



User guide on Portalino

Last update: 14 October 2024

NOTE FOR THE USERS

This user guide has been updated on 14 October 2024 to further clarify the information regarding food-chain dossiers, datasets and requests of confidentiality in scope of Portalino.

The following submission type has been updated:

- Mandates for EFSA's scientific opinions or scientific and technical assistance according to Articles 29 or 31 of Regulation (EC) No 178/2002.

The following submission type has been added to the list:

- Information submitted in support of the review of the approval of pesticides active substances (Article 21 of Regulation (EC) No 1107/2009).



SCOPE AND INDEX

This user guide offers further details and information about the submission of food-chain dossiers and datasets, including the corresponding confidentiality requests via Portalino. As such it should be read together with [EFSA's User Guide on Confidentiality](#) and with any [administrative and scientific guidance documents](#) relevant for the submission.

INDEX

- [1. About Portalino](#)
- [2. Food-chain dossiers, datasets and requests of confidentiality in scope of Portalino](#)
- [3. How to register into Portalino](#)
- [4. How to access Portalino](#)
- [5. Need to know before data submission in Portalino](#)
- [6. How to submit data in Portalino](#)
 - [6.1. How to submit data without confidentiality request\(s\)](#)
- [7. Confirmation of the submission](#)
- [8. Re-submission after a request for missing information \(RFI\)](#)
- [9. Confirmation of the re-submission](#)
- [10. Update submission owner\(s\) and contact\(s\)](#)
- [11. Withdraw the submission](#)
- [12. Notification of studies and pre-submission activities](#)
- [13. Data Collection Framework \(DCF\)](#)



1. ABOUT PORTALINO

Portalino is the e-submission system for the submission to EFSA of food-chain dossiers, documents and datasets, including the corresponding confidentiality requests, for specific cases not covered by the E-submission food chain platform (ESFC) and IUCLID workflows.

Actors of the process

Applicants (or consultants acting on their behalf) or contributors, i.e., legal or natural persons (i.e. organisations and private citizens, respectively) who can use Portalino to submit applications, datasets and documents. This definition does not include “laboratories and testing facilities” as they are defined in EFSA’s Practical Arrangements on pre-submission phase and public consultations.



2. FOOD-CHAIN DOSSIERS, DATASETS AND REQUESTS OF CONFIDENTIALITY IN SCOPE OF PORTALINO

Updated!

- Dossiers for the evaluation of extraction solvents, animal by-products, stunning methods, high risk plants (high risk plants dossiers and plants derogations)
- In the area of GMO: Complementary information for inconclusive EFSA opinions*
- Information, datasets and documents related to:
 - Feed detoxification for chemical contaminants
 - Substances prohibited, restricted or under Community Scrutiny for Article 8(2) of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of other substances to foods
 - Calls for data
 - Contaminants data in the context of Data Collection Framework (DCF)
 - Mandates for EFSA's scientific opinions or scientific and technical assistance according to Articles 29 or 31 of Regulation (EC) No 178/2002
- Information submitted in support of the review by EFSA of an existing opinion or authorisation on a food contact material (Article 12(3) of Regulation (EC) No 1935/2004)
- For pesticide applications for which Transparency Regulation applies confidentiality requests pertaining to assessment reports (DAR/RAR) and the Renewal conclusion
- Information submitted in support of the review of the approval of pesticides active substances (Article 21 of Regulation (EC) No 1107/2009)

* Complementary information following inconclusive EFSA's opinions in the area of feed additives must be submitted through the [e-submission food chain platform \(ESFC\)](#).



3. HOW TO REGISTER INTO PORTALINO

Updated!

The access to Portalino can be requested **on behalf of your organisation** or **as private citizen** by contacting the the EFSA Service desk servicedesk@efsa.europa.eu and providing the following details:

- **Scope of the submission**
- **Personal details of the user requesting the access:**
 - First name and Last name, your Corporate email (should be provided if contributing on behalf of your organisation), your Private email (should be provided in case you are contributing on your personal capacity, as private citizen).
- **Organisation details, in case of access requested on behalf of an organisation:**
 - Organisation name, Organisation English name, Organisation Email

Important: the domain of the Corporate email address should be linked to your organisation, e.g. john.smith@orgname.com

- Phone number, Billing address (street, city, zip/postal code), Billing Country

Important: please check if your organisation is already registered on Connect.EFSA, and if yes specify this in the communication to EFSA Service desk. **If your organisation is not yet registered on Connect.EFSA, you are required to register and create an account.**



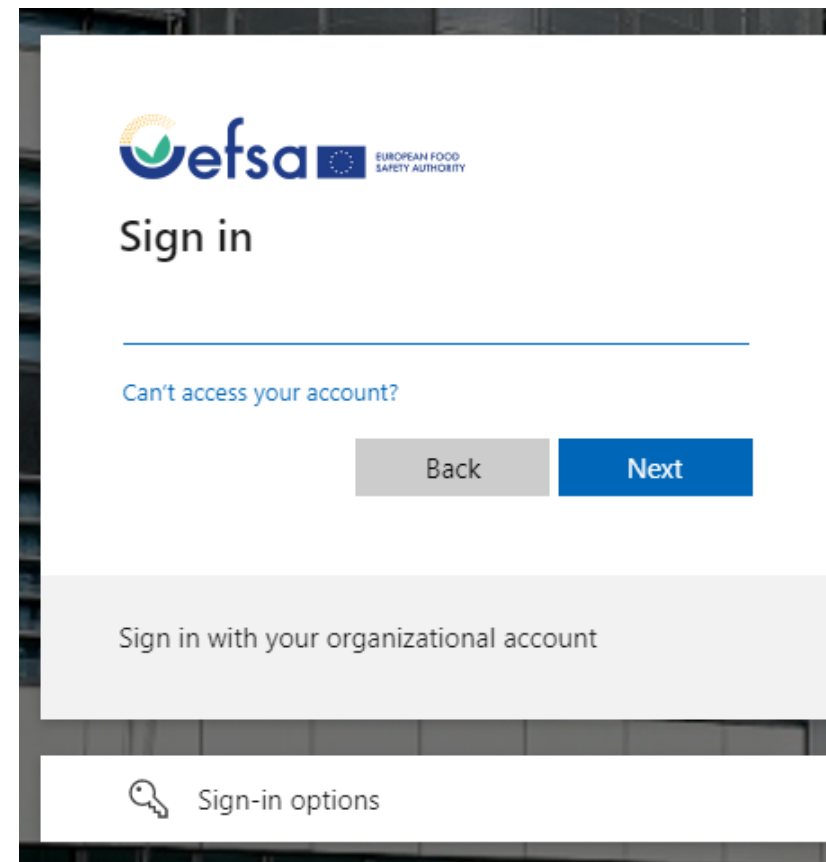
4. HOW TO ACCESS PORTALINO

Once the registration request has been sent, EFSA validates the request and provides the credentials.

Important (for organisations only): the credentials received are valid to access both Portalino and Connect.EFSA.

With the credentials, organisations and private citizens can access the Portalino at the following address:

<https://confportal.efsa.europa.eu/>



5. NEED TO KNOW BEFORE DATA SUBMISSION IN PORTALINO



Users are encouraged to **check the administrative and scientific provisions relevant for the submission** in the EFSA website (<https://www.efsa.europa.eu/en/applications>), and to provide data in line with the minimum requirements set by such documents.



Intellectual Property Rights (IPR): when published data, relevant for the evaluation, are included in the submission, the users must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied.



Publications already available to the public upon payment of fees: in situation where the contributor/applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, a copy of the relevant publications with the relevant bibliographic references/citations should be included in the Confidential version only, for scientific assessment purposes only. In the Public dissemination version, the contributor/applicant should provide only the relevant bibliographic references/citations where this publication is available to the public.



6. HOW TO SUBMIT DATA IN PORTALINO

Once logged-in, **users from organisations and private citizens** will access the 'Overview Submissions' page, containing the submissions previously created, if any. Click on '**New submission**' to start the creation of a submission and the confidentiality requests linked to it.

Overview Submissions

▼ Submission status

☐ Draft

☐ Submitted

☐ Rejected

☐ Withdrawn

☐ Request for Information

☒ Show All

▼ Submission date

▼ Food sector area

☐ Animal Health

☐ Animal Welfare

☐ Biological Hazards and Animal By-products

☐ Contaminants

☐ Decontamination Substances

☒ Show All

Id	Subject	Submission date	Status	Food sector area	Company name
CR-2023-000241	Submission example for user guide		Draft	Animal Welfare	ABC company Spa

Users can filter past submissions according to “Status”, “Submission date” and Food sector area”.



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 1/5

Updated!

Step 1/5 (for organisations and private citizens). General information about the Subject of the submission and the Food Sector Area

Each submission in Portalino should be properly named to allow a clear recognition by EFSA. Users are strongly encouraged to include the following information in the “**Subject of the submission**” section:

- Name of the subject of the submission (e.g., the name of the regulated product to be assessed by EFSA).
- The scope of the submission and the corresponding Regulation (e.g., submission of complementary information following EFSA's inconclusive opinion; application for the authorisation of a high-risk plant, etc).
- For submission of complementary information linked to previous EFSA opinions: the EFSA question number (EFSA-Q) and the dossier number of the previous application are also required.
- The user must select the relevant **Food Sector Area** of the submission.
- Before clicking on **Next**, the user should specify if the submission is an **initial dataset**, or an **additional dataset** submitted following an EFSA request.

Step 1/5: General Info

* = Mandatory field

How to use? ⓘ

Subject of the submission *

provide a brief description of the subject

0 / 4000

How to use? ⓘ

Food Sector Area *

select food sector area

How to use? ⓘ

Submission Type *

☐ Initial Datasets ☐ Additional Datasets

Next >

Save as draft

Cancel

Users can find additional indications on **how to use** the fields of the submission form by hovering over the “?” icon nearby each field.



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 2/5

Step 2/5 (for organisations only). Data owner information

- The data owner is the organisation responsible for the submission.
- In the “**Company or organisation**” field the user can start typing the name of the data owner organisation and select the relevant result from the picklist, if any.
- Fill-in the other fields if required by the form.

Step 2/5: Data owner * = Mandatory field

How to use? ⓘ

Company or organisation *

E-mail

Phone number

Street Address

Postal code

City

Country

Website

< Previous Next > Save as draft Cancel



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 3/5

Step 3/5 (for organisations and private citizens). Submission Owner(s) information

- A submission owner is a contact registered in Connect.EFSA under the company account of the owner organisation indicated in the data owner section. By default the logged user is also a submission owner.
- **The submission owner(s) indicated in this window will be the person that can make changes to the submission (add/remove submission owner(s)/contact person(s), send a confidentiality requests or select when there are no confidentiality requests, withdraw a submission).**
- To add other submission owners, the user indicates the email of another contact and clicks **Search**. The email is that used by the contact to register in Connect.EFSA. **Each submission can be owned by a maximum amount of three owners.**
- By clicking the “x” box next to the submission owner name, the name can be removed from the list of submission owners.
- Click **Next** to continue.

Step 3/5: Submission Owner(s) * = Mandatory field

Submission Owners How to use? ⓘ

List of selected Owners

[< Previous](#)

If the system does not find the contact account in Connect.EFSA, an error message will be displayed.

ⓘ Portalino | Issue adding a new contributor
Unable to retrieve Salesforce account for user: **jim.belushi@othercompany.com..**
Please contact [ServiceDesk](#)



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 4/5

Step 4/5 (for organisations and private citizens).

Submission Contact(s) information

- The user can indicate other contacts to be associated to the submission. **Only contacts indicated in this section will receive communications concerning the submission.**
- **Submission owners that are not named as contacts will not receive communications.**
- There are no limits for the number of contacts that can be added. The only requirement is that the email provided is functioning and monitored.
- The user indicates a valid email for the contact and clicks on “+ Add contact”. Repeat this step to add more than one contact to the submission.
- Click **Next** to continue.

Step 4/5: Contacts * = Mandatory field

How to use? ⓘ

Contact email + Add contact

jim.belushi@ABCcompany.com

antonio.banderas@ABCcompany.com

< Previous Next > Save as draft Cancel

By clicking on the “x” the user can delete a contact from the list.



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 5/5

Step 5/5 (for organisations and private citizens). Data submission

If the submission contains confidential data, it must consist of:

- a zip file with a **confidential version (not for public dissemination)** containing all documents/data related to the current submission in their complete version (**i.e. all information visible and no blackening applied**). In the confidential version all information claimed to be confidential should be earmarked. Detailed instructions on how to submit confidentiality requests are provided in Section D, Chapter 3 of the [EFSA's User Guide on Confidentiality](#).
- a zip file with a **non-confidential version (public dissemination version)** of all documents related to the current submission with the **confidential parts having been permanently blackened**. Users must be sure not to disclose publications for which they do not have intellectual property rights.
- A **signed cover letter** listing the content of the submission and its scope should be provided together with both the confidential and public dissemination versions (i.e. the zip files) of the submission.

Step 5/5: Data Submission * = Mandatory field

Zip files

How to use? ⓘ

Confidential version * + Select

Public dissemination (Non-Confidential) version * + Select

Data Submission

How to use? ⓘ

☐ Please tick the box if your submission does not contain any confidentiality request related to confidential business information or personal data ⓘ

+ Add confidentiality request

< Previous ✓ Submit Save as draft Cancel

After uploading the zip files, the user clicks on the “**+Add confidentiality request**” button to proceed. See next slides for detailed information.



6. HOW TO SUBMIT DATA IN PORTALINO – STEP 5/5

General indications on how to fill-in the mandatory fields of the **Data Submission section** are available by hovering over the “?” icon next to “How to use?”. The “?” icon nearby each mandatory field provides additional detailed information.

Data Submission

How to use? ⓘ

Please make sure the following fields are provided.

- Please provide the **file name** in the full version zip folder in which the confidentiality request can be found.
- Please select the relevant **legal ground** applicable to the information claimed confidential from the drop-down list. If within the same document/dataset you claim as confidential different information that falls under different legal grounds, you must submit one confidentiality request for each legal ground. If within the same document you claim as confidential different information that falls under the same legal ground, you may group the items together under the same confidentiality request, provided it is clearly identifiable which information is claimed confidential in the document/dataset.
- In relation to information other than personal data, please provide a tailored **justification** for each information claimed confidential based on the legal ground invoked that clearly explains the reasons why the information should be granted confidential status and demonstrates how making public the information would result in significant harm.
- Please provide an **excerpt** of the information claimed confidential corresponding to the earmarked text/information in the confidential file by either including the entire text/information claimed confidential in the extract or otherwise by providing a precise description that allows the clear identification of the information claimed confidential in the document/dataset.
- Please provide the **related section** where the confidentiality request is contained, i.e. the section in the document/dataset, not the section in the dossier.
- Please tick the applicable condition boxes and fill in the additional justification boxes where relevant (see Article 10 of EFSA's [Practical Arrangements for Transparency and Confidentiality](#) and the more detailed information provided under the condition boxes).

For more information, please consult [the EFSA User Guide on Confidentiality](#) and [the Webinar on confidentiality assessment and content sanitisation](#). Please note that you can save the confidentiality request(s) as a draft and modify your data at a later date.

Your confidentiality request(s) will be sent to EFSA upon clicking the 'Submit' button, after submitting the submission no further changes will be allowed unless explicitly requested by EFSA.

✓ Submit Save as draft Cancel



6.1. HOW TO SUBMIT DATA WITHOUT CONFIDENTIALITY REQUEST(S)

The following procedure applies only when there is not the intention/need to include any confidentiality request in the submission.

Step 5/5: Data Submission * = Mandatory field

Zip files

How to use? ⓘ

Public dissemination (Non-Confidential) version * + Select

Data Submission

☒ Please tick the box if your submission does not contain any confidentiality request related to confidential business information or personal data ⓘ

[< Previous](#) [✓ Submit](#) [Save as draft](#) [Cancel](#)

The user checks this box to continue without submitting any confidentiality request. The user uploads **only** the .zip file containing **the public dissemination version** of the submission, then clicks **Submit**.



7. CONFIRMATION OF THE SUBMISSION

After the submission, the status changes from **DRAFT** to **SUBMITTED**. The system shows the date, time and the identification code of the submission. The submission owner(s) and the contact person(s) receive **an email alert** which confirms receipt of the submission.

Submission CR-2023-000413

Date of the submission
14/09/2023 - 10:51

Print

SUBMITTED

General Info

Data Owner

Submission Owner(s)

Contact point(s)

Withdraw

Data Submission

Assessment

Close

General Info

Subject
Test submission for User Gude

Food sector area
Feed Additives

Data owner
ABC company Spa

Acknowledgement of submission email

Portalino

Acknowledgement of Submission

EFSA hereby acknowledges receipt of your submission: CR-2023-000413 on behalf of: ABC company Spa
Subject: Test submission for User Gude
Food Sector Area: Feed Additives
Submission date: 14-09-2023

The confidentiality requests linked to this submission, if any, will be considered by EFSA according to Article 39b of regulation (EC) No 178/2002, as applicable, when:

- the application to which it refers has been considered valid or admissible



8. RE-SUBMISSION AFTER A REQUEST FOR MISSING INFORMATION

Submission: CR-2023-000285

REQUEST FOR INFORMATION

Print

EFSA Feedback:

- 1 Example request for missing information (RFI)

Requested by: EFSA Requested on: 06/07/2023 - 12:45

General Info

Data Owner

Submission Owner(s)

Contact point(s)

With...

Step 1/4: General Info

* = Mandatory field

How to use? ?

Subject of the submission *

Submission example for User Guide

33 / 4000

Resubmit

X

What is this ?

Change description *

Cancel

✓ Resubmit

After a submission, the user may receive a request for information from EFSA.

- The status changes from **SUBMITTED** to **REQUEST FOR INFORMATION**.
- The EFSA Feedback appears in the blue box at the top of the page.
- All sections of the submission can be updated/amended by following the same instructions provided in steps 1/5, 2/5, 3/5, 4/5 and 5/5 for the first submission process.
- When the submission is updated/amended with the information required, the user provides a description of the changes done in the dedicated box "**Change description**".
- The user clicks **Resubmit** to continue.

✓ Resubmit




9. CONFIRMATION OF THE RE-SUBMISSION

After the re-submission, the status changes again to **SUBMITTED**, the system shows the date, time and the identification code of the submission and the contact person(s) indicated in step 3/5 receive a **email alert** which confirms the end of the re-submission process.

Submission CR-2023-000248

Date of the submission
27/06/2023 - 17:10

 Print

SUBMITTED

General Info

Data Owner

Submission Owner(s)

Contact point(s)

Withdraw

Data Submission

Assessment

General Info

Subject
Submission example for user guide

Food sector area
Animal Welfare



10. UPDATE SUBMISSION OWNER(S) AND CONTACT(S)

A submission owner can add/remove/replace the information about the other submission owner(s) and contact point(s)

General Info

Data Owner

Submission Owner(s)

Contact point(s)

Withdraw

Data Submission

Assessment

Close

Submission Owner(s)

SURNAME Name
name.surname@ABCcompany.com

Update Submission Owners

Contact point(s)

name.surname1@ABCcompany.com
name.surname2@ABCcompany.com

Update Submission Contacts



11. WITHDRAW THE SUBMISSION

Submission owners can withdraw the submission by clicking on the **Withdraw** button and including a **Justification for Withdrawal**.



Click again **Withdraw** to continue, a pop-up window will ask the user to confirm the action.

Do you confirm your withdrawal of the submission? Please note that this action is irreversible.

No Yes



12. NOTIFICATION OF STUDIES AND PRE-SUBMISSION ACTIVITIES

If the submission falls under the obligations of study notification pursuant to Article 32b of Regulation EC 178/2002 (the General Food Law, as updated by the Transparency Regulation), the user should use the “[Appendix A - Notification of Studies information](#)” and provide the information as showed in the following tables.

Submission for:	Indicate the subject of the submission
Pre-Application ID:	Insert the pre-application identification number EFSA-ID-YYYY-NNNNNN received from EFSA (in Connect.EFSA)

For all studies notified in the database and included in the submission, please fill in the following table:

Studies notified and included in the submission		
EFSA Study identification number	Study title	For studies notified after the study starting date, provide justification for delay in notification
EFSA-YYYY-NNNNNNNN	Study on..	Add justification, if the study has been notified with delay
Add rows as needed		

For studies that were notified in the database, but not included in the submission or withdrawn from the database, please fill in the following table:

Studies notified NOT included in the submission and/or withdrawn from the database			
EFSA Study identification number	Study title	For studies that were previously notified in the database, and not included in the submission, provide justification for the non-inclusion	For study notifications withdrawn from the database, provide a justification for withdrawal
EFSA-YYYY-NNNNNNNN	Study on..	Add justification, if the study was notified but it has not been included in the submission	
EFSA-YYYY-NNNNNNNN	Study on..		Add justification, if the study notification was withdrawn from the
Add rows as needed			

For studies that were not notified in the database, but are included in the submission, please fill in the following table:

Studies NOT notified in the database, but included in the submission						
Study title	Study Objective	Business Operator	Laboratory name*	Test item	Starting date	For studies that were not notified in the database, and included in the submission, provide justification for the non-notification
Study on..	Study to determine..	Provide the name of the company which has commissioned the study	Provide the name of the laboratory which has performed the study, if	provide information on the test item	insert the study starting	Add justification, if the study was not notified in the database, but has been included in the submission
Add rows as needed						

* not relevant for studies performed in internal testing facilities



13. DATA COLLECTION FRAMEWORK (DCF)

Submission within the context of DCF can contain large amount of data. While a call for data is ongoing users can upload data multiple times. Confidentiality requests can be submitted in Portalino only for datasets owned by the applicant/contributor.

The submission of confidentiality requests in Portalino for each record or field of a collection of data may be cumbersome and less efficient. Users can submit their requests in relation to the data structure as showed in the graphic below.

