advice on sensitive issues where necessary. In particular, Unit A2 plays an important role in checking the validity of the exceptions used by SANTE in case of a negative reply or a partial access (when SANTE refuses access to documents or parts of documents), which facilitates defence of the SANTE position in the case of a confirmatory application.

However, Unit A2 is not involved for which concerns negative/partial access replies

- where only personal data of individuals are redacted from the documents, i.e. the only applicable exception is Article 4.1 (b) of the Regulation
- or the only exception is the protection of commercial interests (Article 4.2.1st indent), i.e. the Unit has to follow the opinion of the third party consulted.

3.3. Implementation of the Regulation by the Agencies

Article 255 of the Treaty establishing the European Community, implemented through Regulation (EC) No 1049/2001 of 30 May 2001, grants a right of access to European Parliament, Council and Commission documents.

All SANTE Agencies have either a specific article on access to documents in their founding Regulation or specific provisions adopted after the entry into force of the Regulation. (*See the Reference articles hereafter*).

The Agencies should implement the Regulation in a similar way as the three main institutions and have also to take into consideration the rulings by the Court.

Best practice in the Commission is reciprocal information: the DGs should inform their Agencies when they receive requests for access to Agencies' documents held by the Commission, and the Agencies should inform the Commission when they receive requests for access to Commission documents that they hold. They also should inform each other on decisions to release or not such documents, and on the relevant exceptions to the right of access. While respecting agencies' independence, considering that both agencies and the Commission have to apply the same body of rules on access to documents, the adoption of a consistent approach by both is a good administrative practice that further facilitates the exercise of the right of access granted by these rules. There is still scope for improved cooperation in view of a coherent approach on the implementation of the principles involved in the access to documents (namely transparency versus the protection of third parties' legitimate interests, such as individuals' privacy and integrity, commercial interests and intellectual property rights).

EFSA: Article 41 – Access to documents in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&rid=1>

EMA: Article 73 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0726&rid=1>

ECDC: Article 20 – Transparency and protection of information in Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0851&rid=1>

CPVO: Article 33(a) of Council Regulation (EC) No 1650/2003 of 18 June 2003 amending Regulation (EC) No 2100/94 on Community plant variety rights.

<http://www.cpvo.europa.eu/main/en/home/documents-and-publications/access-to-documents>

CHAFEA: Decision of the Steering Committee of the Executive Agency for the Public Health Programme. Implementing rules for the application of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to documents (SC/2006/2/03 – PHEA(2006) D800064).

http://ec.europa.eu/chafea/documents/about/impl_rules_PHEA_public_access_to_documents_03_02_2006.pdf

4. STEP BY STEP PROCEDURES FOR THE PROCESSING OF THE REQUESTS

Step by step procedures together with **standard model letters** and **typical electronic workflows** are available on My SANTE at:

PROCEDURES & GUIDELINES – ACCESS TO DOCUMENTS

<https://myintracomm.ec.europa.eu/dg/sante/procedures-guidelines/Pages/documents-access.aspx>

4.1. Step 1 – Receipt and assignment

Requests for access to documents are received either directly by SANTE Units or through the SG application GESTDEM. This application automatically registers the requests sent through the electronic form available on Europa. For other requests received by mail or electronic mail at SG, SG.B.4 registers the requests. Then GESTDEM automatically sends an acknowledgement of receipt to the sender and forwards the request to the relevant DG.

When received directly by SANTE Units, the Units must contact SANTE/A4 who will then register the requests in GESTDEM. (Contact mailbox: SANTE ACCESS TO DOCUMENTS, virtual entity in ARES: ve_sante.accdoc). The Units should also send an acknowledgement of receipt to the applicant as soon as they get the GESTDEM registration number.

SANTE/A4 processes directly all requests for documents which have already been published or made public on Europa or through a previous request for access to documents. This represents 40% of the requests.

SANTE/A4 assigns the other requests in ARES including the deadline and a message on the rules of procedure.

Deadline: 15 working days from date of registration (3 weeks)

All Unit secretariats should use the deadlines reports in ARES on a daily basis. Tasks must **not** be closed before the appropriate action has been performed. Each Unit needs to be able to use the relevant ARES functionalities for their tasks and documents received.

See Annex 2 – “How to deal with your pending assignment tasks?” (for administrators), Annex 3 – “How to get informed about pending tasks of your unit?” (for assistants/secretaries), and Annex 4 – “How to deal with a deadline which has been modified/postponed?”.

Once the task is assigned in ARES to a given Unit and desk officer, the colleague in charge should make a rapid assessment of the request. SANTE/A4 should be contacted immediately in case of a problem either to meet the deadline or to identify the documents or as regards the scope of the request.

SANTE/A4 checks after 10 days if a response is being prepared and sends regular reminders to the Units and relevant colleagues in charge of the requests.

SANTE/A4 can provide full advice on the implementation of the Regulation and on the applicable procedure.

4.2. Step 2 – Scope of the request

There is no immediate relationship between registration of documents and their possible release. Usually the requestors do not make a difference between official (registered) documents and unofficial (working) documents. They are interested in “internal” documents as opposed to published ones.

Example: a request for “the list of meetings between the Commissioner and an organisation, minutes of meetings and all correspondence and documents relating to these meetings”. In this specific case where the request speaks of “documents relating to these meetings”, briefings to the Commissioner – if they exist – should normally be part of the list of relevant documents. However, depending on the content of the briefing, it will be released or not, or only partially, on the basis of the exceptions provided in Regulation (EC) No 1049/2001.

4.2.1. Request clarification

Where the “scope” of the request is unclear or very broad, the Unit is advised to contact in writing the applicant to **clarify the scope of the request** (Article 6.2 of the Regulation). The Unit can ask precisions on the topic of the request and/or a limitation of the time span. This can reduce the workload (from hundreds of documents in an initial request to very few documents at the end).

The time-limit to answer the request then runs from the date of the reply from the applicant.

New deadline: 15 working days from the reply by the applicant

Example: 4 vast requests by an organisation on 8/3/2011 on plant protection products and pesticide residues. A meeting of the relevant Unit with the applicant reduced the scope of the request and the applicant agreed on an extension of the deadline. The research of the applicant was on the impact of industry on policy as regards bees, comparing the EU with the US. (*See Annex 4.*)

If the applicant does not reply to the request for clarification within 3 weeks, then the request is closed as “devoid of purpose”.

4.3. Step 3 – Identification of documents relevant to the request

Searches for documents by Units can be facilitated by drawing up the list of relevant documents from the official register of documents (ARES), and then adding the other relevant internal documents to the list as appropriate.

As indicated by the Secretary-General in the note on “Document management and access to documents” (Ares(2015)182108), when processing a request for access, **documents are searched only in Ares or in another document management system.**

In case the request covers a wide range of documents and some (parts of) documents will not be disclosed, the SG has requested the DGs to provide the requestor with the list of documents relevant to that request. The list of documents is therefore part of the reply.

As the requestor has the right to challenge the decision taken by the DG and to send a confirmatory request to the SG, the SG then will have to re-assess whether or not the exceptions apply and on which documents.

For various reasons, the Unit or the desk officer may well foresee that the time-limit cannot be met. The desk officer should seek the advice of SANTE/A4 immediately and even call SANTE/A4 for a meeting.

4.3.1. *Holding letter*

In exceptional cases (for example in the event of an application relating to a very long document or to a very large number of documents), the Unit may send a holding letter which provides for an *extension of the time-limit* by another 15 working days. Detailed reasons must be given for use of this extension (Article 7.3 of the Regulation).

As DG SANTE receives more and more requests with a wide scope and which require the consultation of third parties, the deadline of 15 working days is often too short, thus the holding letter is used quite often.

New deadline: + 15 working days from end of first deadline (6 weeks)

4.3.2. *Fair solution with the requestor*

The Regulation provides for the possibility to agree on a *fair solution* with the applicant (Article 6.3 of the Regulation). The first step is to contact the applicant (this may be done informally by phone) and ask the applicant to reduce the timeframe or the subject matter covered by the request, explaining the detailed reason for a delayed reply (for instance the necessity to consult other Commission services or third parties authors, or the need to retrieve the files from the historical archives service).

It can take the form of an invitation to the applicant to split up the request (by explicitly withdrawing parts of it) or to agree on a calendar. Even if an agreement is reached on the phone, the extension of the time-limit must be confirmed in writing.

Example: 4 vast requests by an organisation on 8/3/2011 on plant protection products and pesticide residues. A meeting of the relevant Unit with the applicant reduced the scope of the request and the applicant agreed on an extension of the deadline. (See Annex 5.)

The recent case *Strack v Commission*, T-392/07⁴, revealed two new elements: First, the Commission cannot impose unilaterally on an applicant a “*fair solution*” according to Article 6, paragraph 3, of Regulation (EC) No 1049/2001 when confronted with an application related to a large number of documents; if such a solution has been refused by the applicant, the legal deadlines established by Regulation (EC) No 1049/2001 keep running, including those to file a case at the Court⁵.

⁴ Judgment of 15 January 2013, EUR-Lex Document CELEX62007TJ0392.

⁵ Points 45-52 of the judgment.

As a lesson of this ruling, it is recommended that the relevant Unit proposes each time a clear *calendar* for the treatment of the request, which becomes then binding for it, when agreed by the applicant.

New deadline: depends on fair agreement with the applicant

In case an agreement on a fair solution cannot be found after several attempts, the Commission is then bound to the usual deadlines.

Only if no fair solution can be reached can the judgment be applied, by refusing, in the final decision, those documents that cannot be handled within the 15+15 working days deadline. In this case the applicant will need to send a new request.

4.3.3. Disproportionate amount of work

If the application really does involve an unreasonable amount of work and no compromise can be reached, the Commission may, in the interest of sound administration, invoke the principle of proportionality to justify a refusal, provided that the amount of work involved in the concrete, individual examination of the documents covered by the request would be excessive in relation to the interest served by disclosure.

If only part of the document requested is covered by one or more of the exceptions provided for in the Regulation, the other parts of the document may be disclosed (Article 4.6 of the Regulation). Granting partial access will mean concealing or deleting the words, sentences or paragraphs to which an exception applies. If access can only be granted to an extract from a document, the applicant must be told what the total volume of the document requested is. The courts⁶ have accepted that, in the interests of sound administration, the Commission may invoke the principle of proportionality as regards the effort it has to make to afford partial access to a document. Thus, in exceptional cases, where the volume of the document or of the passages to be censored would entail a disproportionate amount of administrative work, the Commission may apply this principle to weigh up the interest served by public access to these fragmentary extracts against the workload involved in producing them.

Example: 35 requests for “documents which contain the following information pertaining to Consultation periods opened regarding Food Safety, specifically copies (not summaries) of the original consultations (also described as opinions or comments received) SANCO received regarding the following consultation topics (titles are listed)”: 35 different consultations listed on Europa and concerning 10 Units in 4 Directorates in SANCO (GESTDEM [REDACTED]). SANCO managed to reply in different batches but only to 23 requests. For the other 12 the relevant documents previously published on Europa had been removed and the searches in SANCO archives would have been a disproportional amount of work. (Final reply in Annex 6)

Repeated requests (more than once) from the same applicant for the same document will be met only once.

⁶ Case T-2/03, *Verein für Konsumenteninformation v Commission* [2005] ECR II-1121, paragraphs 101 and 102, and *Williams v Commission*, paragraph 85.

4.4. Step 4 – Assessment of the documents relevant to the request

The Regulation does not allow to exclude a specific category of documents from the scope of the request, and moreover requires a concrete examination of the documents one by one in order to assess whether or not the documents can be released or not and if not, which exception would apply.

The assessment is done by DG SANTE Unit in charge of the request for which concerns DG SANTE documents, but may involve the consultation of the authors of the documents when the documents originate from third parties and it is not clear whether or not an exception would apply.

4.4.1. Requests for Commissioner/Cabinet documents

The Commissioners and their Cabinets do not have correspondents for access to documents. The usual practice in the Commission is that the DGs deal with such requests and reply on behalf of their Commissioner.

The DG in charge of the request will contact the relevant Cabinet and ask them to provide the requested documents. As the DG will make the assessment of the disclosure of the documents, consultation of the Cabinet may be needed in order to agree on a common position as to the release or not of the relevant documents.

In DG SANTE, the Unit in charge contacts the Cabinet through the Assistants of the Director-General, requesting the contribution of the Cabinet for (1) identifying and providing the relevant document(s) and (2) giving a line to take for the possible release of the document(s) including details on the applicable exception(s), if relevant.

For which concerns former Commissioners, their files have been transferred to the historical archives, therefore it is necessary to ask them to make the search in the archives, and in case they find relevant documents, request the documents from the historical archives service, in agreement with the former Heads of Cabinet.

4.5. Step 5 – Consultation of the authors of the documents

The authors of the documents will be consulted in case of a doubt on the opportunity to release the requested documents, but not when it is clear that the documents are published or have already been made public. If the identified third party author (company for instance) does not exist anymore or could not be reached, DG SANTE will have to decide alone.

The authors of the documents must always be consulted in case the request concerns a confidential/sensitive document (*See Point 2.7.*).

The deadline for third parties to reply to a consultation is 5 working days. The initial application should not be attached, and personal data of the applicant cannot be disclosed.

4.5.1. *Other Commission services*

There is a constant practice to consult the other DGs/services on their objections to the release of requested documents, especially where an exception may apply (protection of the internal decision-making process, protection of legal advice, ...) and on sensitive issues.

If a request concerns documents from the Legal Service, then the initial request must be split and a new request must be created and assigned to the Legal Service for which concerns their own documents.

4.5.2. *Other institutions*

The Council, the European Parliament and the Commission agreed (through a “Memorandum of understanding” signed on 9 July 2002) to consult the originating institution automatically in the case of an application for access to a document that the institution in question had not yet made public. The originating institution must respond quickly, within a maximum of five working days. Clearly, the final decision must be taken by the institution to which the application was sent, the originating institution of the document only having a right of veto if the application relates to a “sensitive document” within the meaning of Article 9 of the Regulation.

Specific guidance for “Trilogue” documents has been provided by the SG (Note Ares(2015)282423 of 23/01/2015:

https://myintracomm.ec.europa.eu/sg/docinter/Documents/Guidance_note-Trilogues.pdf

4.5.3. *Member States*

Article 4.5 of the Regulation says that “A Member State may request the institution not to disclose a document originating from that Member State without its prior agreement”. However, this does not give the Member State a general and unconditional “right of veto”.

The note by the Secretariat-General and the Legal Service provides detailed information on the “right to object” conferred to Member States following the Judgment of the Court of Justice of 18.12.2007 in case C-64/05 P, *Sweden and IFAW v Commission*.⁷

It is mandatory to consult the Member State, unless the document is public. There are model letters for Member States’ consultations. The initial application should not be attached, and personal data of the applicant cannot be disclosed. The consultations are done through the Permanent Representations (the list of contact points in Permanent Representations is regularly updated by SG.B.4) in the language of the Member State concerned, and both the consultations and the replies must be duly registered.

⁷ https://myintracomm.ec.europa.eu/dg/sante/procedures-guidelines/Documents/doc-access_note_sg-sj.pdf

4.5.4. Third parties

Commission services must consult the third party author of a document, unless it is clear that the requested document can be disclosed or that an exception applies. Article 4.4 of the Regulation: *“As regards third-party documents, the institution shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed”*.

There are model letters for third parties' consultations. The initial application should not be attached, and personal data of the applicant cannot be disclosed. Both the consultation and the reply must be duly registered.

The third party author who is consulted is given a period of 5 working days for its reply, so that it allows the Commission to meet its own deadline for replying to the application. In the absence of any reply within the stated period, or if the author cannot be found or identified, the Commission will decide according to the system of exceptions provided for in the Regulation, taking account of the legitimate interests of the third party on the basis of the information at its disposal.

4.6. Step 6 – Reply to the applicant

The Unit will prepare the reply following the assessment of the documents. The reply may be positive, negative, partially negative or devoid of purpose.

Positive replies shall include the requested document(s) and are signed by the Head of Unit.

Negative or partially negative replies shall include the reference of the requested document or the list of relevant documents, the relevant exception in Article 4 of the Regulation, and the concrete explanation why the exception applies to the (parts of) document(s), and are signed by the Director-General.

Partially negative replies where **only personal data** are redacted from the document(s) may be signed by the Head of Unit (Note SG Ares(2014)3950212).

Negative or partially negative replies may be challenged by the applicant who has the right to send a confirmatory application to the Secretariat-General. Therefore, they should be signed by the Director-General.

Devoid of purpose replies (document not found, documents do not exist, etc.) may also be challenged by the applicant following a recent Court case (*Strack v Commission*, C-127/13 P⁸). Contrary to negative or partially negative replies, devoid of purpose replies can be signed by the Head of Unit.

Standard model letters and typical electronic workflows are available on IntraComm (SG Access to documents web page):

<https://myintracomm.ec.europa.eu/sg/docinter/Pages/tools.aspx>

and on My SANTE (Procedures & guidelines – Access to documents):

<https://myintracomm.ec.europa.eu/dg/sante/procedures-guidelines/Pages/documents-access.aspx>.

⁸ Judgment of 2 October 2014, EUR-Lex Document CELEX62013CJ0127.

The Secretariat-General has introduced this year the obligation to send all negative or partially negative replies and devoid of purpose replies by registered post with acknowledgement of receipt (Note SG Ares(2014)801872) and meeting Access to documents coordinators with SG on 17.03.2015).

4.6.1. Charges

No charge is made if the documents are consulted on the spot, if the number of copies requested is no more than 20 A4 pages, or if the document(s) can be accessed directly in electronic form or via the register.

A system of invoicing may be applied to applications relating to documents of over 20 pages. The rate charged is €0.10 per page plus postage, i.e. the normal cost of photocopying. The invoicing system is optional. You are advised to invoice costs only in the case of applications for voluminous documents or repetitive requests. Departments can therefore decide whether or not to invoice costs on a case by case basis.

The charges for information supplied on other media (computer data, audio tapes, etc.) will be decided by the DGs and Services case by case, subject to the principle that charges must be reasonable (Article 10 of the Regulation).

See Annex 7 – Procedure for payment through OP

5. EXCEPTIONS TO THE RIGHT OF ACCESS

The exceptions to the right of access are listed in Article 4 “Exceptions” of Regulation (EC) No 1049/2001. These exceptions are to be interpreted and applied as restrictively as possible. A specific exception relates to the protection of the environment (Aarhus Convention) and another one to confidential information.

5.1. Protection of the public interest – Article 4.1 (a)

This exception covers public security, defence and military matters, international relations, the financial, monetary or economic policy of the Community or a Member State. It can be invoked if it is *clear* that disclosure would *harm* the EU’s international relations with third countries and international organisations, complicate international negotiations, undermine its position in international negotiations, endanger international cooperation in matters like the fight on terrorism, etc.

Examples:

Documents containing information about plans to combat terrorism at Community or Member-State level.

Documents containing information about the positions the Commission intends to adopt at multilateral negotiations.

This exception has been used by DG SANTE for the protection of international relations in the context of EU- discussions on GMO’s and recently for the protection of international relations with (Example 1 of Annex 8).

In the case *in 't Veld v Commission*, T-301/10⁹, access to documents regarding the negotiations of the Anti-Counterfeiting Trade Agreement (ACTA) was refused on the basis of the exception for protection of the *public interests as regards international relations* in Article 4, paragraph 1 (a), third indent. The General Court confirmed that a “certain level of discretion to allow mutual trust between negotiators and the development of a free and effective discussion” was necessary in the framework of negotiations of an international agreement. The General Court also confirmed its previous jurisprudence that “initiating and conducting negotiations in order to conclude an international agreement fall, in principle, within the domain of the executive”¹⁰.

5.2. The protection of privacy and integrity of the individual – Article 4.1 (b)

This exception prevents the institutions to disclose the identity of third parties and of some staff, i.e. to disclose their personal data, in order to protect their privacy and integrity.

Examples:

Officials’ personal files, including their medical records

Consultants’ CVs

This exception to the right of access should be interpreted in accordance with Regulation (EC) No 45/2001 on the protection of personal data.¹¹
(Example 2 of Annex 8)

The Commission follows the doctrine that there is no general presumption that documents containing personal data are by definition exempted from disclosure. Rather, every document has to be analysed on its own merits and an overall assessment has to be made, taking into account:

- any prejudice to the (natural) persons exposed;
- the loyalty [“loyauté”] of processing the personal data; and
- the identity/function of the persons exposed and the implications of the file.

When it comes to the names of *Commission staff* in documents which are subject to an access to documents request, the SG has adopted specific guidance:

This approach consists of granting, in principle, **access to the names and functions of Commissioners and their cabinet members, and staff in senior management positions** (Secretary-General, Director-General, Directors, Members of Cabinet). This access is exceptionally extended to the names and functions of non-managerial staff if the need thereto has been clearly substantiated and there are no reasons to

⁹ Judgment of 19 March 2013, EUR-Lex Document CELEX62010TJ0301.

¹⁰ Points 119 and 120 of the judgment.

¹¹ Regulation (EC) No 45/2001 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, OJ L 8, 12.1.2001, p. 1-22. <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1439898222939&uri=CELEX:32001R0045>

assume that the legitimate rights of the individuals concerned might be prejudiced (as required by Article 8(b) of Regulation EC No 45/2001).

Both at the initial and at confirmatory stage, no access should, in principle, be granted to the names and functions of non-managerial staff, unless a clear **need** thereto is established and there are no reasons to assume that the **legitimate rights** of the individuals concerned might be prejudiced.

Reference: Note SG Ares(2015)1350426

These first two exceptions in Articles 4.1 (a) and 4.1 (b) apply directly without any other consideration, whilst the following exceptions apply unless there is an **overriding public interest** in disclosure of the documents. To apply these exceptions there is a need to balance the overriding public interest with the specific interest to be protected. In reference to the Aarhus Convention an overriding public interest in disclosure shall be deemed to exist where the information requested related to emissions into the environment.

5.3. The protection of commercial interests, including intellectual property – Article 4.2 1st indent

This exception applies to incoming documents or parts of these documents containing sensitive information whose release would harm the commercial interests of the sender, documents bearing a marking like “business confidential” and (parts of) documents subject to confidentiality clauses in the legal basis.

Examples in SANTE:

Some parts of applications from companies in the food additives area.

Some part of information on costs and tenders (including other commercial and industrial secrets) provided by tenderers in connection with an invitation to tender.

(Example 3 of Annex 8)

5.4. The protection of Court proceedings and legal advice – Article 4.2 2nd indent

As regards the types of documents covered by Court proceedings, the Court has adopted a *restrictive* interpretation. Only “documents drawn up by an institution solely for the purposes of specific court proceedings” will be covered. These include pleadings and other documents lodged, internal documents concerning the investigation of the case at hand, correspondence concerning the case between the Directorate-General involved and the Legal Service or a lawyers’ office. Documents drawn up in connection with a purely administrative matter are, however, not covered.

As regards legal advice, it covers legal advice given in the framework of legislative and administrative processes and aims at protecting legal advice to the *institution’s interest in receiving frank, objective and comprehensive legal advice*.

Examples:

Opinions given by the Legal Unit on a draft legislative proposal.

Defence pleas.

(Example 4 of Annex 8)

5.5. The protection of inspections, investigations and audits – Article 4.2 3rd indent

To rely on this exception, the institutions need to show, not only that the document concerns an inspection or investigation, but, more importantly, that its disclosure will *endanger the purpose and outcome* of the inspections, investigations or audit. In general, the exception can be invoked *as long as the investigations or inspections are on-going*.

Examples:

Audit report drawn up by a Commission department following an alleged fraud.

Documents drawn up by a department or received from a Member State as part of an on-going investigation into a possible failure to comply with Community law.

(Example 5 of Annex 8)

5.6. The protection of the institutions decision-making process – Article 4.3

This article is meant for the protection of the “space to think” in the context of the internal and inter-institutional decision-making process, i.e.:

- the protection of internal deliberations before (1st paragraph) the decision has taken place; and
- the protection of internal deliberations even after (2nd paragraph) the decision has taken place.

This provision explicitly requires there to be a *serious undermining* of the institution’s decision-making process. It is also subject to a balancing test requiring the protected interest to be weighed off against any potential *overriding public interest* in disclosure.

Documents refused on the ground of this exception include:

Before the decision (Article 4.3 1st paragraph):

Successive versions of a draft legislative proposal and the various contributions from third parties, before adoption of the instrument by the institution. Annual activity reports before the adoption of the summary report by the Commission.

(Example 6 of Annex 8)

After the decision (Article 4.3 2nd paragraph):

Special Commission Minutes (which contain the Members’ individual views expressed during the discussions).

Opinions given as part of inter-service consultations on sensitive topics.

Briefing notes for Members of the Commission.

Individual opinions of members of a selection board or assessors in a tendering procedure.

(Example 7 of Annex 8)

5.7. The protection of the environment – Exception in Article 6.2 of Regulation (EC) No 1367/2006 on the Aarhus Convention

This exception concerns the access to environment information where disclosure of the information would adversely affect the protection of the environment to which the information relates, such as the breeding sites of rare species.

5.8. Confidentiality clauses

Some specific legislative acts contain confidentiality clauses setting out the conditions in which certain documents or information may be disclosed. A detailed analysis of over 120 specific provisions in Community legislation in force shows that they tend to fall into two categories.

Some specific rules should be regarded as special cases falling within one of the general exceptions set out in Article 4 of Regulation (EC) No 1049/2001. An examination of these rules has not shown any incompatibility with the principles of the Regulation. The interests they protect correspond to those that constitute grounds for refusing access under the exceptions provided for by the Regulation. Accordingly, any refusal to grant access to a document must be justified on the basis of one of the exceptions provided for in Regulation (EC) No 1049/2001, the reference to the specific legal instrument serving merely to support the justification.

Other clauses grant interested parties specific rights of access going beyond the public right of access. The more favourable specific provisions which relate to transparency, and provide for greater access for certain categories of person in view of their status as “parties” to a procedure, should be considered to be “lex specialis” in relation to the Regulation. Under these rules, certain people will therefore be granted access to documents which would not be accessible to the public under the system of exceptions provided for by Article 4 of the Regulation.

Contact persons in SANTE/A4:	[REDACTED], tel. [REDACTED]
	[REDACTED], tel. [REDACTED]
Mailbox:	SANTE ACCESS TO DOCUMENTS
Contact persons in SANTE/A2	
for negative and partial access replies:	[REDACTED], tel. [REDACTED]
	[REDACTED], tel. [REDACTED]

ANNEX 1 – Basic principles of Regulation (EC) No 1049/2001

Regulation (EC) No 1049/2001	The public has the right to access all documents of the institutions, unless there is an exception (protection of private or public interests).	
Who gives access?	The Council, The European Parliament, the Commission and its agencies	
Who is the public ?	Any citizen and any natural or legal person in the world	
Which documents ?	All documents drawn up by an institution OR received by it and in its possession (documents from third parties or from Member States), which are not published (by EUR-OP for example) or which are not made available to the public (through Europa for example).	
Written requests	Regular mail or Fax or E-mail or Electronic form posted on Europa	Addressed to DG SANTE or directly to the competent Unit or via the Secretariat-General or via another Directorate-General

3 basic principles : <ul style="list-style-type: none"> Strict deadlines 	For holding reply and for reply	15 working days from the day after the date of registering of the request
	No reply within the deadline = refusal without a reason	
<ul style="list-style-type: none"> Reasoned refusal 	The decision to refuse to grant access to a document or to part(s) of a document MUST be given a REASON based on one of the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001.	
<ul style="list-style-type: none"> Means of redress 	In case of refusal OR partial access	Confirmatory application to the Secretary-General against the decision of the DG
	If refusal is confirmed	<ul style="list-style-type: none"> – Complaint to the Ombudsman (EU citizens only) – Court of First Instance Proceedings (Court of Justice)

ANNEX 2 – ARES tip on how to deal with pending assignment tasks

Dear Ares users,

We would like to inform you that there are a lot of attribution tasks with a passed deadline (especially CF/ASOC/INFO) and which are not closed although, in general, the necessary work has been done.

Why do we have this situation?

1. The work is not done, the deadline has passed and consequently the task is not closed

Please check your Ares profile regularly to see if you have received any tasks with or without an associated deadline (the “Notis” configuration may also facilitate your work). You should treat your task before its deadline or in a reasonable time if no deadline is specified.

Sometimes the deadline for a CF task can be modified. In order to modify it in Ares, and thus avoiding false reports concerning the deadline (obtained under “Deadlines” menu corresponding to secretaries and managers), please take into account the indications given in the document:

How to deal with a deadline which has been modified/postponed (*See Annex 3*)

2. The work is done, but the person who received the task has forgotten to close it

Please keep in mind that the tasks have to be closed manually after having done the necessary work (you do this by clicking on the “Finish” or “Finish with comments” buttons from the “Assignment” tab of your document). For example:

a) If you receive a CF or ASOC task for a document, you should create a draft reply and when it is registered (in other words, finalised) you should close your CF or ASOC task in Ares. This will ensure that your work has been completed. If you leave your task unclosed, the report with the deadlines/unclosed tasks will be affected, even if the work itself was done.

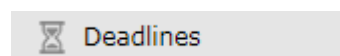
b) If you receive an INFO task for a document, you should read the document and then close your task (by clicking on “Finish” or “Finish with comments” buttons from the “Assignment” tab of your document).

c) If you receive a CLASS task, you should file the document into the corresponding folder and your task will be closed automatically by Ares.

Attention!!! CLASS is the only task closed automatically by Ares after doing the work indicated by the task code.

How to be informed about pending tasks of your Unit?

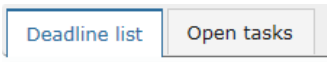
If you are secretary or manager, the option from your Ares vertical menu enables you to see what the pending tasks of your Unit are.



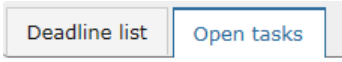
Important! As secretary, you need to check this option under the virtual entity profile (using “Change role”).

The report includes tasks received by all Unit members (i.e. desk officers, HoU/Director) and by Unit virtual entity (i.e. secretaries).

How does it work?

1. Clicking on Deadline List TAB  you can see open tasks received by your Unit, where a deadline is specified by the sender of the task.

By pointing to the cards from the report  , you can quickly see how much time is left until your deadlines expire.

2. Open tasks TAB  shows all non-closed tasks of your Unit, with and without a deadline. So, if you want to see the whole situation of your Unit tasks, here is where you need to check.

If you click on arrows from the top, you can sort the data. Both reports can be also exported as an Excel sheet.

When a task displayed in the reports is closed by its recipient, the task will disappear from the reports.

We recommend that a secretary from the virtual entity checks at least once a week the above reports and:

- reminds people concerned about non-closed tasks;
- deals with CLASS tasks.

ANNEX 4 – How to deal with a deadline which has been changed?

The following scenario (when deadline for assignment task has been modified/postponed) can be applied to CF and ASOC tasks.

Let's say that the secretary or CAD launches a CF task with a deadline of 15 days and thereafter the deadline is postponed by 5 days (initial deadline + 5 days). In order to apply this in Ares:

- the secretaries from the Unit (or CAD) assign another CF with the new deadline

(Important: in the comments field of the new task the secretaries (or CAD) should specify that the deadline was changed)

and

- the person who received the first CF task (the desk officer or the virtual entity) should close it with comments indicating that a new deadline was added.

ANNEX 5 – Request for clarification and extension of the deadline

Fair solution

Initial requests:

Correspondence [REDACTED] + reports meetings between [REDACTED] and Commission, Cabinet on plant protection products, pesticide residues (Gestdem [REDACTED])

Correspondence [REDACTED] + reports meetings [REDACTED] + Dir. Gen. DDG2 D, D1, E, E3, E7 on plant protection products + pesticide residues (Gestdem [REDACTED])

Correspondence + reports meetings [REDACTED] between [REDACTED], [REDACTED], [REDACTED] and Commissioner, Cabinet members (Gestdem [REDACTED])

Correspondence + report meetings [REDACTED] between [REDACTED], [REDACTED], [REDACTED] and Dir. Gen. D-D1-E-E3-E7 (Gestdem [REDACTED])

The Unit in charge of the request invited the requestor to a meeting on [REDACTED] in order to clarify the request and agree on an extension of the deadline.

Clarification of the requests:

You informed us that you have requested access to documents under GESTEM [REDACTED], [REDACTED], [REDACTED], [REDACTED] with an objective to analyse the impact of industry on policy as regards bees, comparing the EU with the US. Accordingly, you would like to receive all communication and meeting reports between DG SANCO, Commissioner and cabinet on the one side and [REDACTED], [REDACTED], [REDACTED] and [REDACTED] on the other side in relation to bees, which took place in context of negotiations on the new pesticide legislation and in relation to the Commission Communication on Honeybee Health [1] from 2009 until today. It was agreed that, at this stage, you are not requesting access to approval dossiers for plant protection products as such.

In order to make the documents available to you without unnecessary delay, DG SANCO agreed with your preference for treating the four GESTEM applications separately, first dealing with your two requests addressed to DG SANCO. In a second stage, we will deal with registered documents in possession of Cabinet Dalli and former Cabinet Vassiliou.

We clarified that the extension of the deadline for reply to [REDACTED] applies to all 4 access requests and is necessary in order to identify those documents which fall under the scope of your requests, to examine their content for information which may need to be protected, and to consult interested third parties.

[1] http://ec.europa.eu/food/animal/liveanimals/bees/docs/honeybee_health_communication_en.pdf

Ref. [REDACTED] – [REDACTED]

ANNEX 6 – Disproportionate amount of work

Initial request concerning 35 different consultations:

Dear Health and Consumers (SANCO),

Under the right of access to documents in the EU treaties, as developed in Regulation 1049/2001, I am requesting documents which contain the following information pertaining to Consultation periods opened regarding Food Safety. I am specifically requesting copies (not summaries) of the original consultations (also described as opinions or comments received) SANCO received regarding the following consultation topics (titles are listed):

1. Consultation on administrative burden, administrative costs and compliance costs related to current Animal Health legislation and the new possible elements of the Animal Health Law.

2. On line consultation on a staff working paper of the services of the Commission on antimicrobial resistance

3. On-line consultation on the protection of animals during transport

[.....]

35. Consultation on the Opinion of the Scientific Steering Committee on Oral exposure of Humans to the BSE agent: infective dose and species barrier.

The consultations listed above can be re-listed here:

http://ec.europa.eu/food/consultations/index_en.htm

Gestdem [redacted] to [redacted]

Final reply:

Concerning the remaining requests (GestDem No. [redacted] - [redacted] - [redacted] - [redacted] - [redacted] - [redacted] - [redacted] - [redacted] - [redacted] - [redacted] numbers 1, 2, 3, 5, 17, 22, 23, 25, 28, 29 and 30 in the attached table, I regret to inform you that my services are no longer able to retrieve the relevant documents.

The received opinions, if any, may not have been registered in our electronic repositories, while the persons involved are no longer in the Directorate-General. The retrieval in paper archives would mean days of searches for many different Units, without knowing exactly what result to expect. According to the ruling of the Court of First Instance in Verein für Konsumenteninformation v. Commission¹ (VKI) when a request relates to a very large number of documents and so imposes a volume of work which is likely to undermine the work of its services, the Commission retains the right to balance the interest in public access to documents with that of good administration.

In light of the circumstances set out above, I consider that the handling of those remaining requests would entail a disproportionate administrative burden for my services and, therefore, cannot be carried out.

Ref. [redacted] – [redacted]

ANNEX 7 – Charges

If the DG or Service intends to invoice costs, it must notify the applicant before sending the document.

If the requestor agrees to the charge, the department will send a second letter, using the model hereafter. This covering letter must always specify the number of pages, to enable EUR-OP to calculate the charge.

A copy of this letter must be sent immediately to EUR-OP to enable it to produce the invoice and follow up the payment. The copy should be sent to [REDACTED] (EUR-OP, Distribution Department).

If necessary a document should be attached to the copy intended for EUR-OP setting out the various details required for billing:

- DG, department, official responsible for the file, administrative address, telephone number;
- requester's name and address for invoice;
- description of the documents sent, exact number of pages, date of dispatch;
- cost of post and packaging;
- list of people who should be sent a copy of the confirmation of dispatch of the invoice.

SENDING A DOCUMENT OF MORE THAN 20 PAGES

for which the DG or department intends to make a charge

Dear Mr/Mrs/Ms,

Thank you for your letter/e-mail/fax of XXX, which we received on XXX, in which you apply for access to documents in accordance with Regulation (EC)

No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

I would draw your attention to the fact that you will be asked to pay €0.10 per page plus €.... postage for this ... page copy in order to cover the costs of reproduction.

Please would you confirm that you wish to proceed with your application, by letter or by fax (32/2/29), as soon as possible.

Yours sincerely,

IF THE REQUESTER REPLIES THAT HE WISHES TO PROCEED WITH HIS APPLICATION

Dear Mr/Mrs/Ms,

Thank you for your letter/e-mail/fax of, which we received on, in which you apply for access to documents in accordance with Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

Please find enclosed a copy of the document(s) which I hope you will find useful.

You will shortly be receiving an invoice, with an indication of the payment arrangements, for the delivery of this copy of ... pages. I would remind you that the document(s) may not be copied for commercial purposes without prior permission from the Commission.

Yours sincerely,

Copy: [REDACTED] (EUR-OP, Distribution Department)

Example 1

Exception “protection of international relations” – Article 4.1 (a) 3rd indent

“We refer to your letter to Commissioner Dalli of [REDACTED] in which you ask for a copy of the letter from [REDACTED] to the European Commission concerning the presence of non-authorised GMO in basmati rice. This is a follow-up request to your application registered as GestDem [REDACTED] under Regulation No 1049/2001¹² regarding public access to European Parliament, Council and Commission documents.

As indicated in our letter of [REDACTED] ([REDACTED]), the [REDACTED] sent an official letter to the European Commission on [REDACTED]. Given that the letter originates from a third party, we have consulted the [REDACTED] on your request in accordance with Article 4 (4) of Regulation 1049/2001/EC which states: *"As regards third-party documents, the institution shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed"*.

[REDACTED]

[REDACTED]

¹² OJ L145, 31.05.2001, page 43.

¹³ That provision reads: *"The institutions shall refuse access to a document where disclosure would undermine the protection of international relations"*.

Example 2

Exception “protection of privacy” – Article 4.1 (b)

Model letter for EU or EEA recipients¹⁴

“[Some of the documents] [The] document/documents to which you have requested access contains/contain personal data [, in particular: (*specify if necessary*)].

Pursuant to Article 4(1) (b) of Regulation (EC) No 1049/2001, access to a document has to be refused if its disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001 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 data¹⁵.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable¹⁶.

According to Article 8(b) of this Regulation, personal data shall only be transferred to recipients if they establish the necessity of having the data transferred to them and if there is no reason to assume that the legitimate rights of the persons concerned might be prejudiced.

We consider that, with the information available, the necessity of disclosing the aforementioned personal data to you has not been established and/or that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, we are disclosing the documents requested expunged from this personal data.

In case you would disagree with the assessment that the expunged data are personal data which can only be disclosed if such disclosure is legitimate under the rules of personal data protection, you are entitled, in accordance with Article 7(2) of Regulation 1049/2001, to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission
Secretary-General
Transparency unit SG-B-4
BERL 5/327
B-1049 Bruxelles

or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,”

¹⁴ Another model to be used when the recipients are from Third countries or International organisations is available. In case of doubt, please contact SANTE/A4.

¹⁵ OJ L 8 of 12.1.2001, p. 1

¹⁶ Judgment of the Court of Justice of the EU of 29 June 2010 in case 28/08 P, Commission/The Bavarian Lager Co. Ltd, ECR 2010 I-06055.

Example 3

Exception “protection of commercial interests” – Article 4.2 1st indent

“I understand your request to refer to all documents containing data on the approval of L-selenomethionine as a source of selenium in food supplements.

We believe that the following documents fall under the scope of your request:

1. Technical dossier for the use of L-selenomethionine in foods for particular nutritional uses (PARNUTS) and supplements. [REDACTED]. Submitted by [REDACTED] on behalf of the petitioner, [REDACTED], [REDACTED].
2. Technical dossier on L-selenomethionine for use in the manufacture of foods supplements. [REDACTED]. Submitted by [REDACTED], [REDACTED].
3. Technical dossier on L-selenomethionine for adding to Directive 2002/46/EC Annex II. December, [REDACTED], [REDACTED].
4. Technical dossier for safety evaluation of selenomethionine for use in the manufacture of foods supplements. [REDACTED]. Submitted by [REDACTED].
5. Technical dossier on selenomethionine. [REDACTED]. Submitted by [REDACTED].

You have been informed by letter on [REDACTED] and on [REDACTED] that the documents you have requested originate from third parties and, in accordance with Article 4(4) of Regulation (EC) No 1049/2001, it was necessary that these third parties were consulted before taking a decision on their disclosure.

Following consultation, we are happy to grant you full access to documents number 2 and 5 and partial access to document number 1. I must remind you that these documents cannot be reproduced or disseminated for commercial purposes unless the Commission or their author has first been consulted and has agreed to the publication.

The author of the dossier identified by number 1 agrees that the Commission discloses the dossier only after protecting information relating to its commercial interests and which includes a description of the composition of specific finished products, as well as their manufacturing process. Such information (included in Annexes 4, 5A, 5B and 6 of the dossier) is to be protected in accordance with Article 4(2) first indent of Regulation (EC) No 1049/2001¹⁷ by being blackened out.

In relation to the dossiers identified by number 3 and number 4, my services consulted [REDACTED] and [REDACTED] on your request. [REDACTED]

¹⁷ The institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property...unless there is an overriding public interest in disclosing.

[REDACTED]

Article 4(2) first indent of Regulation (EC) No 1049/20012 applies "*unless there is an overriding public interest in disclosing.*" [REDACTED]

[REDACTED]

[REDACTED] In these circumstances, I have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001. The public interest in this case is rather to protect the Commission's decision-making process.”

Example 4

Exception “protection of court proceedings and legal advice” – Article 4.2 2nd indent

“Thank you for your email dated [REDACTED] and registered [REDACTED] (No GESTDEM [REDACTED]) requesting access to documents under Regulation (EC) No 1049/2001, regarding public access to European Parliament, Council and Commission documents.

We understood your request as covering all communication between the Commission and the European Food Safety Authority (EFSA) and all internal Commission documents as of 1st May 2010 relating to the implementation of Regulation (EC) No 1924/2006 with regard to botanical substances.

[...]

A list of all relevant communication exchanged between the Commission and EFSA, as well as a list of internal registered communications of the Commission are enclosed.

[...]

The two internal registered documents entitled '*Regulation 1924/2006: Adoption of the permitted list - consideration of claims for botanical ingredients*' and '*Reply from the Legal Service to the consultation Ares (2010)798888 launched by DG SANCO*', also aim at exploring the possible options for the treatment of botanicals. They contain a legal analysis on such options.

Having carefully examined their content, we consider that they cannot be disclosed since they are covered by the exceptions provided for in Article 4(2) second indent and in Article 4(3) first paragraph of Regulation (EC) No 1049/2001.





Ref. [redacted] – [redacted]

Example 5

Exception “protection of investigations, inspections an audit” – Article 4.2 3rd indent

“In particular, you would like to have access to: correspondence between the Commission and public and/or private entities or associations on the subject of Spanish breeders of German shepherd dogs.

We understand your request refers to correspondence between the Commission and [REDACTED]. Please note that so far such correspondence includes Commission request for information of [REDACTED] on the manner in which [REDACTED] implements Directive 91/174/EEC *laying down zootechnical and pedigree requirements for the marketing of pure-bred animals* concerning recognition of animal pedigrees.

I regret to inform you that this document is exempted from access according to Article 4(2) third indent of the Regulation. This provision does not allow for disclosure of documents on a matter under examination by the Commission, unless there is an overriding public interest.



Partial access to the requested document in accordance with Article 4(6) of Regulation (EC) No 1049/2001 is not possible since the document in question is covered entirely by the exception in Article 4(2) third indent.

According to Article 4(2), access shall be granted if there is an overriding public interest in disclosure. In your application you did not submit any grounds concerning a public interest on the basis of which the interests protected in the Regulation (EC) No 1049/2001 would have to be overridden.”

Example 6

Exception “internal decision-making process before decision” – Article 4.3 1st par.

“Your application concerns the following document:

Draft Commission Implementing Regulation laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of frogs' legs, snails, gelatine, collagen, material for the production of collagen and gelatine and honey, royal jelly and other products of apiculture for human consumption and the health certificates requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC.

Having examined the document requested under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, I regret to inform you that your application cannot be granted, as disclosure is prevented by an exception to the right of access laid down in Article 4 of this Regulation.

Therefore the exception laid down in Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 applies to this document¹⁹.

We have considered whether partial access could be granted to the document requested. The document is entirely covered by the exceptions.

The exception laid down in Article 4(3) first subparagraph applies "*unless there is an overriding public interest.*"

In these circumstances, I have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001. The public interest in this case is rather to protect the Commission's decision-making process.”

¹⁸ For more information on SCFCAH meetings:

http://ec.europa.eu/dgs/health_consumer/dgs_consultations/regulatory_committees_en.htm

¹⁹ Article 4(3) first subparagraph reads as follows: "Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

Example 7

Exception “internal decision-making process after decision” – Article 4.3 2nd par.

[Reply to confirmatory application]

“I refer to your letter of [REDACTED], registered on [REDACTED], in which you lodge a confirmatory application, pursuant to Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents, for a review of a reply from the Directorate-General for Health and Consumers to your request for access to draft versions of the Impact Assessment Report regarding the possible revision of the Tobacco Products Directive 2001/37/EC.

I refer further to the Commission's letters of [REDACTED] and of [REDACTED], extending the time-limit for handling your above application. I apologise for the time it took us to reply, which was due to the need to carry out a full analysis of your request.

1. SCOPE OF YOUR REQUEST

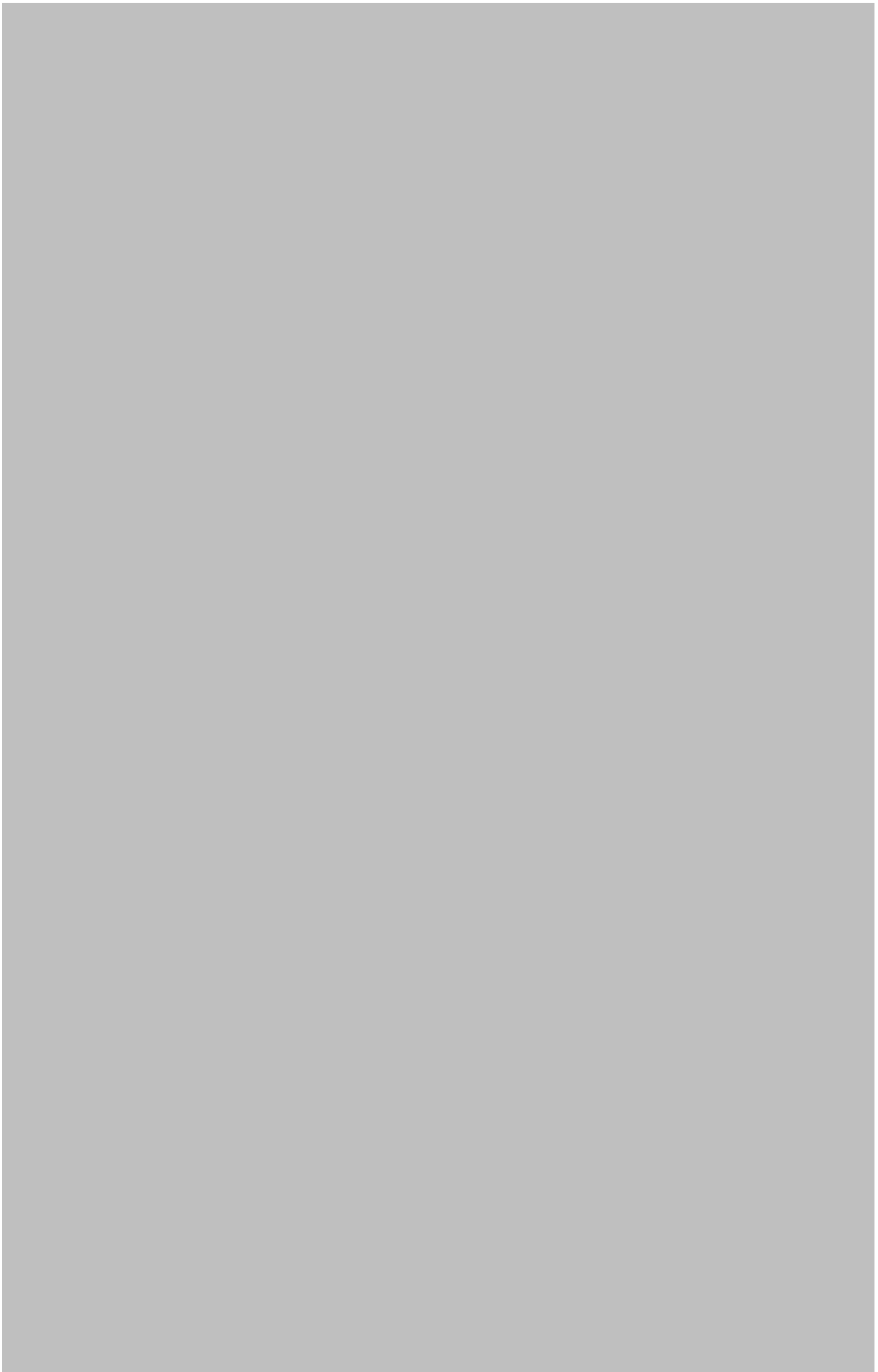
You request access to the following Commission documents:

- (i) The version of the Impact Assessment Report as submitted by the Commission to the Impact Assessment Board on 21 March 2012 ;
- (ii) The version of the Impact Assessment Report as submitted by the Commission to the Impact Assessment Board on 11 June 2012 ;
- (iii) Any marked-up versions of the Impact Assessment Report submitted by the Commission to the Impact Assessment Board on 21 March 2012, drafted by the Commission following submission of the version of the Impact Assessment Report to the Impact Assessment Board on 21 March 2012 and between submission of the version of the Impact Assessment Report to the Impact Assessment Board on 11 June 2012;
- (iv) Any marked-up versions of the Impact Assessment Report submitted by the Commission to the Impact Assessment Board on 11 June 2012, drafted by the Commission following submission of the version of the Impact Assessment Report to the Impact Assessment Board on 11 June 2012 and between the publication of the final Impact Assessment Report on 19 December 2012 (SWD(2012)425 final).

After having examined the scope of your request, we understand that points (iii) and (iv) of your request are limited to track-changed versions of the Impact Assessment Report. We have not been able to identify any track-changed versions of the Impact Assessment Report that would correspond to your original requests under (iii) and (iv) above and fall within the scope of Regulation 1049/2001. Therefore the only documents at our disposal are those mentioned under (i) and (ii) of your request, i.e. the versions submitted to the Impact Assessment board on 21 March and 11 June 2012. Your requests under (iii) and (iv) above are hence devoid of purpose.

2. ASSESSMENT OF YOUR REQUEST AND CONCLUSIONS UNDER REGULATION 1049/2001







3. MEANS OF REDRESS

Finally, I draw your attention to the means of redress available against this decision. You may, under the conditions of Article 263 TFEU, bring proceedings before the General Court or, under the conditions of Article 228 TFEU, file a complaint with the European Ombudsman.

Yours faithfully,”

Ref. [REDACTED] – [REDACTED]