

# **EFSA GUIDANCE DOCUMENT FOR APPLICANTS SUBMITTING APPLICATIONS FOR PUBLIC ACCESS TO DOCUMENTS (PAD)**

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## Introduction

Article 15(3) of the Treaty on the Functioning of the European Union (TFEU) and Article 42 of the Charter of Fundamental Rights enshrine the principle of transparency and the rights of individuals to access documents held by EU Institutions, Agencies and Bodies.

Transparency is a core value of EFSA. Public access to documents is key to the implementation of the transparency principle at EFSA. The legal and regulatory framework governing EFSA's public access to documents is as follows:

- [Regulation \(EC\) No 1049/2001](#) of the European Parliament and the Council regarding public access to European Parliament, Council and Commission documents (hereinafter referred to as "*the PAD Regulation*"). This Regulation provides for the general principles and conditions on such access and has been made applicable to documents held by EFSA by Article 41 of [Regulation \(EC\) No 178/2002](#) laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety, as amended by [Regulation \(EU\) 2019/1381](#) of the European Parliament and the Council on the transparency and sustainability of the EU risk assessment in the food chain;
- [Regulation \(EC\) No 1367/2006](#) of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (hereinafter referred to as "*the Aarhus Regulation*");
- [Regulation \(EU\) 2018/1725](#) of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing [Regulation \(EC\) No 45/2001](#) and [Decision No 1247/2002/EC](#) (hereinafter referred to as "*the EUDPR*");
- [Decision of the Management Board laying down practical arrangements for implementing Regulation \(EC\) No 1049/2001 and Articles 6 and 7 of Regulation \(EC\) No 1367/2006](#), i.e. EFSA's Practical arrangements on access to documents providing for information regarding the process for the handling of applications for access to documents held by EFSA (hereinafter referred to as "*EFSA's Practical Arrangements*"). It lays down detailed procedures highlighting the steps required at each stage for replying to applications for access to documents. The conditions for applying exceptions to disclosure are described as well as the manner in which all legal rights and obligations are reconciled throughout the entirety of the process;
- [Standard Operating Procedure SOP 036 A](#) Applications on public access to documents describing the process for coordinating and handling all applications for access to documents received by EFSA in accordance with [Regulation \(EC\) No 1049/2001](#) and processed in line with the relevant legislations including [Regulation \(EC\) No 1367/2006](#) (hereinafter referred to as "*SOP 36*").

- Other sectoral legislation pertaining to EFSA's areas of work (such as [Regulation \(EC\) No 1107/2009](#); [Regulation \(EC\) No 1829/2003](#), Regulation (EU) 2015/2283, etc.) shall be taken into account when processing PAD applications.

Article 10(2) of the Practical arrangements requires EFSA to draw up a practical guidance for applicants to inform the public of their rights under the PAD Regulation. The guidance shall be published on EFSA's website.

This document provides support to PAD applicants to ease their submission and understanding of the processing of their applications for public access to documents (hereinafter "*PAD applications*"). Therefore, it is not of binding nature and will be updated and reviewed by EFSA as needed with a view to constantly reflect evolving case law and best practices. It shall be read in conjunction and complements the abovementioned legal and regulatory documents and provides in an easy and plain language and in a Questions & Answers format a toolkit for PAD applicants to facilitate the submission of their applications and the understanding on EFSA's processing of PAD applications.

In particular, this Guidance clarifies the different steps of the processing cycle, the ways PAD applicants can interact with EFSA, and provides support regarding the tools and services in place at EFSA facilitating the processing of PAD applications, in particular the use of [Connect.EFSA](#).

This Guidance contains different set of frequently asked questions and answers. The **45** questions are divided into topics and sub-topics as per the PAD process workflow, also depicted below in figure 1:

- (1) Submitting a PAD application;
- (2) Processing the PAD application ;
- (3) Receiving EFSA's initial decision;
- (4) Possibility to challenge EFSA's initial decision.



Figure 1: PAD process workflow

Please find in the table below the four topics, relative sub-topics and overview of questions in each:

Overview of the Structure			
Topics			
Submitting a PAD application	Processing the PAD application	Receiving EFSA's decision	Possibility to challenge the initial decision
Contains all the Q&As related to the submission of a <b>PAD application</b> and the <b>types of documents</b> , which can be requested.	Contains all the Q&As related to <b>how EFSA processes PAD applications</b> , the <b>duration of the process</b> and information regarding the <b>exceptions to the right of access</b> .	Contains all the Q&As related to receiving the <b>final decision, the transmission of the disclosed documents and the use of documents being disclosed by EFSA</b> .	Contains all the Q&As related to the <b>challenging of EFSA's initial decision</b> and on how to submit a <b>confirmatory application</b> .

Overview of the Structure			
Topics			
Submitting a PAD application	Processing the PAD application	Receiving EFSA's decision	Possibility to challenge the initial decision
Sub-Topics			
<b>Application process</b> - 12 Q&As on how to submit a PAD application, who is entitled to submit a PAD application, and the status of the PAD application.	<b>Process of the PAD application</b> - 2 Q&As on how the PAD application is handled, who is responsible for processing PAD applications and what happens in case a PAD application is not sufficiently precise.	<b>Receiving EFSA's decision</b> - 4 Q&As on how EFSA's decision will be received, how the documents will be transmitted and information on the possible use of documents being disclosed.	<b>Confirmatory application</b> - 4 Q&As regarding the confirmatory applications.
<b>Types of documents</b> - 5 Q&As that explains the types of documents that can be requested, including when they originate from third parties or are not in EFSA's possession.	<b>Time duration</b> - 4 Q&As on the time-limit for replying to a PAD application and the possible extension of said time-limit.		
	<b>Exception to the right of access</b> - 14 Q&As on the exceptions to the right of access to EFSA's documents, what happens if those exceptions are applied and how to process PAD applications relating to documents		

Overview of the Structure			
Topics			
Submitting a PAD application	Processing the PAD application	Receiving EFSA's decision	Possibility to challenge the initial decision
	originating from third parties.		

# 1 Submitting a PAD application

## 1.1. Application Process

### 1.1.1. Who can request a document from EFSA?

In accordance with Article 2(1) of the PAD Regulation, any citizen of the European Union and any natural or legal persons residing or having its registered office in an EU Member State can submit a PAD application.

Furthermore, citizens of third countries who are not resident in a Member State and legal persons that do not have their registered office in one of the Member States can also submit a PAD application to EFSA. Subject to registration, the PAD application may be processed by EFSA in accordance with the same principles, conditions and limits.

### 1.1.2. How to submit a PAD application via Connect.EFSA

#### How to register in the Connect.EFSA system:

You can submit a PAD application via EFSA's Connect Platform, which is user friendly and available at the following link <https://connect.efsa.europa.eu/RM/s/>.

EFSA encourages PAD applicants to submit their PAD applications via Connect.EFSA, which enhances cooperation and allows you to check at any time the status of your PAD application and ensure a thorough monitoring of all the different steps, which have been performed in the context of the processing of your PAD application.

You can submit a PAD application via Connect.EFSA either as a:

- **Community user (authenticated):** These users are registered in the community and can login to access the Portal to follow the progress of ongoing PAD applications or submit new ones.

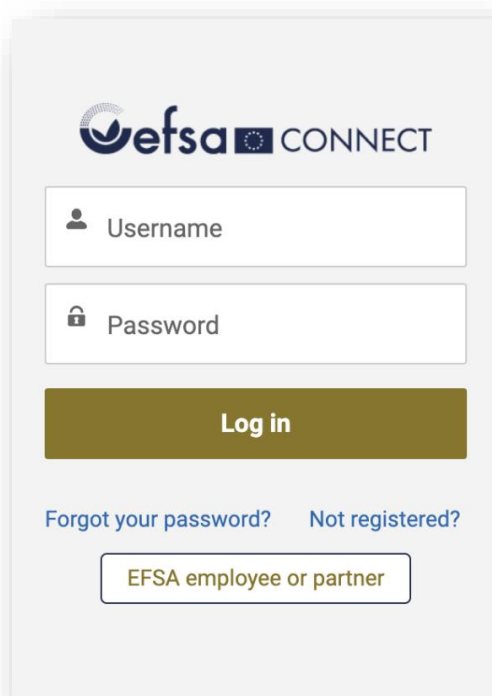


- **Community user (unauthenticated):** These users are not registered in the community. As a result they do not have an username and password and do not need to login to the portal.

Differently than authenticated users, unauthenticated users cannot keep track of their personal details and previous contact/requests, which they have submitted to EFSA.

#### **How to log in as an authenticated community user (authenticated):**

**Log in:** If you are already registered within the [Connect.EFSA system](#), please use your username and password to log in it. For those who are EFSA staff or partners, they can click on the button 'EFSA employee or partner' to directly login.

The image shows a login form for the 'efsa CONNECT' system. At the top is the logo with 'efsa' in a stylized font and 'CONNECT' next to it. Below the logo are two input fields: the first is labeled 'Username' with a person icon, and the second is labeled 'Password' with a lock icon. Below these fields is a large blue 'Log in' button. Underneath the button are two links: 'Forgot your password?' and 'Not registered?'. At the bottom is a button labeled 'EFSA employee or partner'.

#### **How to create an authenticated community user account:**

If you do not have EFSA credentials or are not yet registered on Connect.EFSA, you can register to the platform by clicking [here](#).

**Registration:** You have to complete all the mandatory (\*) fields on personal information and organization, and then click "Submit".

**efsa CONNECT**

By registering to Connect.EFSA you can:

- Ask questions on EFSA's work, on the application process for regulated products, and on career opportunities.
- Submit requests for public access to documents.
- Comment on consultations.
- Create and submit your study notifications to EFSA.
- Prepare and submit a list of intended studies supporting your application and receive renewal pre-submission advice.
- Create and submit your general pre-submission advice requests.

**Register below**  
Already registered? Login [here](#)

\* First name

\* Last name

\* Email

\* Affiliation

\* In what capacity are you registering?

**Next**

### How to submit a PAD application via EFSA Connect as an authenticated community user

Once you are logged in, you can submit a PAD application by selecting "Public access to documents":

Other sites EFSA Open EFSA EFSA Journal Connect

**Welcome to Connect EFSA**

Interact with EFSA in different ways: submit comments through public consultations, ask questions, and request access to documents. Sign up to access additional features and to perform pre-submission activities.

[Login/Register](#)

**Open public consultations**

Public Consultation Number	Title	Food Domain	End Date
PC 0304	Text 1906 single files		19/06/2024

[View All](#)

**Ask a question**

EFSA is at your disposal to answer questions about EFSA's generic mandates, applications for regulated products, public access to documents, career opportunities and much more.

[Ask a question](#)

For technical questions please contact EFSA's IT support at [servicedesk@efsa.europa.eu](mailto:servicedesk@efsa.europa.eu)

[Consultations](#)  
[Newsletters & email alerts](#)  
[Contacts](#)  
[Terms of use](#)

[Frequently asked questions](#)  
[Ask a question](#)  
[Public access to documents](#) (highlighted)  
[Complaints](#)

[EFSA website](#)  
[EFSA Journal](#)  
[Open EFSA](#)

[Pre-submission activities](#)  
[Emerging risk analysis platform](#)  
[Art.36 competent organisations](#)

To submit a new PAD application, you will have to complete the online form (please see a screenshot below): <https://connect.efsa.europa.eu/RM/s/help/padrequest>

**efsa** CONNECT Home Consultations Ask a question More

## Public access to documents

Your requests

Ask a question / Public access to documents

Submit applications for access to documents in EFSA's possession that are not publicly available. Requests will be handled in accordance with Regulation (EC) No 1049/2001.

\*Affiliation  
--None--

EU citizen or resident ☐

\*Country  
--None--

\*Topic  
--None--

Regulated product application/Output ref

\*Subject

\*Request

Upload File

Submit

For technical questions please contact EFSA's IT support at [servicedesk@efsa.europa.eu](mailto:servicedesk@efsa.europa.eu)

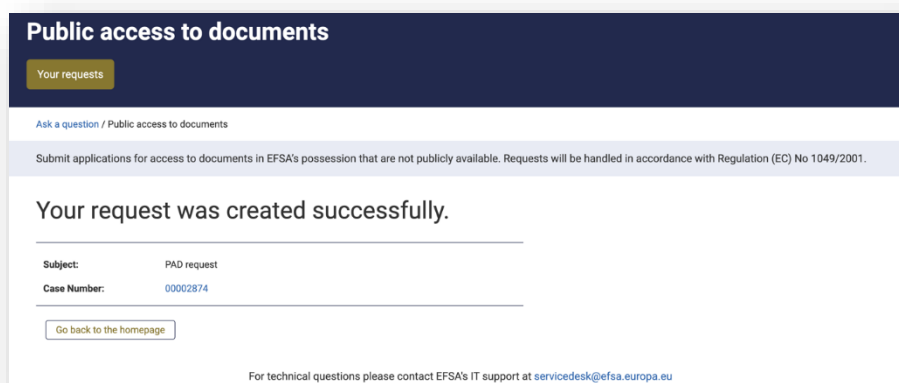
After inserting the mandatory (\*) information click on "Next".

You can also upload a document or a screenshot if needed to complement your PAD application (only if you are an authenticated user).

Please indicate if you are an EU citizen or resident by ticking the box when this is the case.

In order to proceed, you shall agree to the terms of the privacy statement by ticking the box "I have read and understood the privacy notice" and click "Next".

A pop up will appear confirming that the request has been submitted in Connect.EFSA with the subject indicated and a number generated by the tool.



### 1.1.3. How to submit a PAD application via the functional mailbox?

Although we encourage the submission of PAD applications via EFSA.Connect (see above 1.1.2), you can decide to submit a PAD application at any time by sending an email to the following functional mailbox: [EFSA.public.access.to.documents@efsa.europa.eu](mailto:EFSA.public.access.to.documents@efsa.europa.eu).

You can also send a letter(s) and any document(s) you might consider useful for the processing of your PAD application to EFSA by attaching it to your email.

Your e-mail address will be used for any further communication relating to the processing of your PAD application. At any time during the processing, you can also inform us of a different professional or private e-mail address for any further communications concerning your PAD application. This also applies when your PAD application is submitted via third-party internet platforms (see section 1.1.4 for further details).

In order to ensure a thorough monitoring of PAD applications being processed by EFSA, your PAD application will be included in Connect.EFSA. You may thus receive an e-mail of notification after we have included your application in this tool and future communications with you will be sent to your e-mail address via Connect.EFSA.

### 1.1.4. Does EFSA process PAD applications submitted via third-party internet platforms?

In case a PAD application is submitted via a third-party internet platform, EFSA will process this PAD application in accordance with the standards steps.

EFSA cannot be held liable for any errors of any kind occurring as a result of the use of such platforms, nor is EFSA responsible for the processing therein of personal data and any intellectual property rights relating to your PAD application.

#### **1.1.5. In what language may I submit a PAD application?**

You can submit a PAD application in any written form, including electronic form, in one of the 24 official languages of the European Union, as referred to in Article 55 of the Treaty on the European Union. EFSA will confer with you on whether you would agree that future communications relating to the processing of your PAD application are in English, in order to assure a faster response. Should that be the case, you may at any time ask for a translation of the respective communications in your language.

EFSA will disclose the documents in the language in which it holds them and is not obliged to translate the documents.

#### **1.1.6. How to formulate the content of a PAD application?**

PAD applications shall be made in a sufficiently precise manner to enable EFSA to identify the document(s) for which access is requested, in accordance with Article 6(1) of the PAD Regulation and process it in a timely manner. For instance, should you be interested in a particular subject matter of a scientific dossier, or in a specific document, or data relating to a specific year please be as precise as possible in your PAD application (e.g. by specifying if you are interested only in a specific section of a dossier (ecotoxicology, environmental fate, ...) and not in the whole dossier).

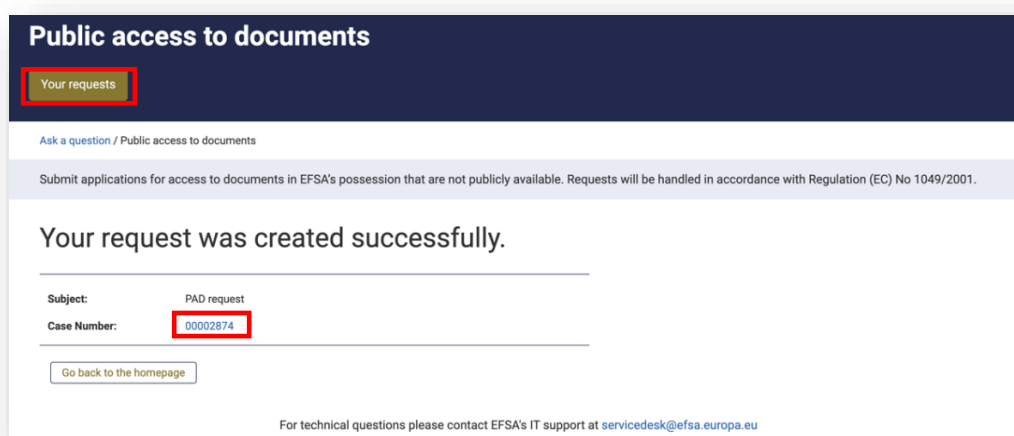
To support the PAD applicants to be clear in the documents they are interested to, it is advisable that the PAD application should, when applicable, contain as many references as possible to background documents in order for EFSA to clearly identify the requested document(s) such as:

- EFSA's scientific outputs
- EFSA's question numbers
- EFSA's publications on its website

PAD applicants are not obliged to state the reasons behind the submission of their PAD application.

#### **1.1.7. Do I receive an acknowledgment of receipt from EFSA when I make the PAD application?**

Upon submission of a PAD application via Connect.EFSA, you will receive an automatic acknowledgment of receipt indicating the deadline by when EFSA's reply will be communicated to you (15 working days from registration of the PAD application in accordance with Article 7(1) of the PAD Regulation). The reference number of your PAD application will also be communicated in the reply.



**Public access to documents**

**Your requests**

[Ask a question](#) / [Public access to documents](#)

Submit applications for access to documents in EFSA's possession that are not publicly available. Requests will be handled in accordance with Regulation (EC) No 1049/2001.

**Your request was created successfully.**

Subject: PAD request

Case Number: 00002874

[Go back to the homepage](#)

For technical questions please contact EFSA's IT support at [servicedesk@efsa.europa.eu](mailto:servicedesk@efsa.europa.eu)

In the same way, for PAD applications submitted via EFSA's functional mailbox, you will receive an acknowledgement of receipt by email as soon as the PAD application is registered by EFSA, indicating the next deadline of 15 working days as well as the reference number of your PAD application. EFSA swiftly registers and acknowledges PAD applications.

#### **1.1.8. Can I edit my PAD application after the submission?**

You can always specify or clarify your PAD application after its submission and at any time during the processing of your PAD application by EFSA.

If the PAD application is submitted via Connect.EFSA and you are an authenticated user, once the PAD application is submitted, there is a specific comment section that can be used to provide EFSA with any additional comment relating to the PAD application in order for you to clarify the scope of your PAD application.

Under Comment tab (1) the authenticated user can see the comments received by and submitted to EFSA.

Click on *"Add new comment"* to create a new comment (2).

**Request detail**

Submitted Clarification Needed In Progress Closed

Request PAD request [Printable View](#)

Status Submitted Final Feedback Deadline 04/07/2024

Detail **Comments & Files** History

Please use the text area below to leave a comment.

Also you can find:

- all the comments received and submitted in the "Request Comment" list below. Please, refresh the page after you submitted a comment to see it in the related list Request Comment.
- all the files submitted and exchanged with EFSA in the "Files" list below.

Write a new comment...

[Submit](#)

[Request Comments \(0\)](#) [New](#)

[Files \(0\)](#) [Upload Files](#)

**Process Guidance**

Your request has been successfully submitted to EFSA, and will be picked up and reviewed by the relevant parties as soon as possible.

You will be updated about the status of this request via email and via the **Request Comments** list on the right-hand side of this record. To communicate with EFSA, please write a new comment.

To write a comment use the text box showed below and click on "Submit" (3).

Alternatively, if you are an unauthenticated user or if you submitted the PAD application to the functional mailbox, you can send any comment you might have and at any time by e-mail, ensuring that the PAD reference number of your PAD application is in the subject line.

### 1.1.9. Can I view the status of my PAD application?

If the PAD application is submitted via Connect.EFSA as an authenticated user, you can view the tabs to check the status of the PAD application submitted. The different status of a PAD application are as follows: submitted, clarifications needed, in progress, closed.

**Request detail**

Submitted Clarification Needed In Progress Closed

Request  
PAD request

Status: Submitted Final Feedback Deadline: 04/07/2024

Detail Comments & Files History

Please use the text area below to leave a comment.

Also you can find:

- all the comments received and submitted in the "Request Comment" list below. Please, refresh the page after you submitted a comment to see it in the related list Request Comment.
- all the files submitted and exchanged with EFSA in the "Files" list below.

Write a new comment...

Submit

Request Comments (0) New

Files (0) Upload Files

Title	Owner	Last Modified	Size
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**Process Guidance**

Your request has been successfully submitted to EFSA, and will be picked up and reviewed by the relevant parties as soon as possible.

You will be updated about the status of this request via email and via the Request Comments list on the right-hand side of this record. To communicate with EFSA, please write a new comment.

If the PAD application is submitted via email to the functional mailbox, you can always ask questions or clarifications on the status of the processing of the PAD application by sending an e-mail to the functional mailbox. In any event, EFSA will update you on the status of your PAD application in all communications with you.

#### 1.1.10. If I submitted my PAD application via Connect.EFSA, do I receive any form of notification when the status of my PAD application is updated?

When the PAD application submitted by an authenticated User has been accepted, the "Submitted" and "Clarifications needed" tabs turn green and the "In progress" tab turns blue. This means that the scope of the PAD application is clear and the PAD application is being processed, without any further clarification needed.

**Request detail**

Submitted Clarification Needed In Progress Closed

Request  
Access to the whole Application dossier

Status: In Progress Priority: Medium Request Number: 00013044

Detail Comments & Files History

Request Information

Request Number: 00013044 Contact Name: Peggy Wood

Parent Request: EU citizen or resident: ☒

Request Details

Subject: Access to the whole Application dossier

**Process Guidance**



**Request detail**

Submitted → **Clarification Needed** → In Progress → Closed

**Request**  
Access to the Section III of the application for agar as feed additives

[Printable View](#)

Status: Clarification Needed | Priority: Medium | Request Number: 00013043

**Detail** | Comments & Files | History

Request Information

Request Number: 00013043 | Contact Name: [Peggy Wood](#)

Parent Request: ☐ EU citizen or resident: ☐

Request Details

Subject:

### 1.1.11. If I submitted my PAD application via the tool, can I see the history of all my PAD application requests?

If you are an authenticated user, in Connect.EFSA, after login-in (1), you can access all “My requests” (2), “My open requests” (3) and “My closed requests” (4).

You can also use the “search” button (5) to find a particular request.

**My requests**

[Ask a question](#)

Home / Ask a question / My requests

View your open and closed requests.

**3** [My open requests](#) **4** [My closed requests](#)

**My open requests**

Request Number	Subject	Area	Status
00002521	<a href="#">Subject 00527930</a>	General Question about EFSA	Submitted
00002743	<a href="#">test</a>	Question about Scientific Application Process	Submitted
00002874	<a href="#">PAD request</a>	Public Access to Documents	Submitted

[View All](#)

### 1.1.12. If I receive an e-mail from EFSA, how can I reply?

If you receive an e-mail from EFSA in relation to the processing of your PAD application, you will receive a notification from Connect.EFSA. The e-mail you will receive will originate from the following mailbox: "EFSA Public access to documents [pad.crm@efsa.europa.eu](mailto:pad.crm@efsa.europa.eu)".

If EFSA expects a reply from you, you will receive information on how to provide EFSA with a reply as follows:

For replying to this e-mail, please make sure you press "Reply" from your e-mail management tool (Outlook, Gmail, etc)

Please make sure you copy the EFSA mailbox [EFSA\\_public\\_access\\_to\\_documents@efsa.europa.eu](mailto:EFSA_public_access_to_documents@efsa.europa.eu) in all your communications with EFSA.



This e-mail and its attachments is intended for the recipient(s) named in the message. If you are not an intended recipient, please let the sender know immediately. Any disclosure or copying of the message content is unauthorised and may be unlawful if you are not the intended recipient.

Please make sure to select "Reply" or "Reply to all" from your e-mail management tool. In this way, the PAD Tool will track back your reply into the system.

Should you instead select "Forward" or type a "New e-mail", we will not be able to read your e-mail and your communication will be lost in the PAD Tool. In order to avoid losing your exchanges, you are kindly invited to always include in **copy (Cc) of your messages the main functional mailbox: [EFSA\\_public\\_access\\_to\\_documents@efsa.europa.eu](mailto:EFSA_public_access_to_documents@efsa.europa.eu)**.

## 1.2. Types of documents

### 1.2.1. What type of documents can be requested from EFSA?

In accordance with Article 2(3) of Regulation (EC) No 1049/2001 and settled case law, all existing documents held by EFSA, *i.e.* documents within EFSA's possession that it has produced or received, which relate to all areas of activity of EFSA and EFSA's policy on documents management, including e-mails, database, text messages and instant messages, can be subject to a PAD application.

As defined under Article 3(a) of the PAD Regulation, a "document" shall mean "any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording)" concerning a matter relating to EFSA's policies, activities and decisions falling within EFSA's sphere of responsibility.

### **1.2.2. What if the document to which access is requested does not exist or is not in EFSA's possession?**

When EFSA receives a PAD application, EFSA performs a thorough verification of the documents in EFSA's possession in accordance with EFSA's policy on documents management in order to identify which documents are falling within the scope of the PAD application. In case the requested documents do not exist, or should the documents not be in EFSA's possession, EFSA will inform the PAD applicant accordingly.

In this respect, according to settled case law, a presumption of veracity shall be applicable in situations whereby an EU institution, body, office or agency declares that it is not in possession of documents requested. By analogy, this presumption also applies to situations whereby an institution declares that the requested documents do not exist. You may challenge EFSA's reply by means of relevant and consistent evidence.

EFSA shall process PAD applications and disclose documents in their existing version and format. Therefore, EFSA is not required to create a document, which does not exist, as this falls outside the scope of PAD Regulation.

### **1.2.3. What if the query concerns access to information and not specific documents?**

If you are interested in receiving any information relating to EFSA's activities and not a specific document, you can submit a request for information at any time via Connect.EFSA, selecting "*Ask a Question*", filling in the form and choosing "*Question about Scientific Application Process*" or "*General question about EFSA*" in the area field.

Accordingly, should your request qualify as a request for information rather than a PAD application, your request will be forwarded and processed by the competent services at EFSA that will provide you with the reply.

### **1.2.4. What if the document requested is already publicly available?**

If upon verifications, EFSA identifies that the document requested is publicly available, EFSA will provide you in its reply letter with a link to the webpage where that document is located, e.g. the link to the relevant question number on OpenEFSA.

### **1.2.5. Can I request access to documents held by EFSA but originating from third parties or Member States?**

You can submit a PAD application relating to documents originating from third parties and from Member States, which are in EFSA's possession. In such a case, EFSA may engage with the third-party document owner concerned and/or the relevant Member State(s), in accordance with Article 4(4) and Article 4(5) of the PAD Regulation, as detailed in Section 2.3.13.

## 2 Processing the PAD application

### 2.1. Process of the PAD application

#### 2.1.1. How will my PAD application be processed?

PAD applications are processed in a centralised manner by the Legal Affairs Services Unit (LA) in cooperation with the concerned Unit(s) (*i.e.* EFSA's Unit(s) holding the document(s) in the scope of the PAD application, in charge of the process relating to the drawing up or receipt of document(s) in the scope of the PAD application). All written communications relating to PAD applications are centralised at the level of the Team in LA dealing with public access to documents.

Following the submission of a PAD application, EFSA identifies the documents falling within its scope and proceeds with its assessment on the accessibility of the requested documents (see section 2.3 for further details).

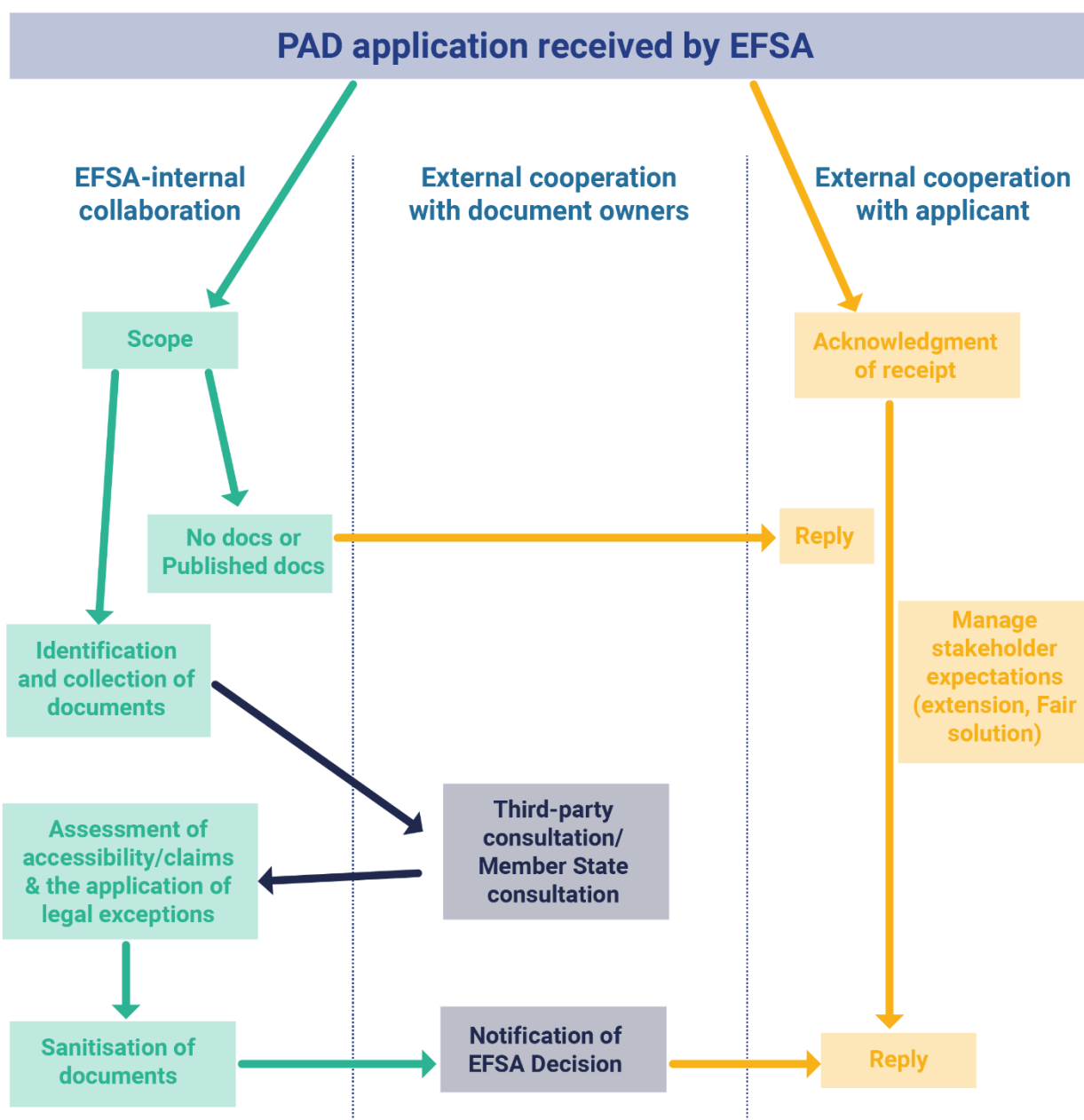
In accordance with settled case law EFSA shall perform a concrete and individual assessment of the information contained in the documents falling within the scope of your PAD application.

If the documents requested are not originating from EFSA and unless it's clear that the document(s) can or cannot be disclosed (see section 2.3.13), EFSA identifies the relevant document owners in order to consult them with a view to assessing whether any exception to disclosure applies to the document(s) requested (see section 2.3.13).

Upon conclusion of the consultation process, EFSA will take the final decision on the accessibility of the requested documents. The final decision will then be notified to each document owner.

EFSA will redact manually (see section 2.3.14) the requested documents as needed, in accordance with its decision (*i.e.* blackening the information for which EFSA concluded that an exception set out in Article 4 of the PAD Regulation applies and that should not be disclosed, if any). EFSA's decision and, if any, the requested masked documents will then be shared with the PAD applicant (see section 3).

The below flowchart outlines the main steps of the processing of a PAD application, further detailed in the below sections:



### 2.1.2. What if the PAD application is not sufficiently precise?

If the PAD application is not sufficiently precise, upon receipt of your PAD application, EFSA will swiftly contact you in order to assist you to define as accurately as possible the requested documents in line with the principles of sound administration, and in accordance with Article 6(2) of the PAD Regulation. EFSA may ask you to reply within a specific deadline indicated to you.

In particular, EFSA supports PAD applicants, *inter alia*, by referring to the publicly available information, by providing further details on the relevant subject matter and a list of any background

information which might help them in better clarifying the scope of their request. By means of example, if your PAD application refers to a general remit of EFSA's work, such as all documents relating to the novel food, feed additives, food contact materials, EFSA will contact you by providing you with information on its work on novel food, pointing out where to find published additional information allowing you to identify the documents of your priority interest.

If you do not provide the necessary clarifications allowing defining the scope of your request within the deadline indicated by EFSA, EFSA will reply as adequately as possible to your PAD application by taking into consideration the elements at its disposal.

Nevertheless, in case the elements at its disposal do not allow EFSA to adequately identify the relevant documents, EFSA may close your PAD application after having informed you accordingly. This is without prejudice to the possibility for you to submit a new PAD application at anytime.

If, following the request for clarification, you provide the requested clarifications, EFSA will process your PAD application accordingly.

## **2.2. Time Duration**

### **2.2.1. What is the time-limit for replying to a PAD application?**

A written reply shall be provided within 15 working days from registration of the PAD application. In exceptional circumstances, for example when an application relates to a very long document or a very large number of documents, the prescribed time limit may be extended by 15 working days. In case the extension is needed to process your PAD application, you will be informed of the extension of the time limit as well as of the reasons thereof.

### **2.2.2. What happens if EFSA does not reply to a PAD application within the prescribed time-limit?**

If EFSA does not reply to a PAD application within the prescribed period of 15 working days or within the extended period of 15 working days, this absence of reply is equivalent to a refusal to grant access to the requested documents and shall entitle the PAD applicant to submit a confirmatory application as detailed in section 4.1.

### **2.2.3. How does EFSA implement the fair solution of Article 6(3) of the PAD Regulation?**

In addition to the possibility to extend the deadline of 15 working days for replying to a PAD application as detailed in section 2.2.1, in the event of a PAD application relating to a very long document or to a very large number of documents or to a complex case entailing, for example, the consultation with multiple actors, that may not be addressed within the mandatory time limits foreseen in the PAD Regulation, EFSA will engage with you in order to reach an agreement

(hereinafter referred to as "*fair solution*") regarding the scope of your PAD application, in accordance with Article 6(3) of the PAD Regulation and as interpreted by the Union Courts.

In this respect, according to settled case law EFSA may seek to reach a fair solution with you with regards to the number and content of the documents applied for. Specifically, the fair solution proposal will be shared with you in writing, with a specific deadline for you to reply. In order to support reaching the fair solution, where appropriate, EFSA will prepare a list of documents which EFSA identified as falling within the scope of the application which will be shared with you in order to help you selecting the priority documents that you wish to receive first and within the mandatory time-limits. In this respect, EFSA is working to develop a tool that supports the automatization of the creation of such lists of documents, that are currently drafted mainly manually.

EFSA will further process your PAD application taking due account of your reply on the documents which you would like to receive in priority. Should you maintain an interest in receiving additional documents upon receipt of our reply as concerns the priority documents, your request(s) for accessing these additional documents will be processed by means of one or more new PAD application(s).

Should you not agree with the fair solution proposed, EFSA will consequently continue liaising with you in order to reach an agreement that would allow the processing of your PAD application within the mandatory time-limits. In the absence of any agreement, EFSA will make all efforts to provide you with a reply relating to as many documents as possible, on which EFSA will be in the position to finalise the assessment on their accessibility by the legal deadlines.

With a view to determining the documents that can be processed within the mandatory deadline, EFSA will take into account statistical data collected throughout the years, applying an estimating calculation of the number of documents that can be processed within the mandatory deadlines.

By means of an example, if the estimating calculation will provide EFSA the outcome that the full scope of your PAD application cannot be satisfied in 30 working days, but in 60 working days, EFSA will propose to you a fair solution as detailed above and therefore provide you a reply on part of the documents, which you identified as a priority within 30 working days, and a reply on the remaining documents under a new PAD application, should you maintain an interest in receiving them, after having received a reply as concerns the priority documents.

#### **2.2.4. What if the PAD application entails a disproportionate administrative burden for EFSA?**

According to EU case-law, EFSA can refuse processing a PAD application related to very large number of documents or to very long documents if the work needed to reply to the request would lead to a disproportionate administrative burden. By way of example, should you ask access to a number of documents in which the volume of documents for which access is applied or in which the number of passages to be redacted would involve an inappropriate administrative burden, EFSA will refuse access balancing the interest of the PAD applicant for access against the workload

resulting from the processing of the PAD application in order to safeguard the interests of good administration.

## **2.3. Exceptions to the right of public access to documents**

### **2.3.1. Are there any exceptions to the right of access to EFSA's documents?**

In accordance with Article 4 of the PAD Regulation, EFSA may refuse access (in part or in full) to a requested document if one or more of the below exceptions apply:

- Absolute exceptions of Article 4(1):

EFSA shall refuse access to a document where disclosure would undermine the protection of:

- the public interest as regards: public security; defence and military matters; international relations; the financial, monetary or economic policy of the Union or a Member State;
- the privacy and the integrity of the individual, in particular in accordance with Union legislation regarding the protection of personal data, in particular the General Data Protection Regulation (EU)2018/1725.

- Relative exceptions of Article 4(2) and (3):

EFSA shall refrain from disclosing a document where disclosure would undermine the protection of:

- the commercial interests of a natural or legal person, including intellectual property;
- court proceedings and legal advice;
- the purpose of inspections, investigations and audits,

unless there is an overriding public interest in disclosure.

Access to a document, drawn up by EFSA for internal use or received by EFSA, which relates to a matter where the decision has not been taken by EFSA, shall be refused if disclosure of the document would seriously undermine EFSA's decision-making process, unless there is an overriding public interest in disclosure.

Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within EFSA shall be refused even after the decision has been taken if disclosure of the document would seriously undermine EFSA's decision-making process, unless there is an overriding public interest in disclosure.



### **2.3.2. How does EFSA apply the exceptions to disclosure?**

EFSA assesses the accessibility of the documents requested and interprets the exceptions provided for in Article 4 of the PAD Regulation in light of the case law of the European Union Courts, on a case-by-case basis.

In this respect, it is settled case-law that the exceptions to disclosure must be interpreted and applied strictly given that they constitute an exception to the principle of the widest possible access to documents held by EU institutions, which is laid out in Article 1 of the PAD Regulation.

With respect to the applicability of relative exceptions it is also settled case-law that, if EFSA applies one of the exceptions provided for in Article 4 of Regulation No 1049/2001, it is for EFSA to weigh the particular interest to be protected by non-disclosure of the document concerned against, *inter alia*, the public interest in the document being made accessible having regard to the advantages stemming from increased openness, in that this enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system.

Furthermore, when assessing the applicability of the exceptions, EFSA takes into account the fact that the risk of the protected interest being specifically and actually undermined by the disclosure must be reasonably foreseeable and not purely hypothetical.

In accordance with Article 4(6) of the PAD Regulation, should only a part of the documents for which public access is requested fall into an exception to disclosure, the remaining parts shall be released.

Documents or parts of documents that are already in the public domain may not be claimed confidential.

### **2.3.3. What are the most applied exceptions at EFSA?**

The most frequent exceptions that EFSA encounters when processing PAD applications are related to privacy and integrity of the individual as well as, in light of the remit of EFSA's activities the commercial interests of a natural or legal person, including intellectual property.

Experience shows that there are instances where also the other exceptions are relevant in the context of PAD applications, such as the protection of court proceedings and the purpose of audits.

### **2.3.4. How does EFSA apply exception foreseen in 4(1)(a) of the PAD Regulation?**

The exceptions foreseen by Article 4(1)(a) of the PAD Regulation, related to the protection of the public interest as regards public security, defence and military matters, international relations and the financial, monetary or economic policy of the Community or a Member State, in light of the remit of EFSA's activities, are not often applicable to EFSA's documents.

Should any of the documents in the scope of a PAD application be partially or fully covered by the above exceptions, EFSA will apply them as interpreted by the case law.

### **2.3.5. How is the exception to disclosure relating to the protection of privacy and integrity of the individual assessed and applied by EFSA?**

Article 4(1)(b) of the PAD Regulation provides that EFSA shall refuse access to information where the disclosure would undermine the protection of the "*privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data*". The EU legislation of reference is Regulation (EU) 2018/1725 ('the EUDPR'), which according to settled case law is applicable in its entirety including:

- The definition of personal data - Article 3(1)
- The provision related to the transmission of personal data - Article 9(1)(b)

The scope of personal data is broad and must be interpreted in accordance with the EUDPR and settled case law.

Should you be seeking access to personal data, you must demonstrate the necessity to receive this data by means of expressed and legitimate justifications and convincing arguments. In the absence of such justification, personal data is protected in full. For instance, if you are asking for a document which is not in the public domain and which contains names, contact details and addresses of individuals, in the absence of any justifications, EFSA will mask this personal information. On the contrary, should it be concluded that you put forward expressed and legitimate justifications and convincing arguments supporting the transmission of personal data to you, EFSA will apply the further requirement provided in Article 9(1)(b) of the EUDPR and determine whether there is any reason to assume that a transmission of the personal data might prejudice the legitimate interests of the concerned person(s) and balance the different interests at stake.

A case-by-case assessment is required to establish whether or not certain information contained in a document subject to a PAD application qualifies as personal data and whether the requirements for the transmission of this personal data pursuant to the EUDPR are fulfilled for the PAD application in question.

### **2.3.6. How is the exception to disclosure relating to the protection of the commercial interests of a natural or legal person, including intellectual property, assessed and applied by EFSA?**

The exception of Article 4(2), first indent, of the PAD Regulation provides that EFSA 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 disclosure. This constitutes a relative exception that requires EFSA to balance the protection of commercial interests of the natural or legal person concerned against the overriding public interest served by the disclosure (see section 2.3.11 on the application of the Aarhus Regulation).

The documents to which access is requested must contain elements which disclosure risks undermining the commercial interests of the person concerned. That is generally the case when, according to the case law, the requested documents contain commercially sensitive information relating to, for example, economic and technical information contained in a tenderer's bid, as well

as the business strategies of the undertakings concerned, taking into account any relevant provision contained in the sectoral legislation, when applicable.

EFSA will concretely assess how access to the document specifically undermines the commercial interests of the natural and legal persons concerned, including intellectual property, and the risk of that interest being undermined must be reasonably foreseeable and not purely hypothetical.

Furthermore, should EFSA conclude that the commercial interests would be undermined by the disclosure of the documents, EFSA will refuse access, unless it ascertains that there is an overriding public interest justifying the disclosure.

### **2.3.7. How is the exception to disclosure relating to the protection of legal advice and court proceedings applied by EFSA?**

The exception of Article 4(2), second indent, of the PAD Regulation provides that EFSA shall refuse access to a document where disclosure would undermine the protection of court proceedings and legal advice, unless there is an overriding public interest in disclosure.

In order to determine whether the exception relating to the protection of legal advice applies, as clarified in settled case law, EFSA shall assess whether the requested document indeed relates to legal advice and whether disclosure of (the parts of) the document in question which have been identified as relating to legal advice would concretely and specifically undermine the protection which must be afforded to that advice. Furthermore, should EFSA conclude that disclosure of a document would undermine the protection of legal advice as defined above, it will ascertain whether there is an overriding public interest justifying disclosure.

As regards the exception relating to the protection of court proceedings, this exception ensures compliance with the principles of equality of arms and the sound administration of justice. In accordance with settled case law this exception relates primarily to “*documents drawn up solely for the purposes of specific court proceedings*”, which includes, *inter alia*, pleadings, or other documents lodged, internal documents concerning the investigation of the case before the court. Furthermore, this exception applies to all court proceedings, including those outside the EU and Member States.

### **2.3.8. How is the exception relating to the protection of the purpose of inspections, investigations and audits applied by EFSA?**

The exception of Article 4(2), third indent, of the PAD Regulation provides that EFSA shall refuse access to a document where disclosure would undermine the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure. This exception is applicable only to the extent that the disclosure of the requested documents risks undermining the completion of the inspection, investigation or audit in question, and the attainment of their goal, and provided there is no overriding public interest in disclosure. This exception applies not only to audits, inspections and investigations carried out by EU institutions, bodies or agencies, but also to those carried out at national level.

### **2.3.9. How is the exception relating to the protection of the decision-making process applied by EFSA?**

In accordance with Article 4(3), first paragraph, of the PAD Regulation *"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"*.

Furthermore, pursuant to Article 4(3), second paragraph, of the PAD Regulation *"access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure"*.

In accordance with settled case-law, EFSA may rely on the exception relating to the protection of its decision-making process and refuse the disclosure of documents only on the basis of tangible elements. In particular, disclosure may be refused when it would seriously undermine EFSA's decision-making process, i.e. where the disclosure of the document in question has a substantial impact on the decision-making process, and when such risk is not purely hypothetical, unless there is an overriding public interest in disclosure.

### **2.3.10. When does the public interest in disclosure prevail over the interests protected by means of the exceptions?**

The legislator foresees that each time a relative exception applies, EFSA shall assess whether an overriding public interest in accessing the requested document exists. If EFSA decides to apply one of the exceptions provided for in Article 4(2) and (3) of the PAD Regulation, it is for EFSA to weigh the particular interest to be protected through non-disclosure of the document concerned against the public interest served by the document being made accessible.

Should EFSA conclude that an overriding public interest to disclosure exists and should the document(s) requested originate from a third party, EFSA will ensure that disclosure will occur after the notification process has been concluded as detailed in section 2.3.13.

EFSA will carry out a case-by-case assessment taking into account elements related to the specific circumstances of the PAD application concerned (such as for instance health and environmental concerns, including in emergency situations).

### **2.3.11. How does EFSA process PAD applications related to environmental information?**

When a PAD application relates to environmental information, EFSA will apply the Aarhus Regulation in conjunction with the PAD Regulation.

Article 6(1) first sentence of the Aarhus Regulation establishes a legal presumption that an overriding public interest in disclosure shall be deemed to exist when the document requested qualifies as “*information which relates to emissions into the environment*”, prevailing over the interests protected by the exceptions of Article 4(2) first indent of the PAD Regulation (the protection of commercial interests including intellectual property) and third indent (the protection of the purpose of the inspections and audits with the exception of investigations).

The concept of “*information which relates to emissions into environment*” is defined by the case-law of the Court of Justice of the European Union.

EFSA implements the concept of “*information which relates to emissions into the environment*” as interpreted by Union Courts, taking into account the latest case law developments, that EFSA closely monitors.

Thus, in the event the documents requested contain information for which the protection of commercial interests of a natural or legal person, including intellectual property, or to the purpose of inspections and audits would apply, EFSA will not protect the concerned information if it is concluded that it qualifies as “*information which relates to emissions into the environment*”, and therefore that an overriding public interest in disclosure exists. In the event the document requested originates from a third party, EFSA will ensure that disclosure will occur after the notification process has been concluded as detailed in section 2.3.13.

As far as the other exceptions of Article 4 of the PAD Regulation are concerned, the legal presumption does not apply and the grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment.

### **2.3.12. What if only a part of the document requested is protected by one or more of the exceptions to disclosure?**

If only parts of the requested document are covered by any of the exceptions stemming from Article 4 of the PAD Regulation, the remaining parts of the document must be released. In such cases, EFSA will release a “redacted version” of the requested documents in which the confidential information has been blackened out. If EFSA considers that the entire document falls within one or more of the exceptions provided by Article 4, EFSA may refuse access to the document in full.

### **2.3.13. What happens when the requested document originates from a third party?**

The document held by EFSA to which you requested access may originate from a Member State or from a third party.

In accordance with Article 4(4) of the PAD Regulation and Article 7 of the Practical Arrangements, EFSA shall consult the Member-State or third-party concerned on the accessibility of the requested document, unless it is clear that the document shall or shall not be disclosed. In particular, upon preliminary assessment, EFSA will consult each document owner to ascertain whether one or more of the exceptions to disclosure set out in Article 4(1) or (2) of the PAD Regulation may apply. The

document owners by a given deadline are requested to give a verifiable and detailed indication and justification of any part of each of the concerned documents which should not be released, justifying the protection in accordance with one of the exceptions of Article 4 of the PAD Regulation.

Once the feedback from the document owners in response to EFSA's consultation has been received, and in case the document owners claim partial or full protection of the documents requested, EFSA will verify the compliance of the claims for protection with the PAD Regulation and applicable law and take its final decision on the accessibility, unless further clarifications are required. The final decision will be notified to the document owner(s), providing the remedies to object against this decision, notably the possibility to bring an action for annulment before the Court of Justice of the European Union in accordance with Article 263 of the Treaty on the Functioning of the European Union (TFEU) or to file a complaint before the European Ombudsman, subject to the limitations of Article 228 of the TFEU, with regard to instances of maladministration.

The third party or Member State concerned can request your identity and/or affiliation as PAD applicant (i.e. the name of the organization to which you belong to/works for). In such case, while your identity will not be disclosed, in accordance with the EUDPR, EFSA will liaise with you in relation to the possible disclosure of your affiliation.

If the requested document originates from a Member State, EFSA is required to consult the Member State concerned in accordance with Article 4(4) and 4(5) of the PAD Regulation. In accordance with Article 4(5), a Member State may request EFSA not to disclose a document originating from that Member State without its prior agreement. Notwithstanding the fact that Member States do not have a discretionary right of veto on the disclosure of documents originating from them, the prior agreement of the Member State referred to in Article 4(5) is to be interpreted as a form of assent confirming that none of the grounds of exception under Article 4(1) to (3) of the PAD Regulation apply.

If it is clear that the document shall be disclosed (in part or in full), the document owner will be notified in advance of EFSA's decision including on the remedies available to object against the disclosure in case of different interpretation on the accessibility of the documents concerned.

On the contrary, if it is clear that the document enjoys full protection, EFSA will not interact with the document owner and protect the document, replying to your initial PAD application accordingly.

#### **2.3.14. How are the documents blackened by EFSA?**

Following the assessment on the accessibility of the requested documents, if EFSA concludes that the concerned documents shall be partially released, it will proceed with a manual masking (i.e. blackening in a permanent manner the concerned information covered by an exception) or removing the elements of information included therein falling within one or more of the exceptions to disclosure.

In view of the principle of concrete and individual examination of the documents, this step is a particularly resource intensive and time consuming exercise. In particular, and in order to ensure



that the information to be protected is properly masked, EFSA applies a “four-eyes-check” principle, which implies that the documents are masked and then checked by two different staff members.

Taking into account that the disclosed documents are redacted manually, and in particular as regards the redactions of personal data, EFSA cannot fully exclude the possibility that few personal data are inadvertently disclosed to you. Should this be the case, we urge you to treat any such residual personal data with the utmost discretion in order to avoid undermining the privacy and integrity of the individual(s) concerned. We shall remind you about your responsibilities under the EUDPR in case of any further processing by you of any personal data inadvertently disclosed to you.

### **3 Receiving EFSA’s decision**

#### **3.1. How will I receive EFSA’s initial decision?**

The reply to an initial PAD application will be submitted in writing, by means of a referenced letter. EFSA’s initial decision will be sent electronically, on behalf of the Team Leader of the Independence and Access Team, to the email address you used to submit your PAD application. If the PAD application has been submitted via Connect.EFSA, you will receive a notification via email with a link to EFSA’s initial decision.

#### **3.2. How will the document be transmitted by EFSA?**

The documents to which access is granted will be released electronically by EFSA. The documents will be made available to you in the form of an electronic copy in their existing format.

In general, documents are transmitted by electronic means, via Connect.EFSA or via e-mail. In particular, the documents will be transmitted via Microsoft OneDrive. In this case, the invitation to the shared folder will follow by means of a separate e-mail providing you with a link to the folder containing the documents. When you open the link to that folder, you will receive an e-mail with a Verification Code in order to access the shared content. Please note that the e-mail with the Verification Code may be received in your Spam folder. EFSA staff will contact you for further guidance in case the documents requested will be transmitted via Microsoft OneDrive. Please find [here](#) some practical explanations on how to access shared folders via Microsoft OneDrive.

You may be given the option to consult the requested documents at EFSA’s premises in accordance with Article 10(2) of the PAD Regulation, including in exceptional cases where the electronic transmission of the requested documents is not possible because the documents are only available in a certain format making the extraction of the documents technically impossible.

### 3.3. Can I reproduce or reuse the documents released by EFSA?

Documents are released to you in response to your PAD application. In line with Article 16 of the PAD Regulation all persons intending to reproduce, redistribute, exploit or to make commercial use of the information released are expected to adhere to the terms and conditions asserted by the copyright holder(s).

If upon receipt of the documents disclosed to you by means of EFSA's decision you would like to use (*inter alia* reproduce, publish, redistribute, exploit, make commercial use) the disclosed documents for purposes other than mere access pursuant to the PAD Regulation, you need to first verify whether the documents are protected by copyright and/or regulatory data protection provisions and contact any respective copyright and/or data holders.

EFSA shall assume no liability for any unlawful or unauthorized use or reproduction of the documents.

### 3.4. What if my PAD application is totally or partially rejected by EFSA?

In the event that EFSA totally or partially refuses access to the requested documents, you are entitled to submit a confirmatory application in accordance with Article 7(2) of the PAD Regulation, as detailed in section 4, within 15 working days upon receipt of EFSA's decision, asking EFSA to reconsider its position.

The submission of a confirmatory application is the only available legal remedy against EFSA's decision concerning the initial application.

Failure by EFSA to reply within the indicated deadline shall also be considered as a negative reply and can be challenged by submitting a confirmatory application.

Confirmatory applications must be sent:

- For registered users, by clicking "confirmatory application" once the initial PAD application is closed in Connect.EFSA,
- For non-registered users, by introducing a new application in Connect.EFSA Portal mentioning the reference number of your initial application in relation to which you would like an administrative review of the initial decision, or
- Via e-mail to  
EFSA  
Dirk Detken, Head of Unit - Legal Affairs Services  
Via Carlo Magno 1/A  
IT – 43126 Parma  
Italy  
e-mail: [Dirk.DETKEN@efsa.europa.eu](mailto:Dirk.DETKEN@efsa.europa.eu)



Following the submission of a confirmatory application, EFSA will carry out an independent review of its initial decision by way of a specific and individual re-examination of the accessibility of the requested documents and provide its reply by means of a confirmatory decision.

## **4 Confirmatory application**

### **4.1. Who is responsible for handling confirmatory applications?**

Confirmatory applications lodged by PAD applicants in case of disagreement with EFSA's initial decision are handled by the Head of Unit of the Legal Affairs Services of EFSA.

### **4.2. What is the time-limit for replying to a confirmatory application?**

Confirmatory applications must be handled within 15 working days from their registration. If the confirmatory application is not sufficiently precise, EFSA will contact you in order to assist you to define as accurately as possible the scope of your request. EFSA may ask you to reply within a specific deadline indicated to you.

### **4.3. Can this time-limit be extended?**

In exceptional circumstances, for example when a PAD application relates to a very long document or a very large number of documents, the prescribed time limit may be extended by 15 working days. You will be then informed of the extension of the time limit and of the supporting reasons.

Furthermore, in the event of an application relating to a very long document or to a very large number of documents or to a complex case entailing, for example, the consultation with multiple actors, that may not be addressed within the mandatory time limits foreseen in the PAD Regulation, EFSA will seek to reach a fair solution with you as detailed in section 2.2.3.

### **4.4. How can I challenge EFSA's total or partial refusal in reply to my confirmatory application?**

In its confirmatory decision EFSA will outline the legal remedies available to you to challenge EFSA's confirmatory decision. In particular, you have the right to bring an action for annulment before the Court of Justice of the European Union in accordance with Article 263 of the TFEU or to file a complaint before the European Ombudsman, subject to the limitations of Article 228 of the TFEU, with regard to instances of maladministration in the processing of the confirmatory application.

The absence of a confirmatory decision from EFSA within the indicated deadline shall be considered a negative reply and entitles you to initiate court proceedings against EFSA and/or make a complaint to the European Ombudsman as detailed above.