



03 March 2022  
EFSA webinar series

## Webinar on application procedure for GMO

Trusted science for safe food



**Time**



**Topic**



**Speaker**

| 11.00-11.05 | Welcome and introduction  | Goran Kumric   |
|-------------|---|--|
| 11.05-12.00 | Lifecycle of an application<br>Account creation and management<br>Pre-application ID, Pre-Submission Advice and Notification of Studies (NoS)<br>Applications and modification of authorisation<br>E-submission (demo)<br>Dossier intake and portal updates<br>Confidentiality assessment of requests submitted with regard to GM food and feed applications<br>Public consultations<br>Risk Assessment, Adoption and Publication | Bénédicte Vagenende<br>Anastasia Livaniou<br>Simone Gabbi  |
| 12.00-12.30 | Q&A session and conclusions   | Stefano Cappé<br>Sara De Berardis<br>Pietro Piffanelli<br>Dafni Kagkli<br>Goran Kumric<br>Francesca Volpi<br>Anastasia Livaniou<br>Simone Gabbi<br>Federico Morreale |



## Who we are

### Presenters of this webinar

- Bénédicte Vagenende
- Anastasia Livanou
- Simone Gabbi

### Q&A contributors:

- Stefano Cappé
- Sara De Berardis
- Pietro Piffanelli
- Dafni Maria Kagkli
- Francesca Volpi

### Webinar moderator:

- Goran Kumric



## Goals

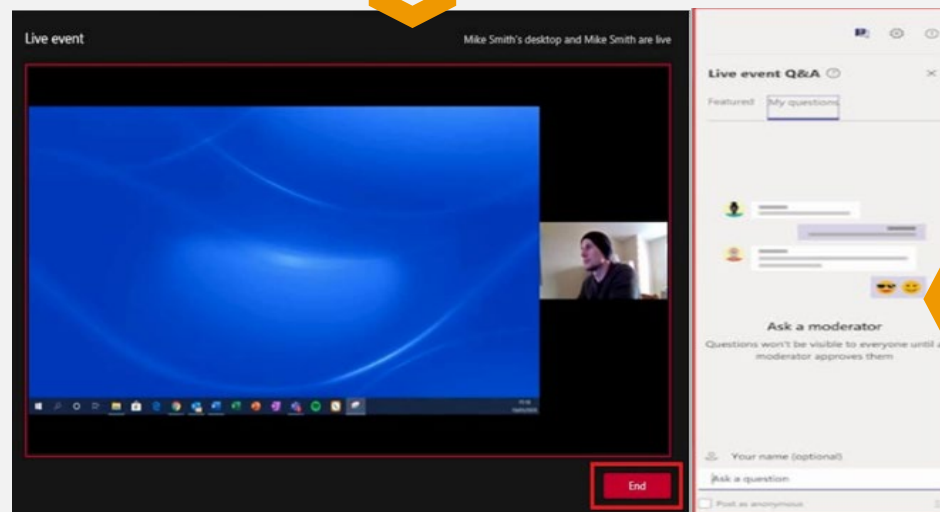
- To explain the arrangements, steps and the tools of the application procedure for GMO food and feed implemented by EFSA following the entry into force of the Transparency Regulation.
- Applicable to applications (new applications and renewals) submitted pursuant to Regulation No 1829/2003 on genetically modified food and feed.
- Address questions encountered by applicants since the entry into application of the Transparency Regulation.

### Out of scope:

- Clarifications about aspects of the authorization process which have not been affected by the Transparency Regulation.
- Clarifications related to the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

- You are **automatically connected** to the audio broadcast. One-way audio (listen only mode).
- You can submit questions throughout the webinar via the **dedicated Q&A tab** on the top right navigation bar
- The **webinar is in English** and questions should be submitted in English through the platform.
- Some questions will be **answered in written** and some others will be answered **live**
- If some questions remain unanswered you can **resubmit** them via the **Ask a question** Connect.EFSA tool (<https://connect.efsa.europa.eu/RM/s/askefsa>)
- This webinar **is being recorded**

Presentation window



**Q&A box:**  
For any questions related to the topic or unexpected IT issues

# Lifecycle of an application

## 4 pillars

### Transparency

- Better access to scientific studies

### More reliable independent studies

- EFSA will have more access to relevant scientific evidence in requests for authorisation

### Better governance

- Member States will contribute more to EFSA's governance and scientific Panels

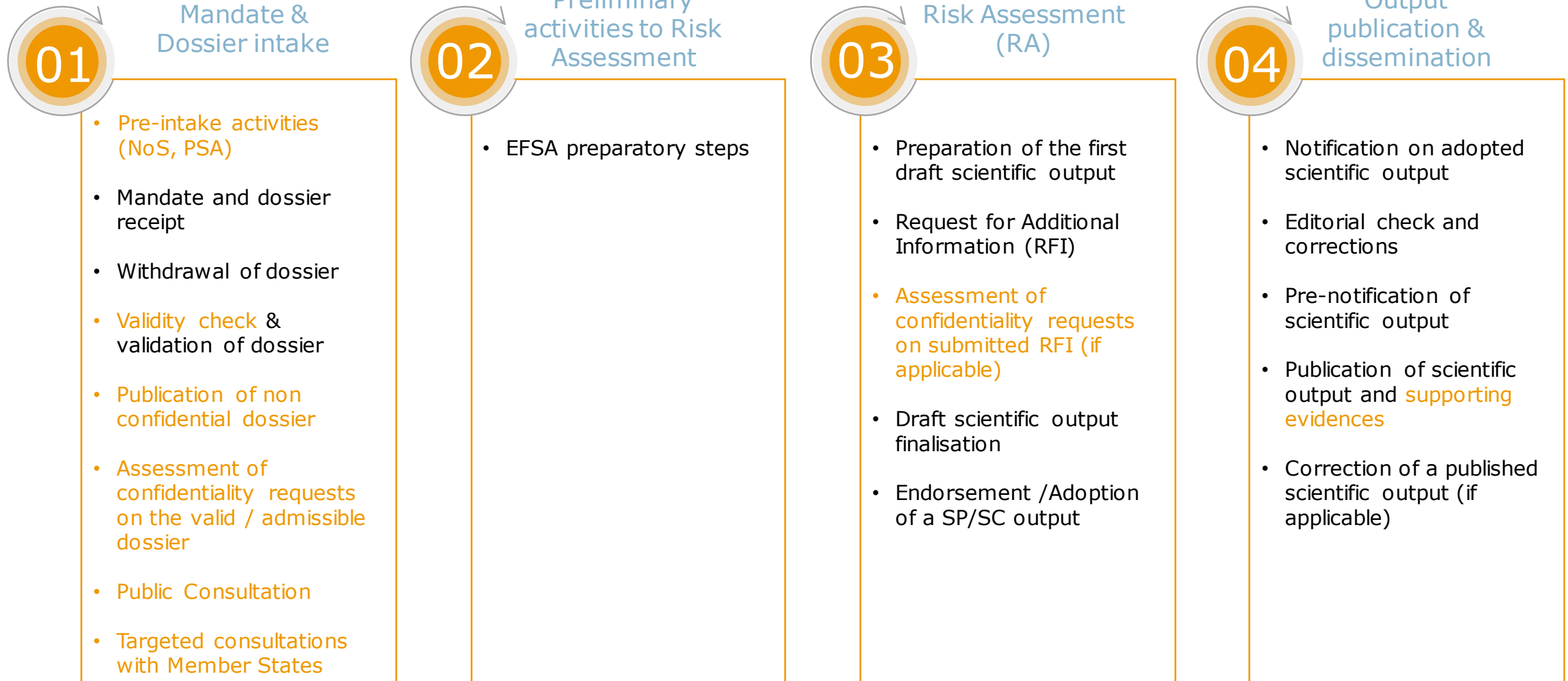
### Effective risk communication

- Improve coordination between risk assessors and risk managers to ensure better communication to stakeholders and general public

**Applicable For** - New dossier/applications submitted on or after 27<sup>th</sup> March 2021



[Click here to access the Factsheet: "A Modern and Sustainable Food Law in the EU"](#)



Confidentiality

## Connect EFSA

- ✓ Notification of Studies (NoS)
- ✓ Pre-submission Advice (PSA)
- ✓ AskAQuestion
- ✓ Public access to document
- ✓ Targeted consultation
- ✓ Public consultation

## eSubmission Food Chain Platform

- ✓ Dossier eSubmission
- ✓ Request for Information (RFI)
- ✓ Follow-up lifecycle

## Open EFSA

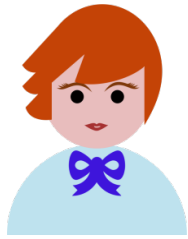
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

## PORTALINO

- ✓ Used by legal or natural persons for submitting **confidentiality requests** related to applications, datasets and documents supporting the generic mandates



# **Account creation and management**



**Sarah**  
**Potential Applicant**



**John**  
**Laboratories  
Testing facilities**



**Martin**  
**Third Parties**



**The public**  
(during PC or once studies  
are published)

1

In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system ...<sup>1</sup>

2

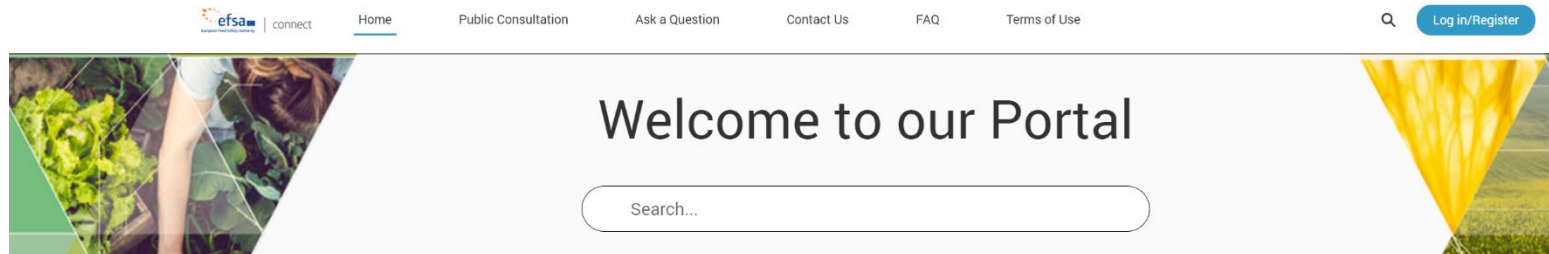
Third parties representing one or more entities shall also register in the Authority system supporting pre-submission activities ...<sup>1</sup> and obtain the authorization by represented entities to act on their behalf

3

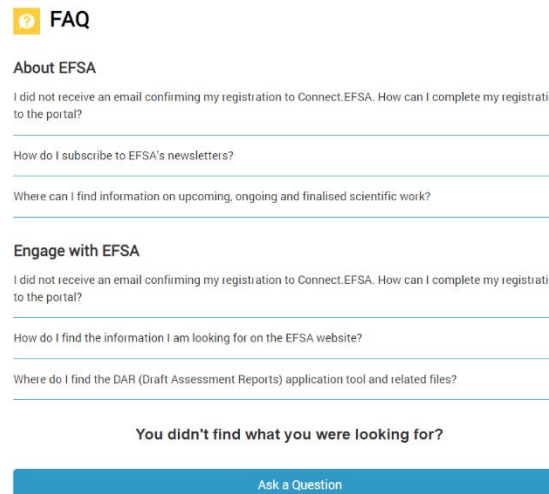
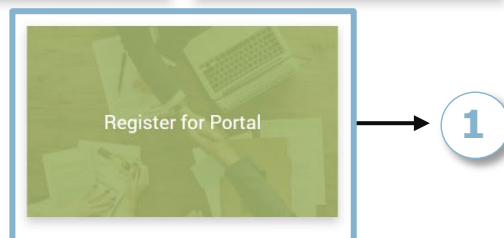
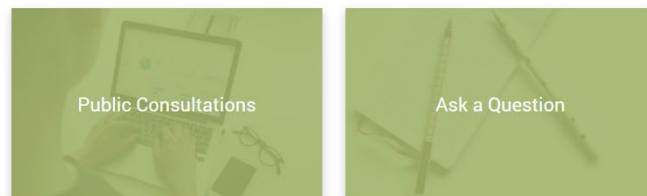
Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.<sup>1</sup>

<sup>1</sup>) [Practical arrangements on pre-submission phase and public consultations](#)


# Connect.EFSA Portal - Account Registration



This portal gives you the possibility to engage with EFSA on a variety of topics. You will be able to check the Frequently Asked Questions, consult and submit comments to EFSA's public consultations, and send requests for access to documents. You can also register for the Portal. Before sending EFSA a question, please read the Frequently Asked Questions.



**1** Click here to register



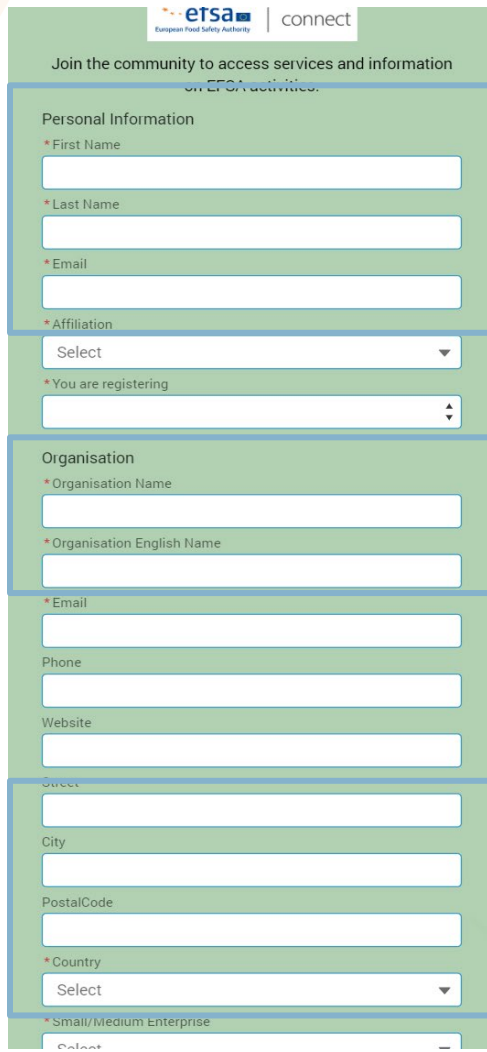
**Sarah**

The potential applicant starts the registration in the portal.

The potential applicant must register as the entity he/she is representing (e.g. a company).

The account name will then be the entity (company) name

# Connect.EFSA Portal - Account Registration



The screenshot shows the registration form with the following sections:

- Personal Information:** Fields for First Name, Last Name, Email, and Affiliation (dropdown menu). A checkbox for "You are registering" is also present.
- Organisation:** Fields for Organisation Name, Organisation English Name, Email, Phone, and Website.
- Billing Address:** Fields for Street, City, Postal Code, Country (dropdown menu), and Small/Medium Enterprise (checkbox).

Information related to the **contact person** of the account. The information and the e-mail address must be person specific and linked to the entity registered. No functional and generic mailboxes (e.g @gmail).

Each account can register a **maximum of 6 contact persons** (NEW since 30 June).

Information related to the organisation (e.g company). The name inserted will be the **account name**.

A **complete billing address** is essential for a clear identification of the company.

After the registration, the account and the contact(s) are not active yet.



Upon registration, EFSA performs a security check of the account in few days.



Once the account is considered valid, EFSA activate the account and the contact(s) inside.



The applicant is ready to use the functionalities of the portal.

As regards **multinational companies** made up of several entities, any of these entities may register provided that the registered entity is recognised as having a **separate legal personality** under the national law of the country in which it has its registered office.

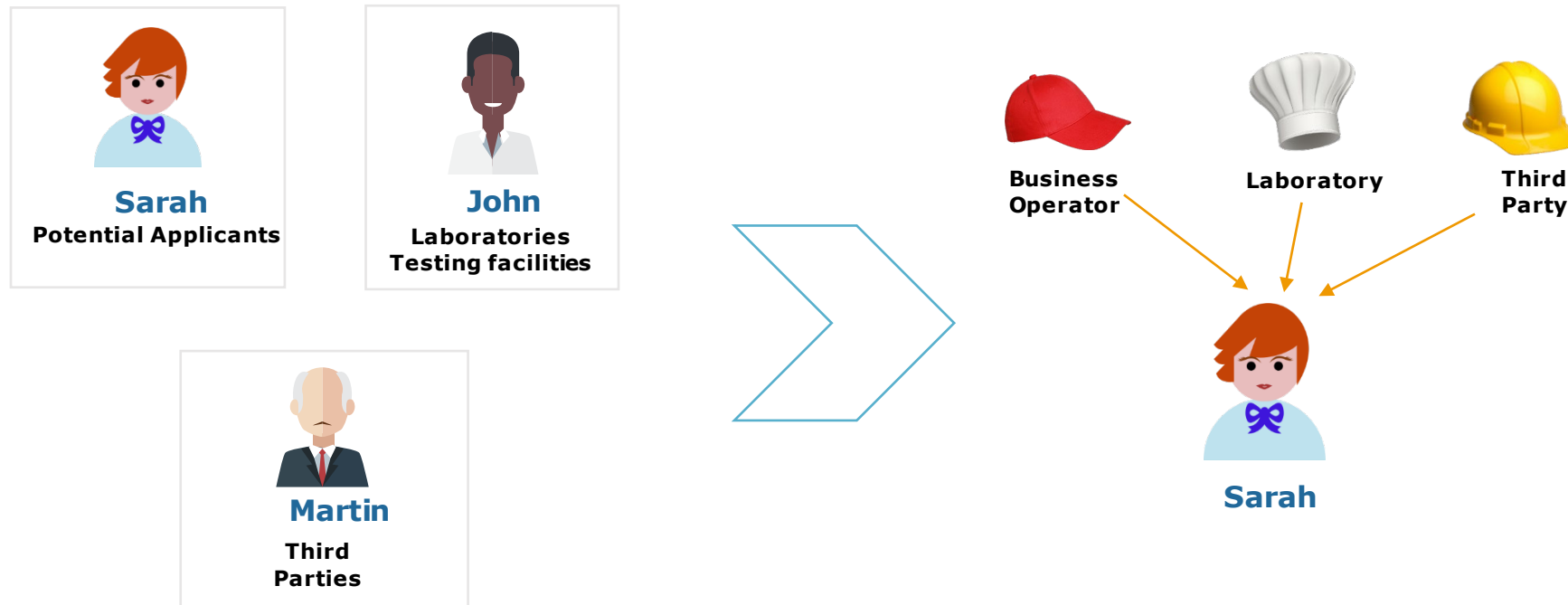
# Authorisation of delegation to third parties



The third party must notify studies indicating as business operator the applicant they represent. Additional applicants of a group of applicants can be indicated with "share with" functionality.

Example: A consultant creates a pre-application ID and add the business operator (the potential applicant, not the consultant!) in the 'Business Operator' field. If applicable the consultant shares the pre-application ID with other business operator(s).

# Organisations playing multiple roles



Potential applicants, laboratories and third parties can choose when submitting studies if they are submitting them as Business Operator or Laboratory

Detailed information is available in the **user guides** on [pre-application ID](#) and [study notification updated on 4 February 2022](#) and available on the [EFSA Toolkit page](#)

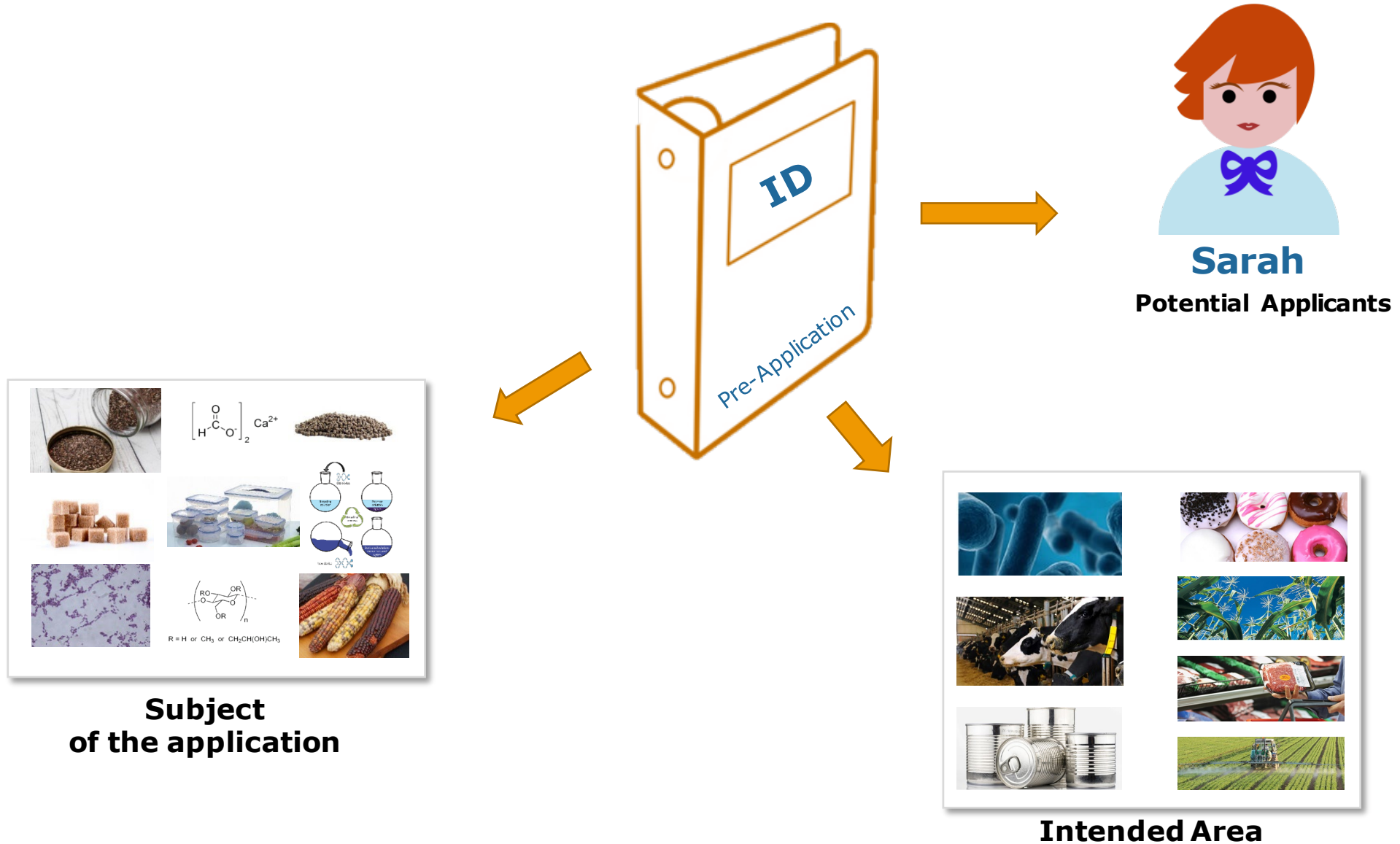
Webinars: Webinar 16 February ([here](#)). Webinar 25 March ([here](#)).

**Pre-Application ID**  
**Pre-submission advice**  
**Notification of Studies**

**New applications**



# Pre-Application Identification



## Step 1 Pre-application ID



**Sarah**

The potential applicant gets the pre-application ID

The potential applicant can ask pre-submission advice anytime before submission



*Pre-Submission  
Advice tool*  
**Connect.EFSA**



## Step 2 General Pre-Submission Advice

**EFSA**  
Provides the general pre-submission advice



## Step 3 Validation of application



**EFSA** publishes summary of general pre-submission advice after application is declared valid

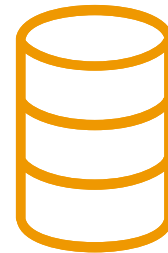
## Step 1 Pre-submission phase



Sarah

The potential applicant gets the pre-application-ID

**Both Business Operator and Laboratory** notify Studies (Article 32b)



Database of Study Notifications  
**Connect.EFSA**

## Step 2 Submission of application

The potential applicant includes in the dossier information on studies notified and any justification for non-compliance with study notification obligations

**EFSA** performs the validation of the application



## Step 3 Validation of application



**EFSA** publishes study notifications with related studies upon validation and after a decision on confidentiality requests is taken

# Pre-Application ID for new applications: Application type - GMO


When requesting a new pre-application ID, the potential applicant must select the **Food Domain**, the **Authorisation Type** and the related **Application Type** (see the example below).

## New Pre-Application ID

\* Request Name

GMO


\* Business Operator

Search Accounts... 

\* Food Domain

GMO 

\* Authorisation Type

Food and Feed - Regulation (EC) No 1829/2003 

\* Application Type

--None-- 

✓ --None--

Application for authorisation of a new genetically modified food and/or feed

Application for modification of an existing authorisation of a genetically modified food and/or feed

Application for renewal of authorisation of genetically modified food and/or feed

# Renewal applications

## Step 1 Pre-application ID



Sarah

The potential applicant gets the pre-application ID **for renewal**

The potential applicant can ask pre-submission advice anytime before submission



*Pre-Submission  
Advice tool*  
**Connect.EFSA**



## Step 2 General Pre-Submission Advice

**EFSA**  
Provides the general pre-submission advice



## Step 3 Validation of application



**EFSA** publishes summary of general pre-submission advice after application is declared valid

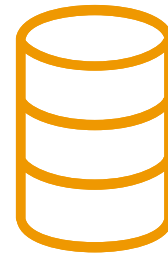
## Step 1 Application renewal



Sarah

The potential applicant gets the pre-application-ID for renewal

The **potential applicant submit the list of intended studies and study design** (Article 32c(1))



Database of Study Notifications  
**Connect.EFSA**

## Step 2 Public consultation and Renewal Pre-Submission Advice

**EFSA**  
Provides the renewal pre-submission advice



## Step 3 Notify studies



**The potential applicant** notifies studies (Article 32b)

# Pre-Application ID for Renewal

For renewal, the potential applicant should also prefill some information for the pre-application ID

## New Pre-Application ID for Renewal

\*Request Name

GMO

\*Business Operator

Search Accounts...

\*Former Application ID ⓘ

\*Subject Of The Application ⓘ

\*Food Domain

--None--

Authorisation Type

--None--

Application Type

--None--

Note ⓘ

Confirm



Link to the EFSA question number of the application related to the authorisation to renew



# Pre-Application ID for Renewal: Application type - GMO

When requesting a new pre-application ID for renewal the potential applicant must select the **Food Domain**, the **Authorisation Type** and the related **Application Type** (see the example below).

\* Food Domain

GMO

\* Authorisation Type

Food and Feed - Regulation (EC) No 1829/2003

\* Application Type

--None--

✓ --None--

Application for authorisation of a new genetically modified food and/or feed

Application for modification of an existing authorisation of a genetically modified food and/or feed

Application for renewal of authorisation of genetically modified food and/or feed

# Pre-Application ID for Renewal: fill in intended study information

From the pre-application for renewal create a "new study"

Fill in relevant information for **intended studies**

Once all intended studies are completed, submit the **list of intended studies for renewal**



Edit

Please, use the fields below to update the study information.

\* Study Title  
GMO renewal intended study

Study English Name  
GMO renewal intended study

Former Application ID  
EFSA-Q-00000000

Study Starting Date  
[Calendar icon]

Study Planned Completion Date  
[Calendar icon]

**Study Scope**

Study Type  
--None--

\* Food Domain  
GMO

International Standard Certification  
--None--

\* Authorisation Type  
Food and Feed - Regulation (EC) No 182

\* Application Type  
Application for renewal of authorisation

Study Internal Reference ID  
[Text field]

Test Item  
GMO XXXXX

Other Components  
[Text field]

Next

## Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of Intended Studies within the Pre-Application ID for renewal. You can transform an intended study in a draft study notification any time via the button by clicking on Select 'Operation button' and then 'Notify' (in the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title
- In Study Scope section:
- Study Type
  - Food Domain
  - Authorisation Type
  - Application Type
  - Study Objective
  - Study Test Item
  - Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

In the Study Design section, the Study Guideline field is mandatory. If you select 'Other', the Study Design Description also becomes mandatory.

# Public consultation on intended studies for renewal




**Receipt** of the list of intended studies for renewal



## Step 1 Administrative Check

EFSA launches the consultation of third parties on the **intended studies** for renewal

Including on the proposed **design** of the studies



Within 10 working days from the completion of the administrative check

## Step 2 Consultation

The consultation of third parties shall remain open for a period of **three weeks**

## Step 3 Comments

All **comments received** by stakeholders and the public shall be made public by EFSA

## Step 4 Summary of R-PSA

The **results** of the consultation of third parties shall be inserted in the summary of the renewal pre-submission advice

**E-Submission (demo)**

**FSCAP v.1** EC web system, operational since Jan 2018

## v.2 → E-Submission Food Chain Platform (ESFC)

- **TR compliance:** NoS, Confidentiality assessment, Dissemination
- **All Regulated Products** dossiers (excl. pesticides)
- **Single point of entry** for Applicant, European Commission, Member States

## 6 Food Domains - 37 Application Types (new applications, modifications & renewals)

- **Food Contact Materials:** Substances, Active & Intelligent materials, Recycling processes
- **Food Improvement Agents:** Food Additives, Food Enzymes, Food Flavourings, Smoke Flavourings Primary Products
- **GMO: Food-feed (Regulation),** GMO Directive;
- **Nutrition:** Novel/Traditional Foods, Health Claims, Infant formulae, Food allergens, Nutrient sources
- **Biological hazards:** Decontamination substances
- **Feed Additives**



[URL for ESFC](#)

Hyperlink



[Video Tutorials](#)

Hyperlink



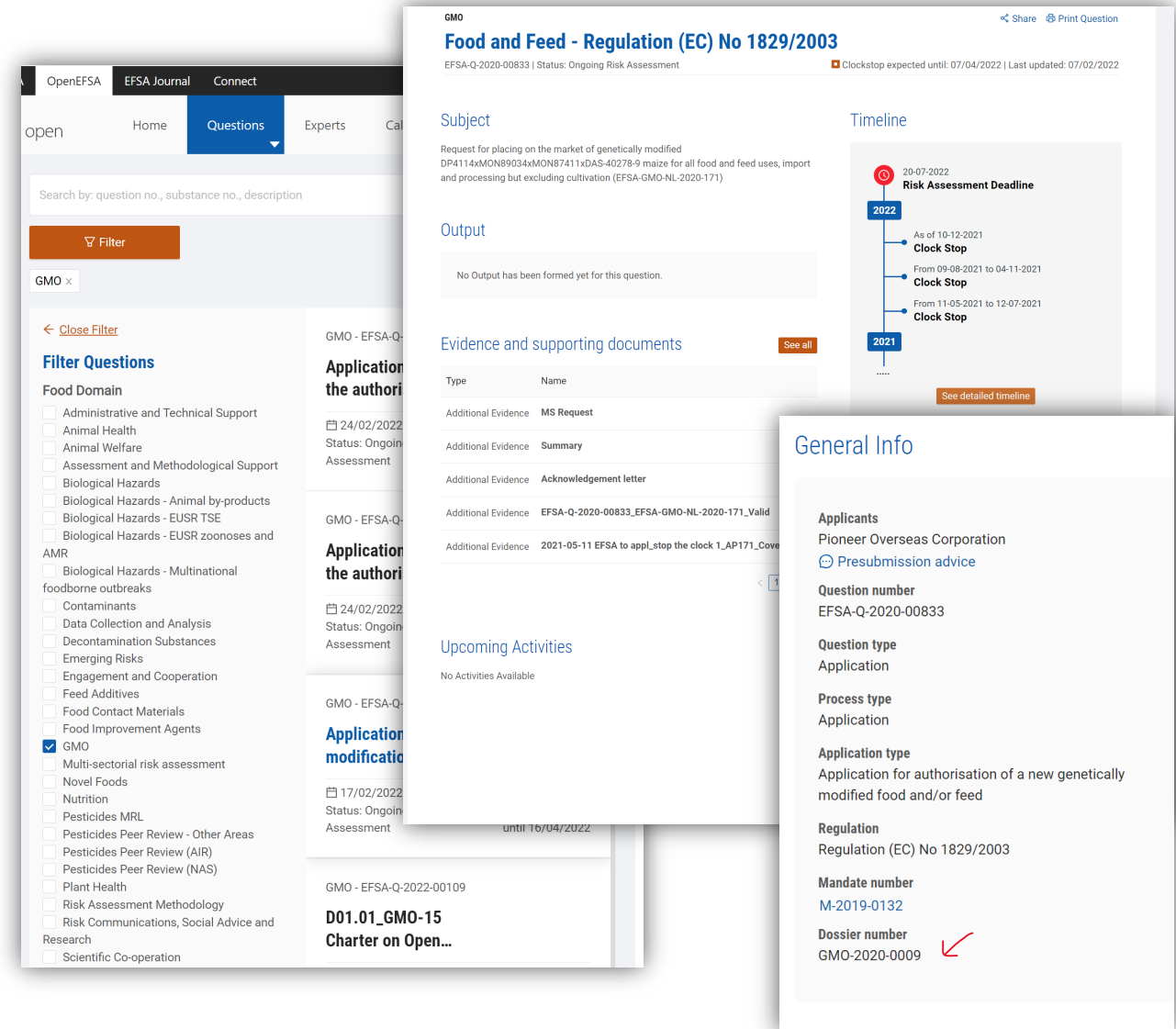
[User Guide](#)

Hyperlink

# Dossier Intake and Portal Updates

# Mandate and Dossier Intake

- MS (or EC for renewal applications) sends mandate and makes the application available to EFSA
- Question # assigned and linked to Mandate
- Basic info visible in Open.EFSA Portal
- EFSA performs Completeness check, incl. NoS check
- Request for Information (RFI): received & replied via ESFC
- EFSA declares application valid for risk assessment
- EFSA publishes non confidential valid dossier (+ pre-submission advice summary, if any)
- Risk Assessment & Assessment of confidentiality requests



The image shows a screenshot of the EFSA Open portal. On the left, there is a 'Filter Questions' sidebar with various categories like 'Food Domain', 'AMR', and 'GMO'. The 'GMO' category is selected. The main area displays a list of questions, with the first one being 'Application the authori...' with a date of 24/02/2022 and status 'Ongoing Assessment'. Below this, there is a detailed view of a question titled 'Food and Feed - Regulation (EC) No 1829/2003'. This view includes a 'Subject' section with a request for placing on the market of genetically modified maize, an 'Output' section stating 'No Output has been formed yet for this question.', and a 'Timeline' section showing a 'Risk Assessment Deadline' for 2022 with several 'Clock Stop' events. A 'General Info' sidebar on the right provides details for the application, including the applicant 'Pioneer Overseas Corporation', question number 'EFSA-Q-2020-00833', and dossier number 'GMO-2020-0009' (highlighted with a red arrow).

# **Confidentiality assessment of requests submitted with regard to GM food and feed applications**



Application submitted  
before 27/03/2021



Application submitted  
on/after 27/03/2021

**Pre-Transparency Regulation  
Regulation 178/2002 applies**

- Confidentiality requests assessed in accordance with Article 39 of original Regulation 178/2002

**Regulation 178/2002 as amended by  
Transparency Regulation applies**

- Practical Arrangements concerning transparency and confidentiality apply
- Confidentiality requests assessed in accordance with Articles 39-39e of the amended Regulation 178/2002



## Proactive Disclosure

**Article 29(1) of Reg 1829/2003 referring to Art 38 of Reg 178/2002**

**Proactive disclosure e.g. for:**

- Information data or studies submitted to support an application dossier
- Other information identified by EFSA and used as basis for opinion



## Confidentiality

**Article 30 of Reg 1829/2003 referring to Articles 39-39e of Reg 178/2002 - Confidential status:**

- Only for items included in the closed positive list of the Practical Arrangements concerning transparency and confidentiality Annex
- Only if substantive and procedural requirements are met

# Underlying principles



Proactive disclosure of non-confidential version of application dossiers as of validation



Confidentiality as exception to transparency



Burden of proof on applicants



Non-disclosure of information claimed confidential pending decision-making

# Procedural requirements



Submission through ESFC for applications or Portalino for follow up to inconclusive opinions and data supporting generic mandates



Including verifiable justifications, a confidential and a non-confidential version of the document



Providing clarifications ONLY if requested to do so by EFSA (via ESFC or email)



Submit clarifications within the deadline set by EFSA (via ESFC or email)




Modifications of submitted requests not allowed, unless requested by EFSA



No fees

## Confidentiality requests only on items in closed positive list – for GM food and feed applications:

- 
- the **manufacturing or production process**, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, **except for** information which is relevant to the assessment of safety;
  - **commercial links** between a producer or importer and the applicant;
  - **commercial information** revealing sourcing, market shares or business strategy of the applicant;
  - **DNA sequence information**, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and
  - **breeding patterns and strategies**



The non-confidential version of the application/notification dossier **shall not contain personal data** falling under Regulations (EU) 2016/679 and (EU) 2018/1725, with the exception of:

- name and address of the applicant
- names of authors of published/publicly available studies supporting the application
- names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the application

**Legal Ground:  
GFL Art 39e(1)**

**Submit confidentiality requests for other personal data** to be withheld from disclosure, **including** names and addresses of NATURAL PERSONS involved in testing on vertebrate animals or in obtaining toxicological information.

**Legal Ground:  
GFL Art 39e(2  
& 3)**



Identifying clearly the information claimed confidential, with references



Indicating the legal basis (grounds)



Explaining why the item should be kept confidential:



Information not publicly available



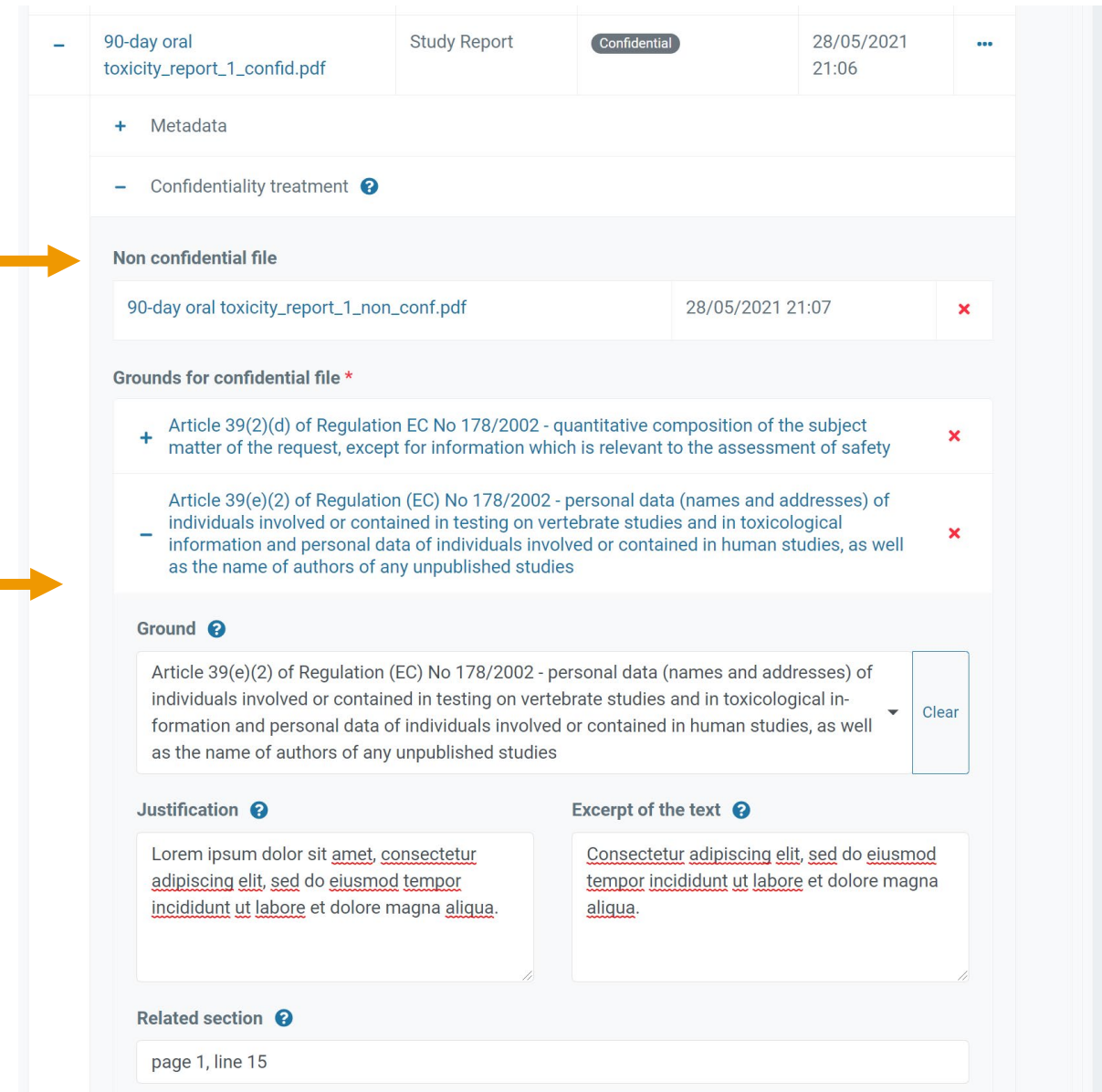
Potential harm to a significant degree

- Information acquired legitimately
- Negligible harm – rebuttable presumption
- Novelty – rebuttable presumption



Clarification on whether information claimed confidential falls under “environmental information” (Art 2 of Aarhus Regulation)

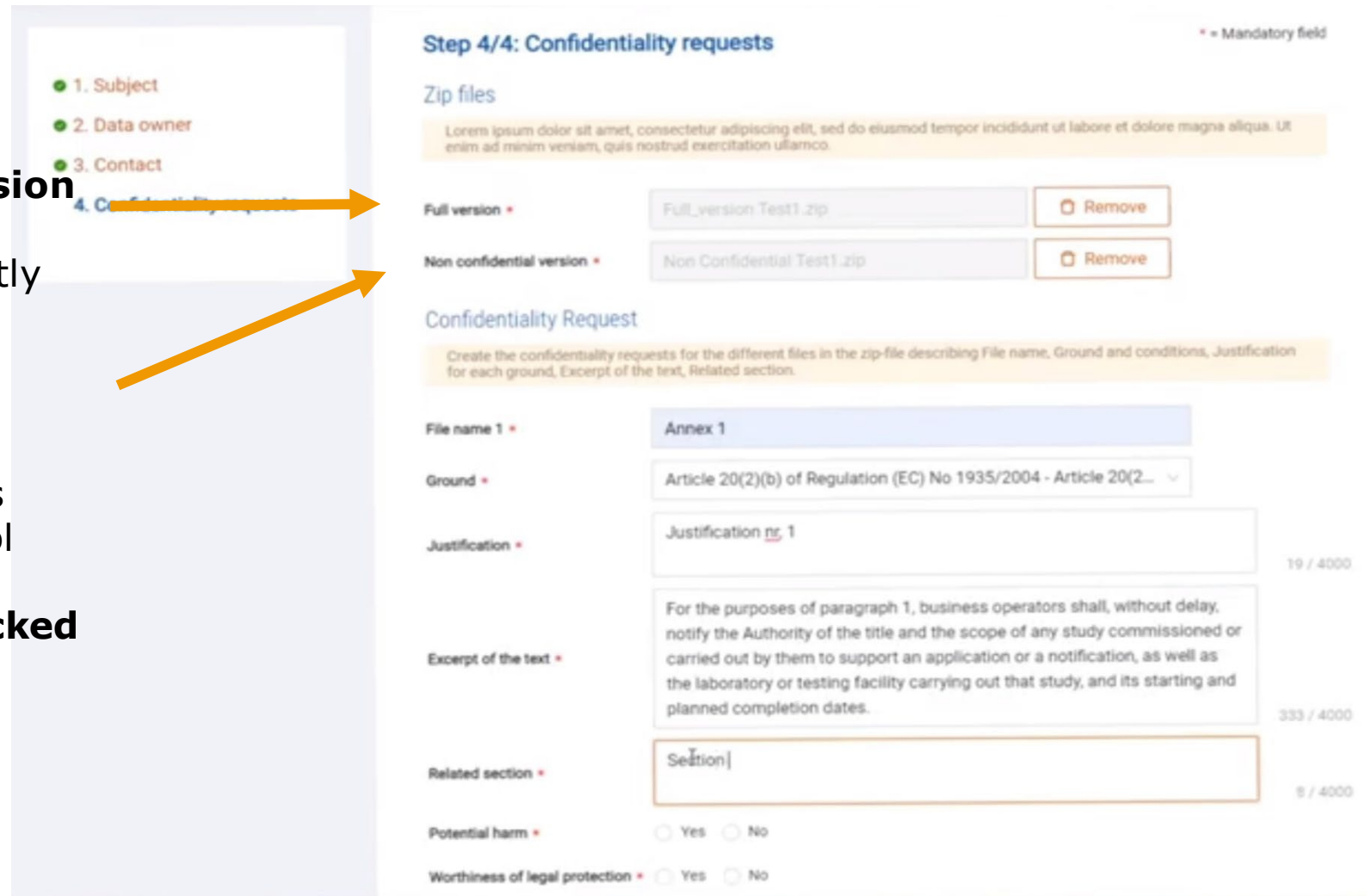
- Provide non-confidential file AND confidential version of the file
- Provide non-confidential file
  - Ensure that information claimed confidential is redacted by using a redaction tool which ensures that the **redacted information is irreversibly blocked out.**
- Define and support your request:
  - Legal ground
  - Justification
  - Excerpt
  - Location in file



The screenshot shows a web interface for submitting a confidentiality request. At the top, a table lists the request details: a minus sign, the filename '90-day oral toxicity\_report\_1\_confid.pdf', the document type 'Study Report', a 'Confidential' status badge, the date '28/05/2021 21:06', and a three-dot menu. Below this, there are expandable sections: '+ Metadata', '- Confidentiality treatment', and 'Non confidential file'. The 'Non confidential file' section contains a table with one entry: '90-day oral toxicity\_report\_1\_non\_conf.pdf' with a timestamp of '28/05/2021 21:07' and a red 'x' icon. Below this is the 'Grounds for confidential file' section, which lists two grounds with plus and minus signs and red 'x' icons. The first ground is 'Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety'. The second ground is 'Article 39(e)(2) of Regulation (EC) No 178/2002 - personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies and in toxicological information and personal data of individuals involved or contained in human studies, as well as the name of authors of any unpublished studies'. Below the grounds is a 'Ground' dropdown menu with a question mark icon, currently showing the second ground. To the right of the dropdown is a 'Clear' button. Below the ground dropdown are two text areas: 'Justification' and 'Excerpt of the text', both with question mark icons. The 'Justification' text area contains the text: 'Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.' The 'Excerpt of the text' text area contains the text: 'Consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.' At the bottom is a 'Related section' dropdown menu with a question mark icon, currently showing 'page 1, line 15'.



- Provide non-confidential file AND confidential version of the file
- Ensure that the **confidential version** of the document **includes earmarked parts** matching exactly the blackened parts of the non-confidential version
- Ensure that information claimed confidential is redacted by using a redaction tool which ensures that the **redacted information is irreversibly blocked out.**



**Step 4/4: Confidentiality requests** \* = Mandatory field

Zip files

Full version \*

Non confidential version \*

Confidentiality Request

Create the confidentiality requests for the different files in the zip-file describing File name, Ground and conditions, Justification for each ground, Excerpt of the text, Related section.

File name 1 \*

Ground \*

Justification \*  19 / 4000

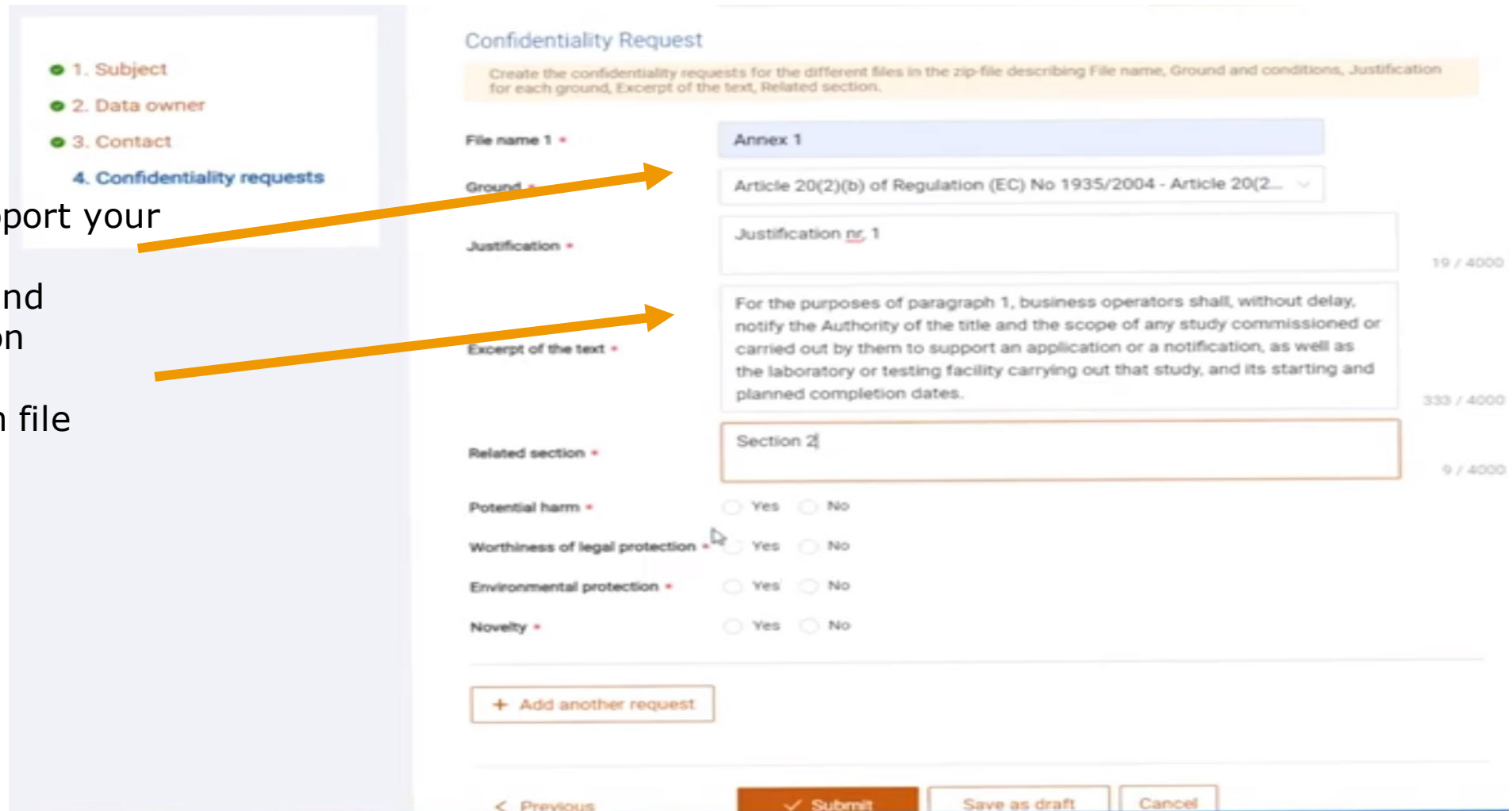
Excerpt of the text \*  333 / 4000

Related section \*  8 / 4000

Potential harm \*  Yes  No

Worthiness of legal protection \*  Yes  No

- Define and support your request:
  - Legal ground
  - Justification
  - Excerpt
  - Location in file

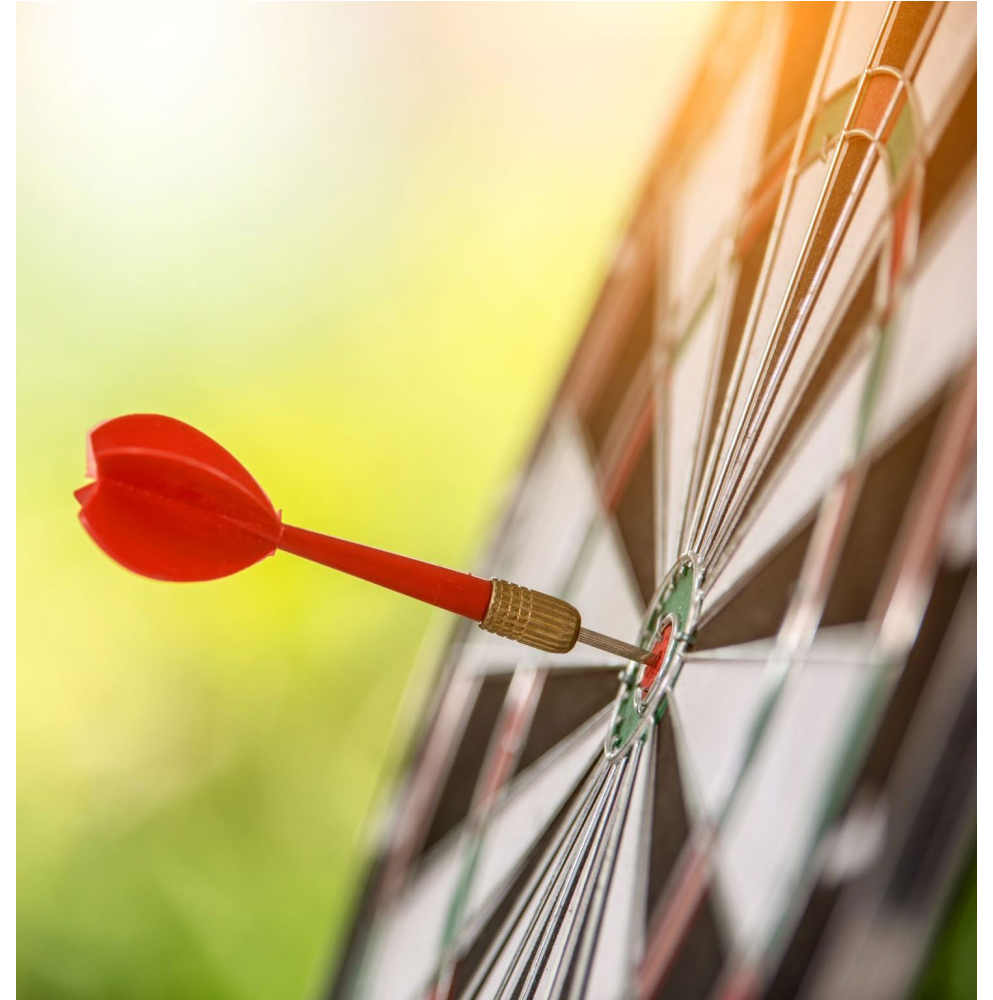


The screenshot shows the 'Confidentiality Request' form in Portalino. The form is titled 'Confidentiality Request' and includes a sub-header: 'Create the confidentiality requests for the different files in the zip-file describing File name, Ground and conditions, Justification for each ground, Excerpt of the text, Related section.' The form is divided into several sections:

- File name 1 \***: A text input field containing 'Annex 1'.
- Ground \***: A dropdown menu showing 'Article 20(2)(b) of Regulation (EC) No 1935/2004 - Article 20(2...'. An orange arrow points from the 'Ground' label in the left sidebar to this dropdown.
- Justification \***: A text input field containing 'Justification nr. 1'. A character count '19 / 4000' is visible to the right.
- Excerpt of the text \***: A text input field containing a paragraph of text: 'For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.' A character count '333 / 4000' is visible to the right. An orange arrow points from the 'Excerpt of the text' label in the left sidebar to this text area.
- Related section \***: A text input field containing 'Section 2'. A character count '9 / 4000' is visible to the right.
- Potential harm \***: Radio buttons for 'Yes' and 'No'.
- Worthiness of legal protection \***: Radio buttons for 'Yes' and 'No'.
- Environmental protection \***: Radio buttons for 'Yes' and 'No'.
- Novelty \***: Radio buttons for 'Yes' and 'No'.


At the bottom of the form, there is a button '+ Add another request' and a navigation bar with buttons: '< Previous', '✓ Submit', 'Save as draft', and 'Cancel'.

- ✓ Confidential version of the document to highlight **info claimed confidential as boxed or earmarked**, matching exactly with the blackened parts of the non-confidential version
- ✓ **In the public version, use a redaction tool which ensures that the redacted information is irreversibly blocked out.**
- ✓ Only **one confidentiality request per document per legal ground** is submitted
- ✓ justification must comply with Articles 9 and 10 of EFSA's Practical Arrangements concerning transparency and confidentiality
- ✓ No duplications
- ✓ **No confidentiality requests on publicly available information**




# Procedural steps EFSA confidentiality assessment


## STEPS



Mandatory notification of draft decision to the applicant for comments via ESFC or email [confidentialityrequestassessment@efsa.europa.eu](mailto:confidentialityrequestassessment@efsa.europa.eu)




Notification of the final decision to the applicant via ESFC or email [confidentialityrequestassessment@efsa.europa.eu](mailto:confidentialityrequestassessment@efsa.europa.eu)



Possibility to file confirmatory application via tool or email to

[Confidentialityconfirmatoryapplication@efsa.europa.eu](mailto:Confidentialityconfirmatoryapplication@efsa.europa.eu)



Implementation of confidentiality decisions – sanitization – by EFSA

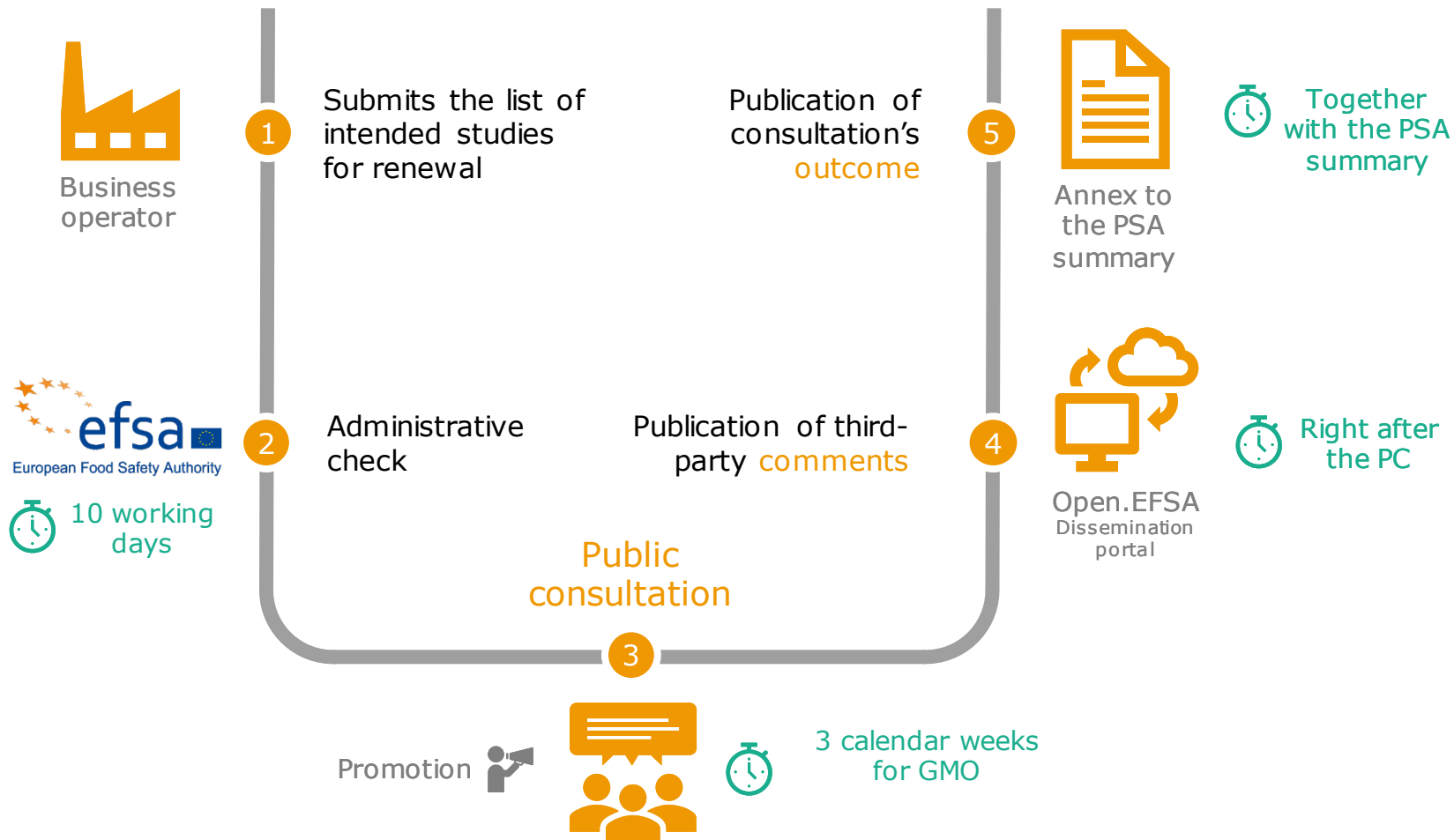


EFSA may review its decision in case scientific output identifies foreseeable effects on human health, animal health or the environment (*Art 39c GFL*)

# Public Consultations

- Draft risk assessment protocol
- Draft scientific output
- DAR/RAR/ED report (PEST)
- **List of intended studies for application for renewal**
- **Non-confidential version of a validated application**

## PC on the list of intended studies for application renewal

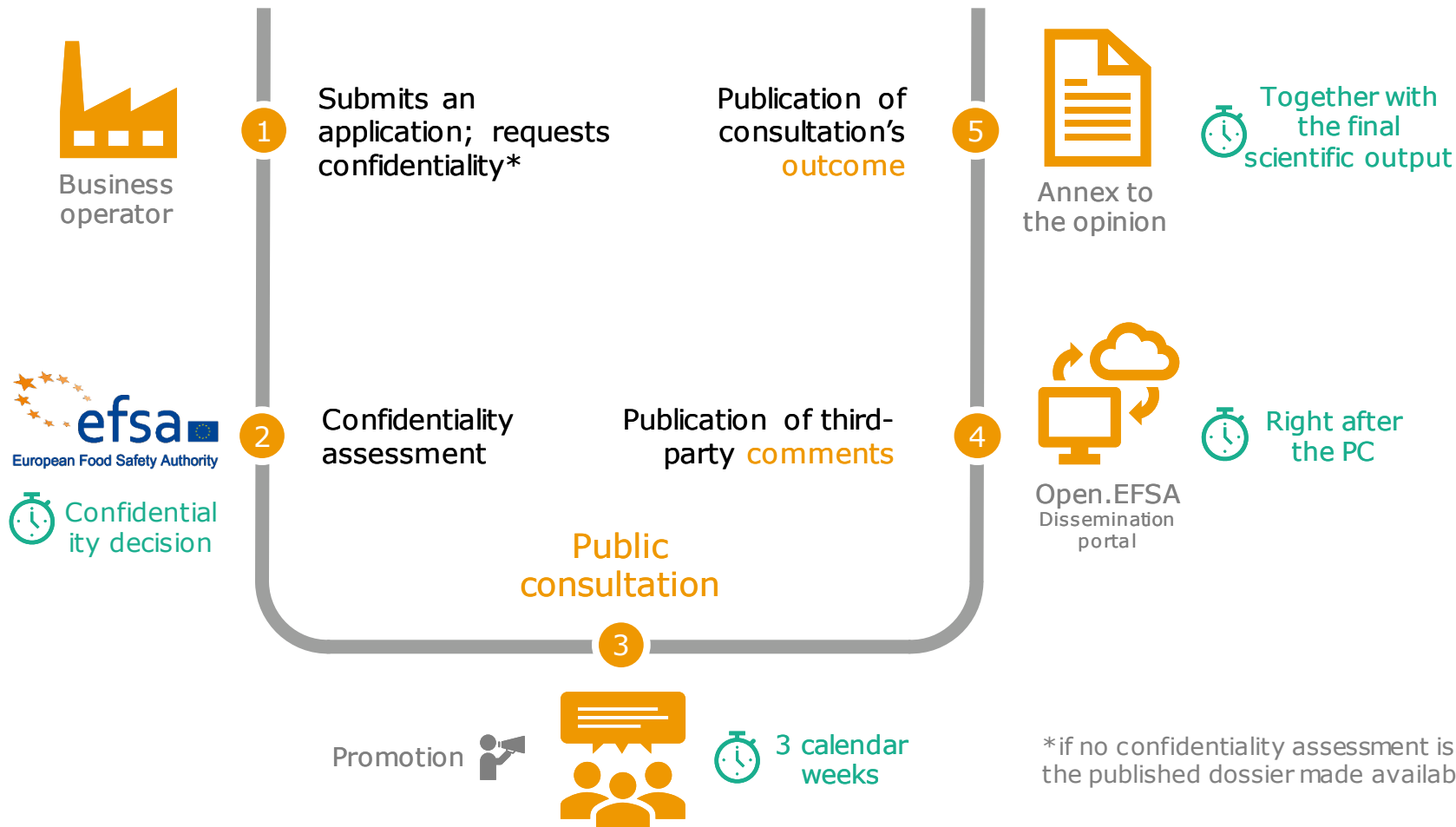


**Aim:**  
Inform the elaboration of the renewal pre-submission advice to a potential applicant



**When:**  
Pre-application phase (ahead of renewal)

## PC on the non-confidential version of a validated application



**Aim:**  
Collect new or additional evidence/data/information to assess an application

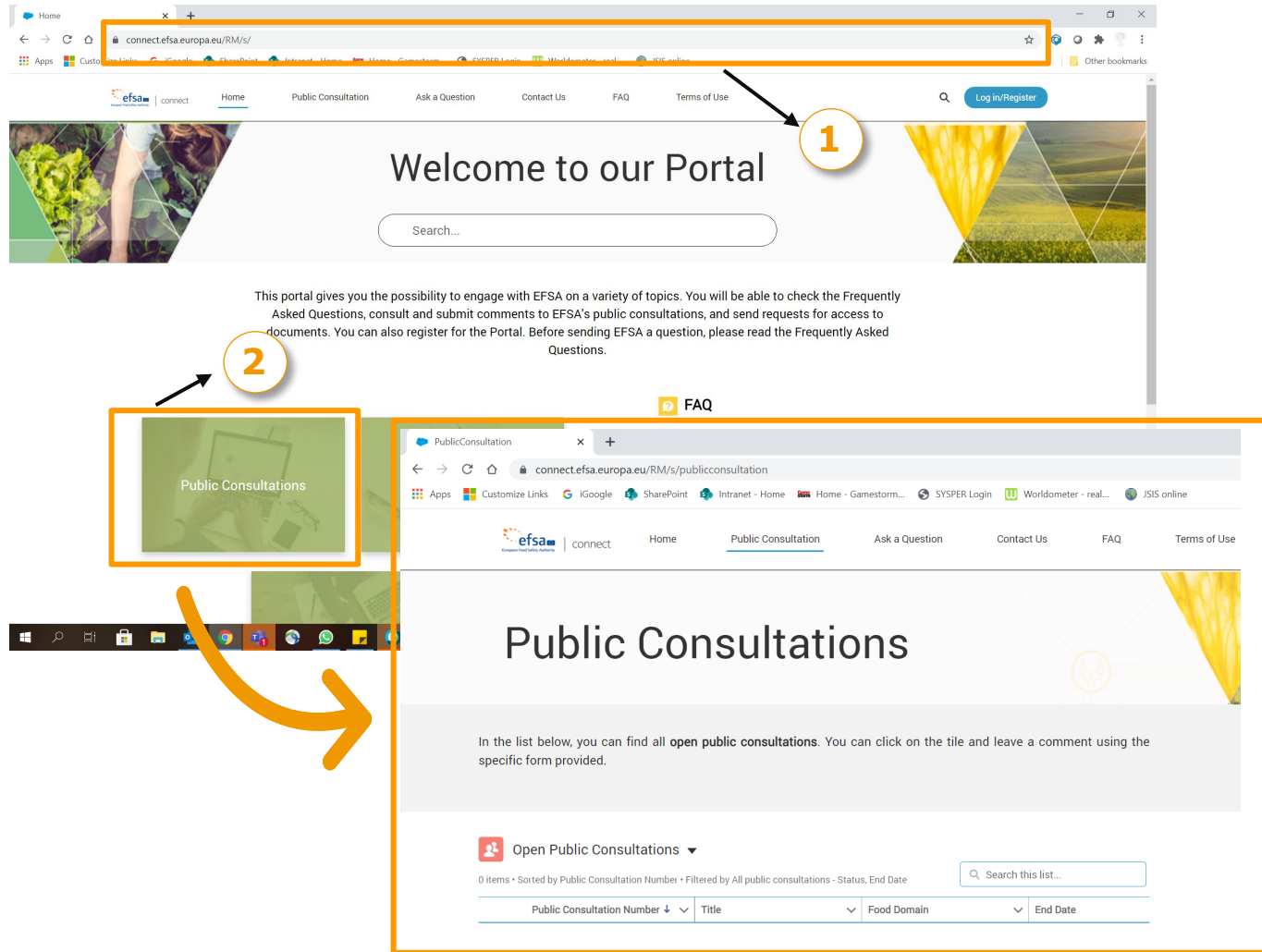
**When:**  
After the confidentiality assessment of the dossier

\*if no confidentiality assessment is requested by the applicant, the consultation is run on the published dossier made available through the Open.EFSA portal. Step 2 is skipped.



# Public interface: The Connect.EFSA community portal

## Screen



## How to access the portal

- 1 Click **this link**  
<https://connect.efsa.europa.eu/RM/s/publicconsultation>
- 2 Click on '**Public Consultations**'
- 3 Display the **list** of planned/open/closed consultations

The portal is easily accessible from the EFSA website

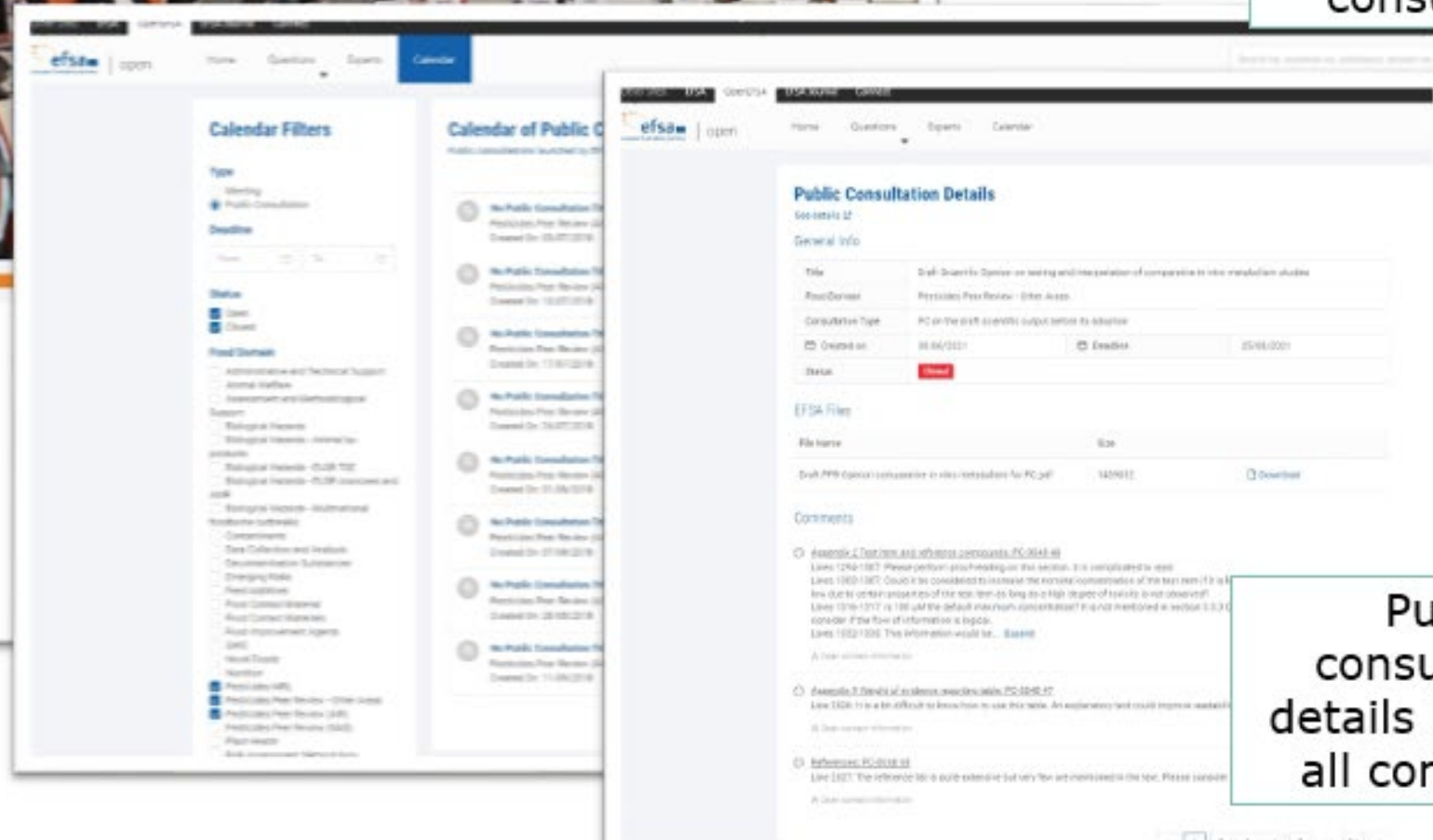
# Open EFSA - Publishing of comments

Open EFSA

Calendar

Closed consultations

Public consultation details including all comments

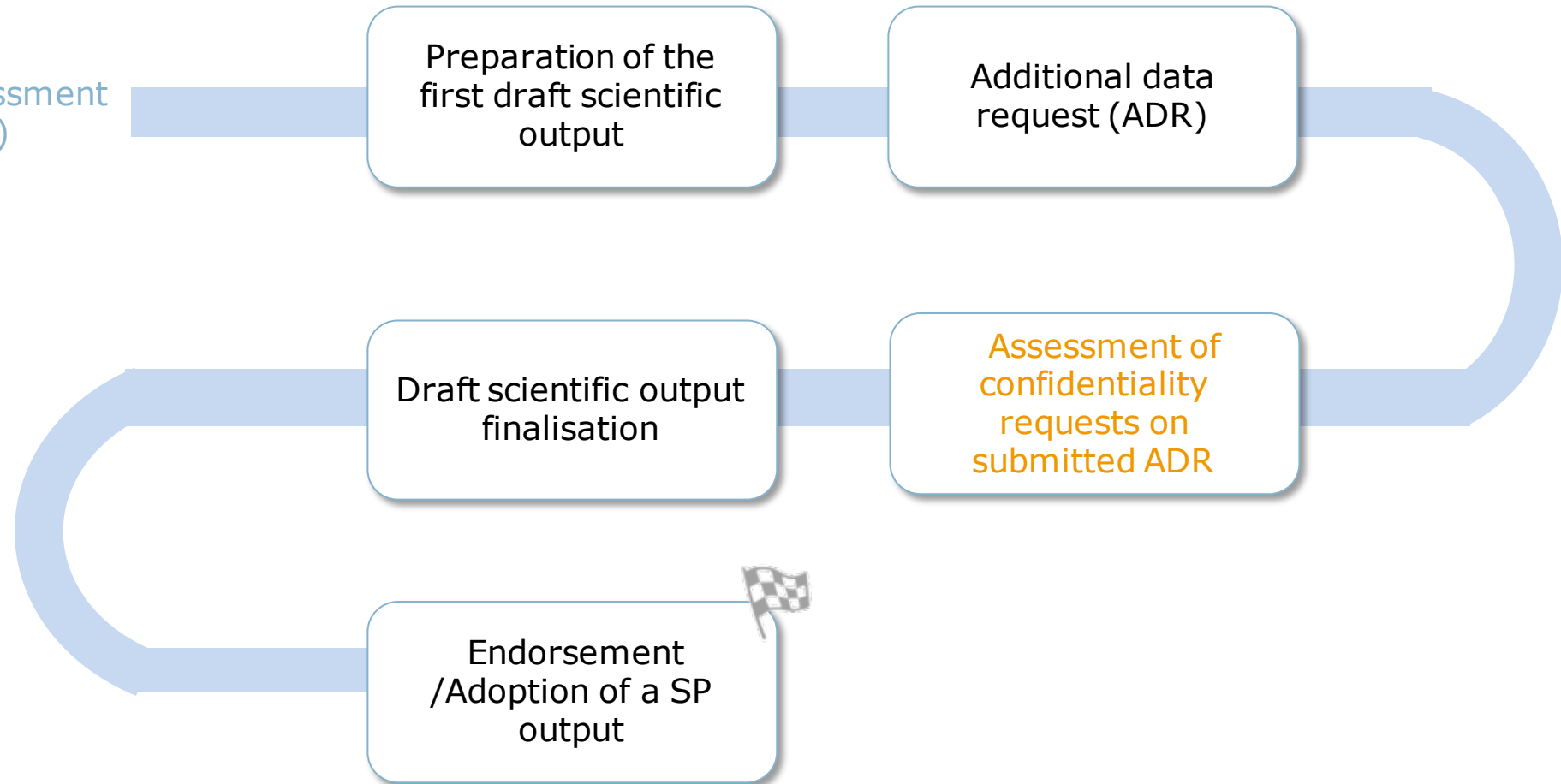


The screenshot displays the EFSA Open website interface. On the left, there is a 'Calendar Filters' sidebar with sections for 'Type' (Public Consultation), 'Deadline', 'Status' (Open, Closed), and 'Food Domain' (Administrative and Technical Support, Animal Health, etc.). The main area shows a 'Calendar of Public Consultations' with a list of entries. One entry is selected, showing 'Public Consultation Details' for 'Draft Study to Support on testing and evaluation of comparative in vitro metabolism studies'. The details include 'General Info' (Title, Period, Consultative Type, Created on, Deadline) and 'EFSA Files' (File Name, Size, Download). The 'Comments' section contains several entries with text and links.

# **Risk Assessment, Adoption and Publication**

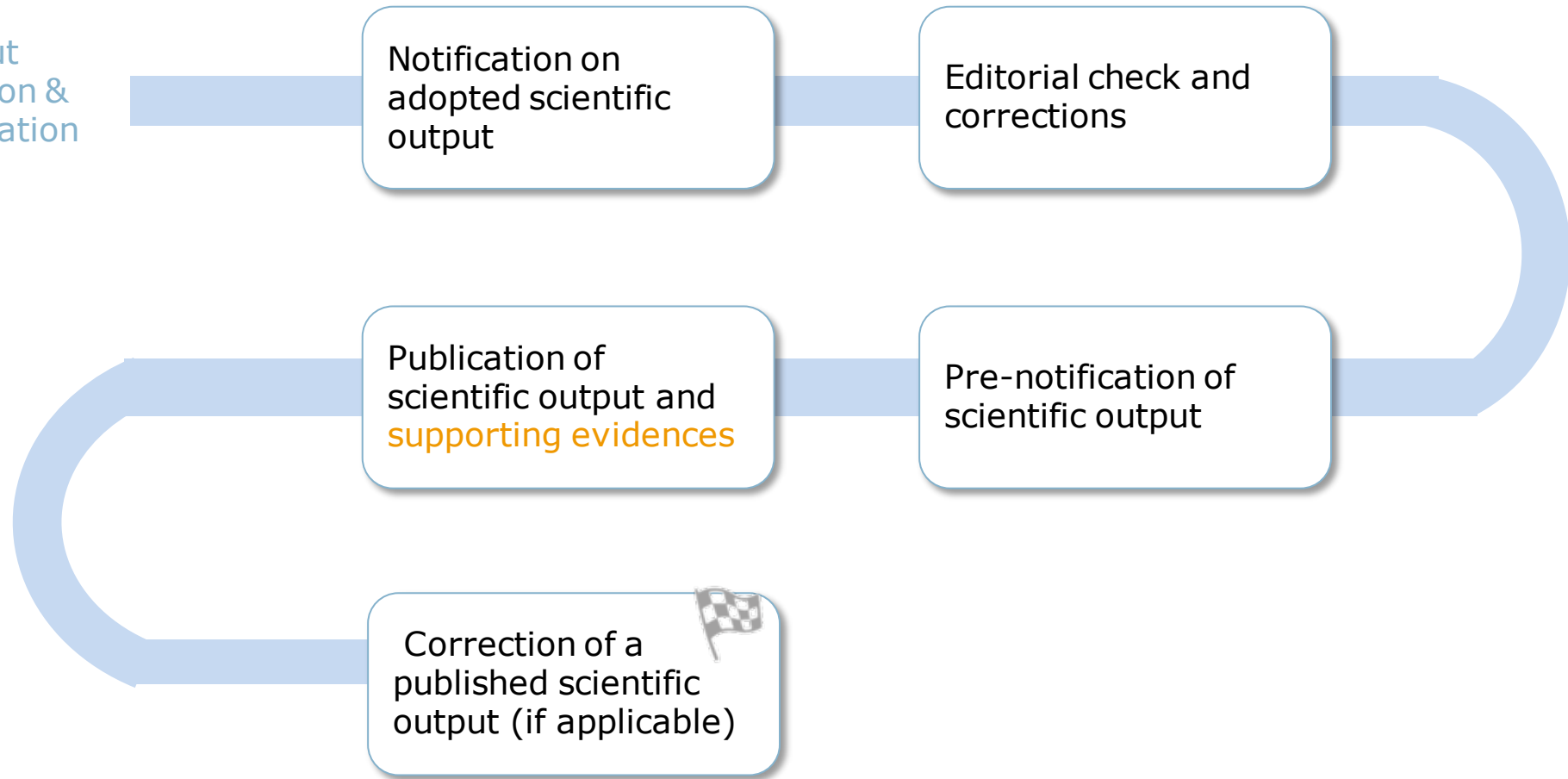


## Risk Assessment (RA)



04

Output  
Publication &  
Dissemination



## Legal documents:

- TR: [Regulation \(EU\) 2019/1381](#)
- General Food Law: [consolidated text of Regulation \(EC\) No 178/2002](#)
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003R1829>
- PAs on transparency and confidentiality: [Practical Arrangements concerning transparency and confidentiality](#)
- PA on pre-submission phase and public consultations; [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf)
- Q&A on Practical arrangements: <https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>

## Guidance/training material:

- [GMO: guidance web section](#)
  - [Administrative guidance for the preparation of applications on genetically modified plants;](#)
  - [Administrative guidance for the preparation of renewal applications on genetically modified food and feed](#)
- [Catalogue of services \(update 2021\)](#)
- [Administrative guidance for the processing of applications for regulated products \(update 2021\)](#)
- [Training programme on Transparency regulation](#)
- Toolkit page: <https://www.efsa.europa.eu/en/applications/toolkit>
- [User Guide - Notification of Studies \(updated on 4 Feb 2022\)](#)
- [User Guide - Pre-application ID \(updated on 4 Feb 2022\)](#)



# Questions & answers session

Trusted science for safe food

## Join our new LinkedIn group: “EFSA support to applicants”

A space where you will find:

- Information and support materials
- Updates on the developments and progress of IT tools and platforms
- Alerts on new training material and upcoming events
- Clarifications to the most frequently asked questions received by applicants
- A space for interaction with your peers.



<https://www.linkedin.com/groups/9083910/>

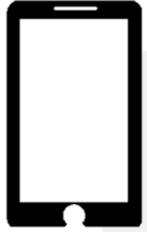


# Thank you for attending our webinar

In case we did not manage to answer all your questions, please feel free to re-submit them via **EFSA Ask a question** webform (EFSA.Connect at: <https://connect.efsa.europa.eu/RM/s/askefsa>)

The **recording of today's webinar** will be available on the EFSA website in coming days

Please take few minutes to fill out the **evaluation form** that you will receive shortly in your inbox. Your feedback is essential to improve our future webinars



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