03 March 2022

EFSA webinar series

Webinar on application procedure for GMO

Trusted science for safe food

efsa
European Food Safety Authority

Agenda

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

Welcome and Introduction

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.

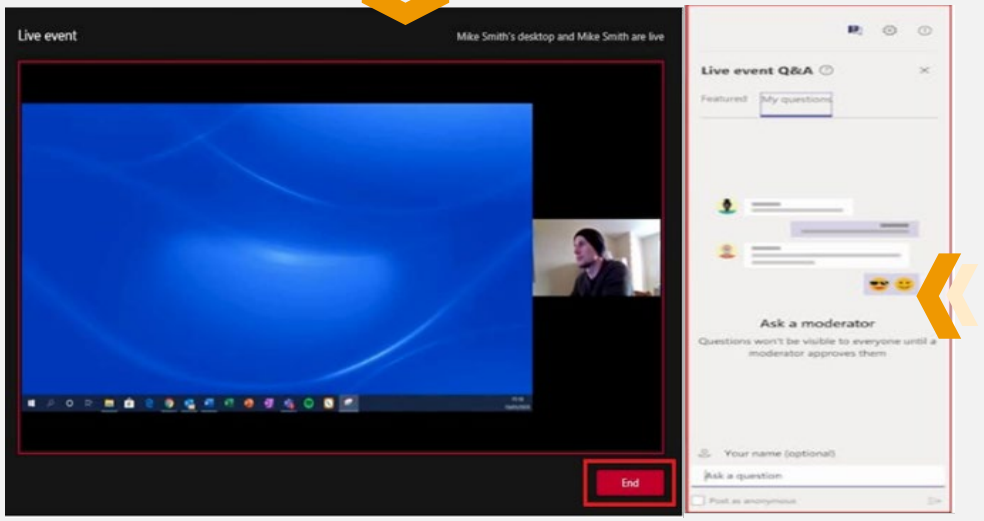
Out of scope:
- Clarifications about aspects of the authorization process which have not been affected by the Transparency Regulation.
- Clarifications related to the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Webinar guide for attendees

- 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

Transparency Regulation from 27th March 2021

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 27th March 2021

Click here to access the Factsheet: ”A Modern and Sustainable Food Law in the EU”

Applications Workflows

01 Mandate & Dossier intake

- Pre-intake activities (NoS, PSA)
- Mandate and dossier receipt
- Withdrawal of dossier
- Validity check & validation of dossier
- Publication of non confidential dossier
- Assessment of confidentiality requests on the valid / admissible dossier
- Public Consultation
- Targeted consultations with Member States

02 Preliminary activities to Risk Assessment

- EFSA preparatory steps

03 Risk Assessment (RA)

- Preparation of the first draft scientific output
- Request for Additional Information (RFI)
- Assessment of confidentiality requests on submitted RFI (if applicable)
- Draft scientific output finalisation
- Endorsement /Adoption of a SP/SC output

04 Output publication & dissemination

- Notification on adopted scientific output
- Editorial check and corrections
- Pre-notification of scientific output
- Publication of scientific output and supporting evidences
- Correction of a published scientific output (if applicable)

Confidentiality

New TOOLS for Business Operators

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

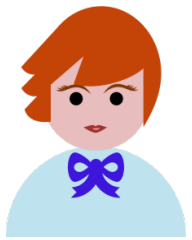
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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

Registration Process



Sarah

Potential Applicant

John

Laboratories
Testing facilities

Martin

Third Parties

The public
(during PC or once studies are published)

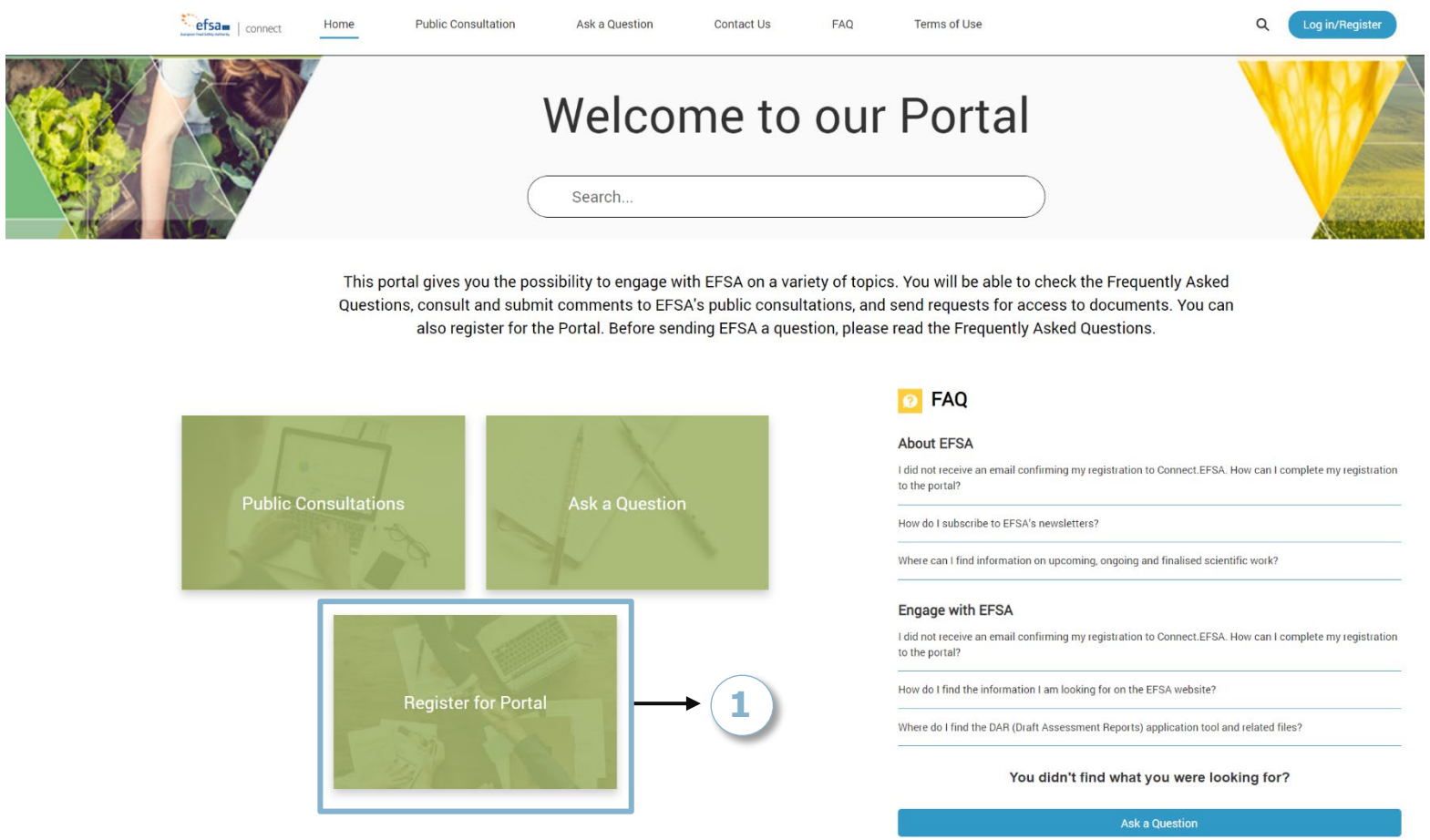
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

2. Third parties representing one or more entities shall also register in the Authority system supporting pre-submission activities …[1] 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.[1]

[1]) Practical arrangements on pre-submission phase and public consultations

Connect.EFSA Portal - Account Registration



Sarah

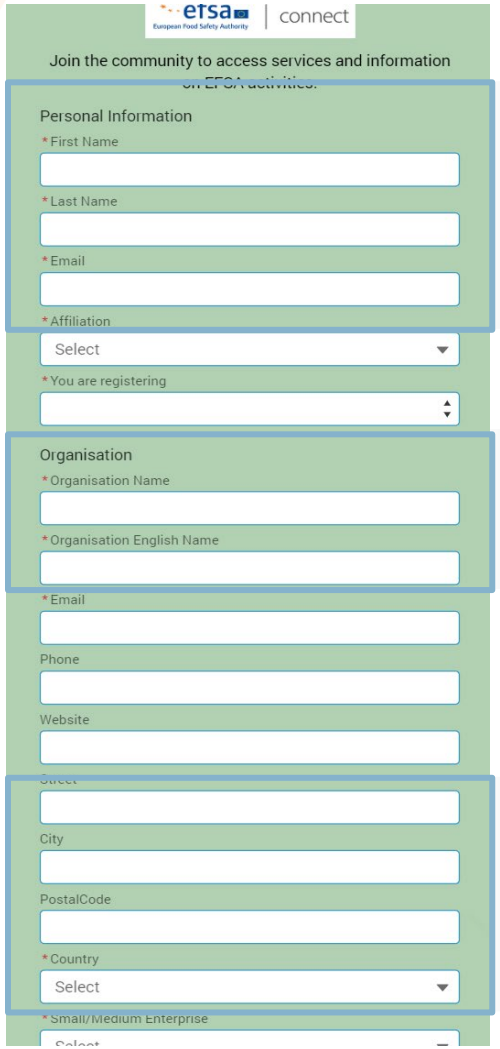
The potential applicant starts the registration in the portal.

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

1 Click here to register

Connect.EFSA Portal - Account Registration



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.

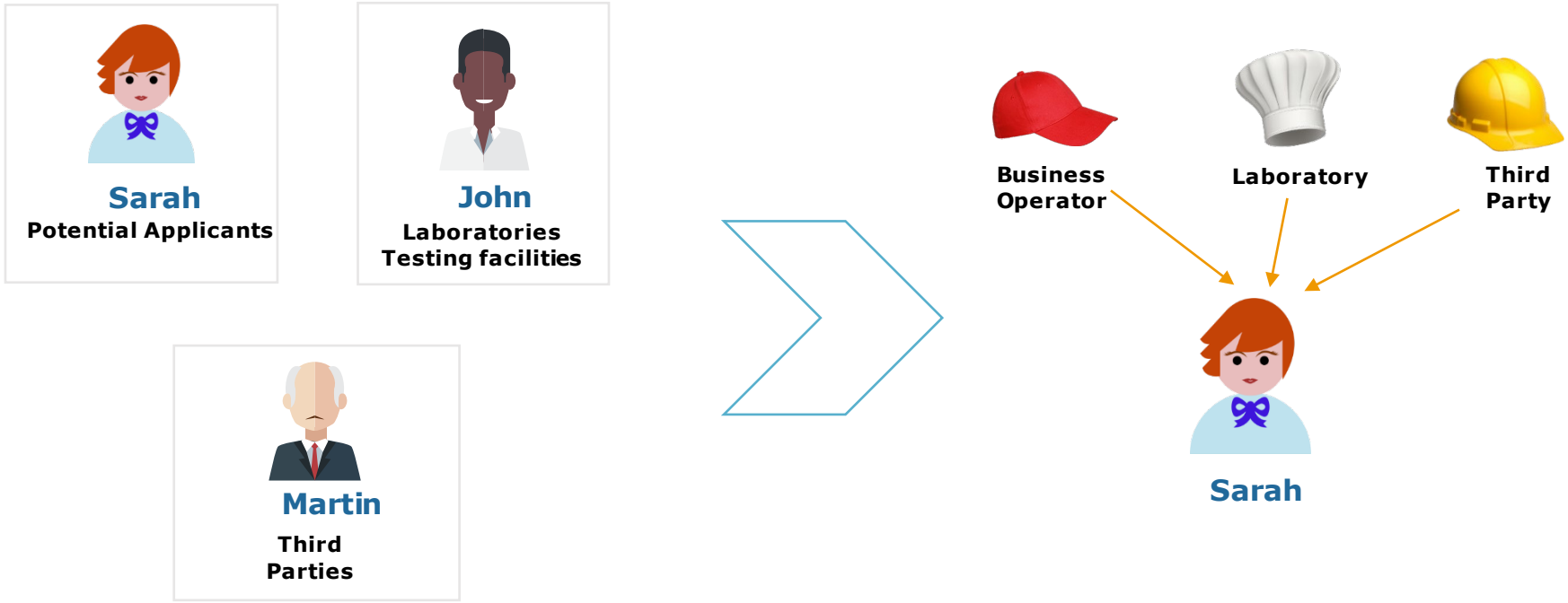
As regards **multinational companies** made up of several entities, any of these entities may register provided that the registered entity is recognised as having a **separate legal personality** under the national law of the country in which it has its registered office.

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

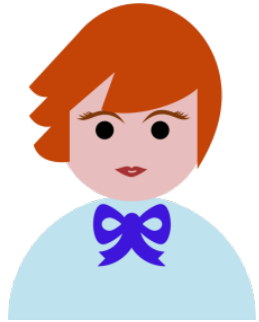
Detailed information is available in the **user guides** on **pre-application ID** and **study notification** **updated on 4 February 2022** and available on the **EFSA Toolkit page**

Webinars: Webinar 16 February (here). Webinar 25 March (here).

Pre-Application ID
Pre-submission advice
Notification of Studies

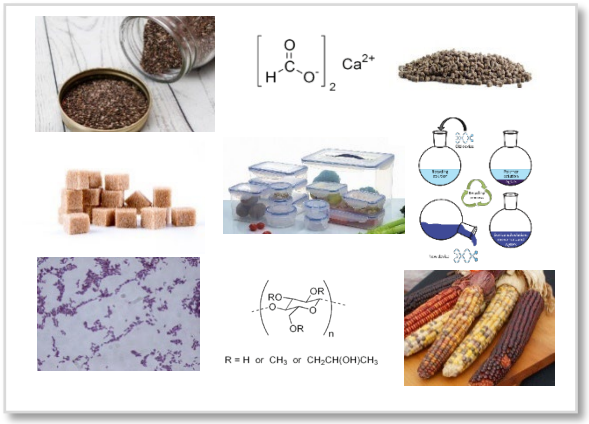
New applications

Pre-Application Identification



Sarah

Potential Applicants



Subject of the application

Intended Area

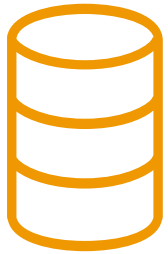
General Pre-Submission Advice

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

Notification of Studies for new application

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

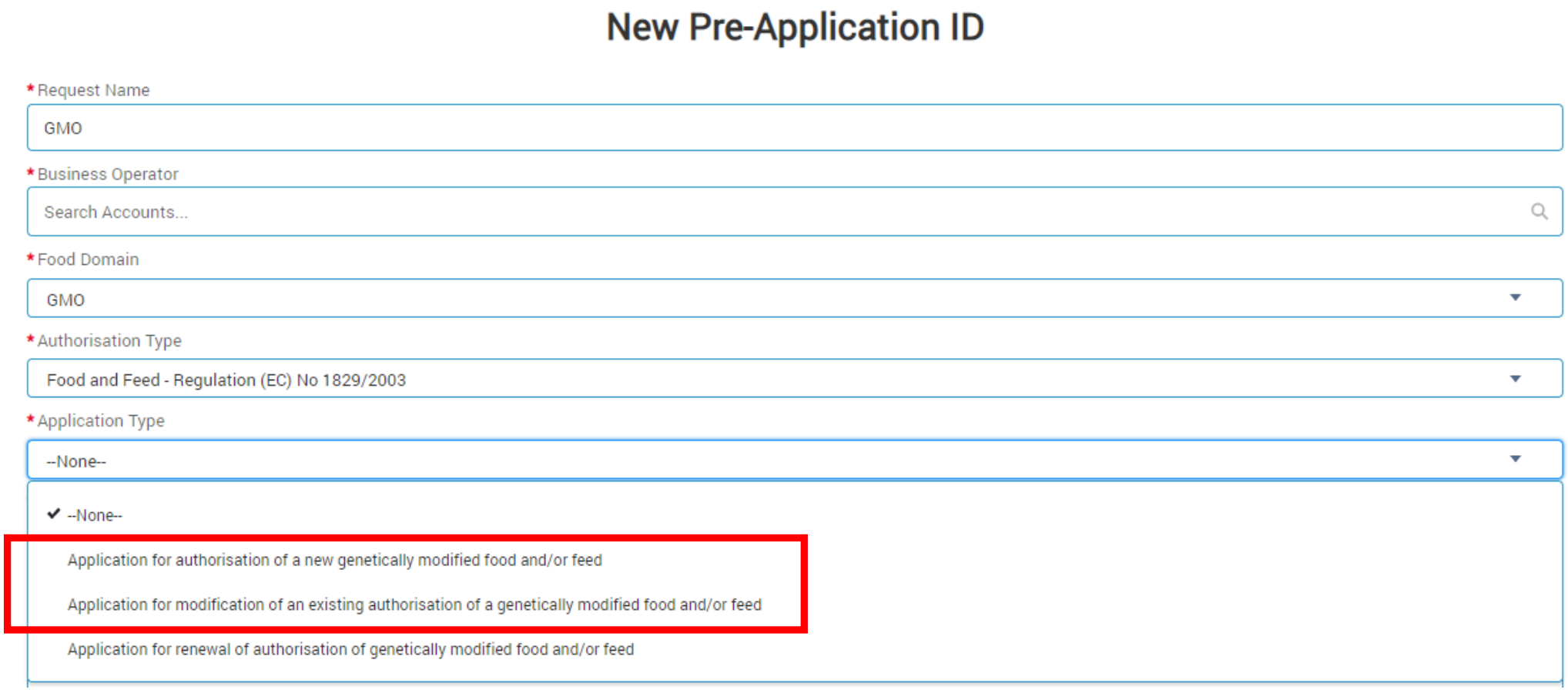
EFSA performs the validation of the application

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).



Renewal applications

General Pre-Submission Advice (for renewal)

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

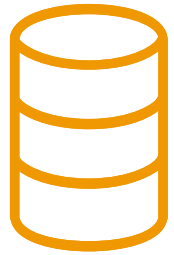
Notification of Studies for renewal application

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

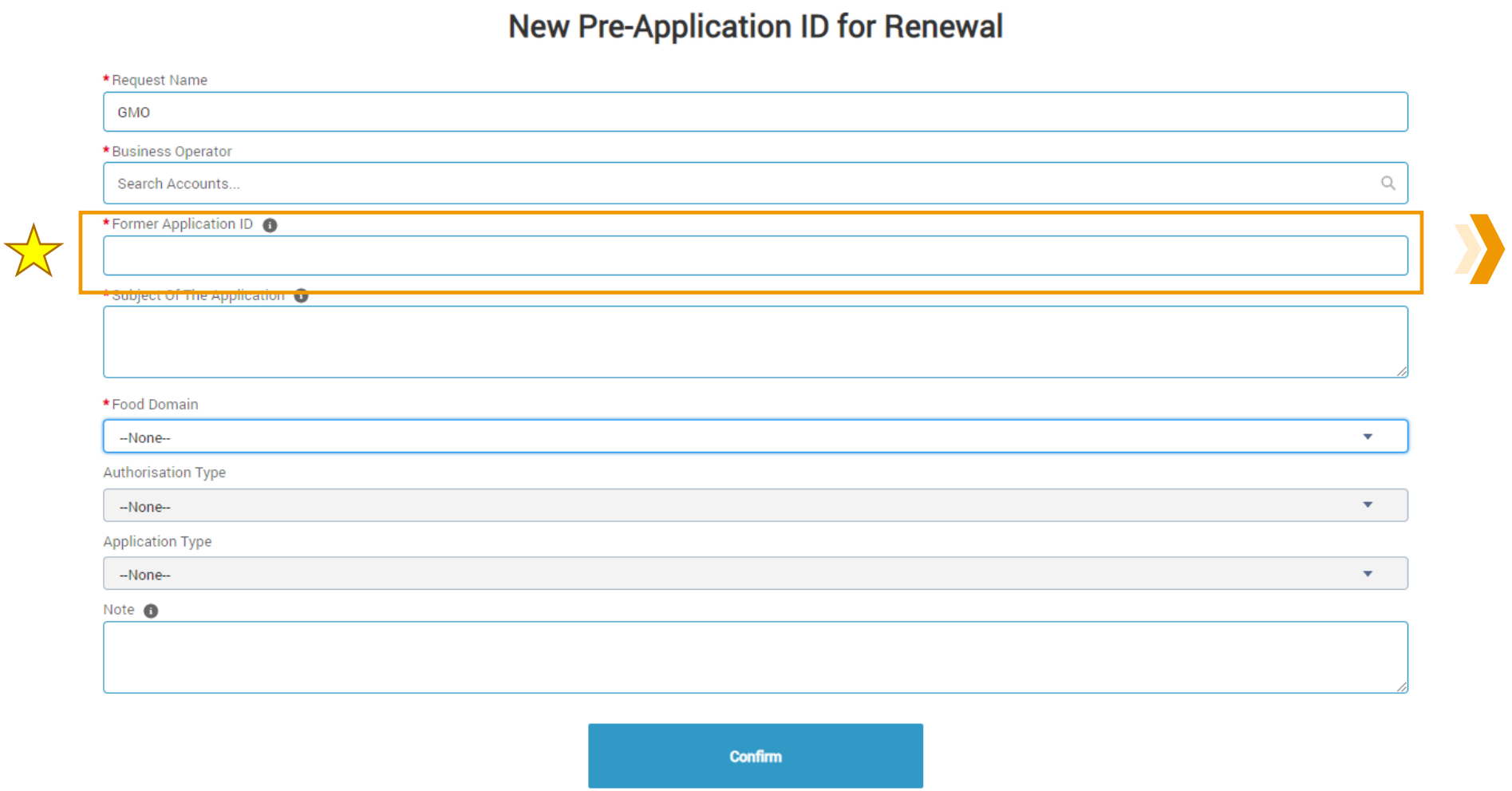
EFSA
Provides the renewal pre-submission advice

Step 3
Notify studies

The potential applicant notifies studies (Article 32b)

Pre-Application ID for Renewal

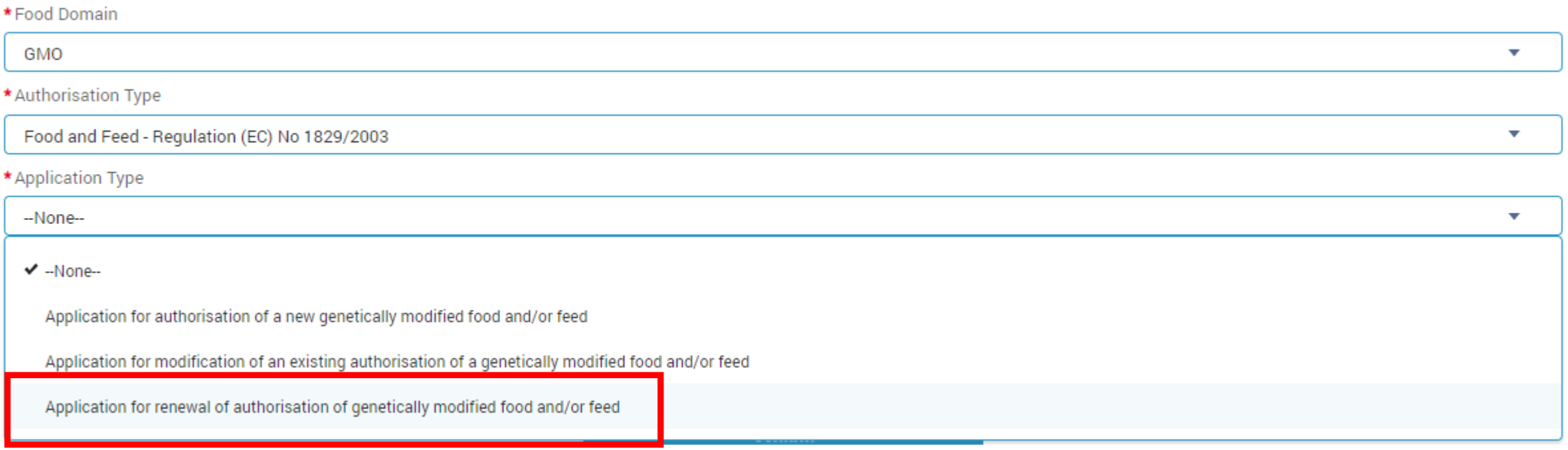
For renewal, the potential applicant should also prefill some information for the pre-application ID



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).

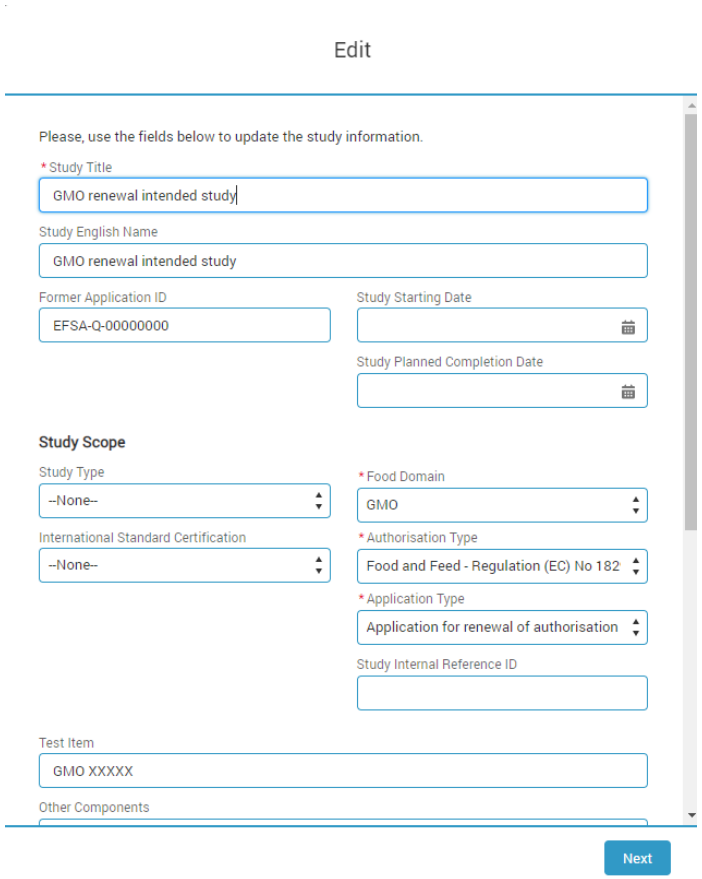


Pre-Application ID for Renewal: fill in intended study information

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

Fill in relevant information for **intended studies**

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



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)

E-submission Food Chain Platform (ESFC)

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

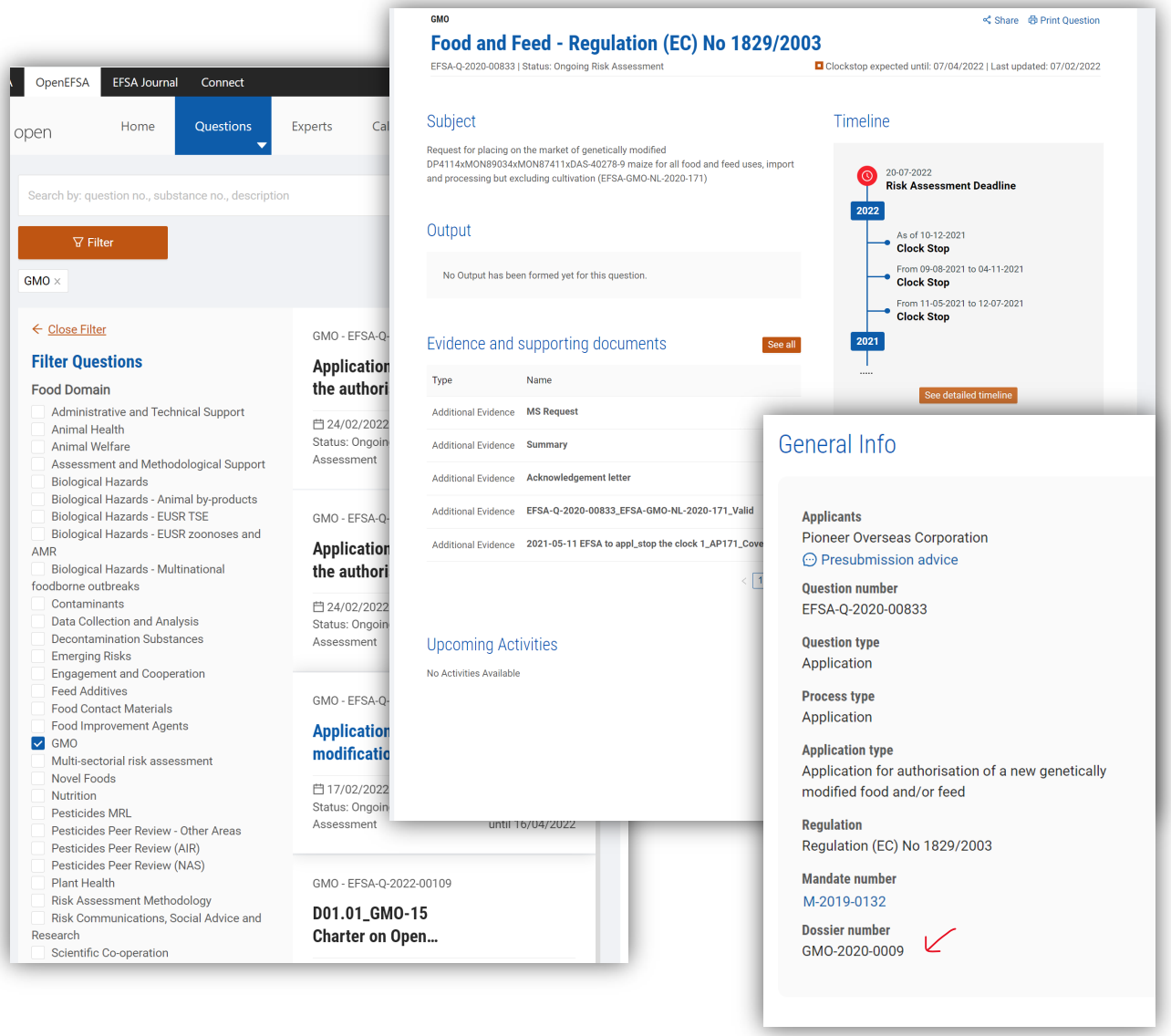
Dossier Intake and Portal Updates

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



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

GMFF 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

Transparency Regulation principles

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

Procedural requirements – Closed positive list

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**

Non-disclosure of Personal Data

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)

Substantive requirements

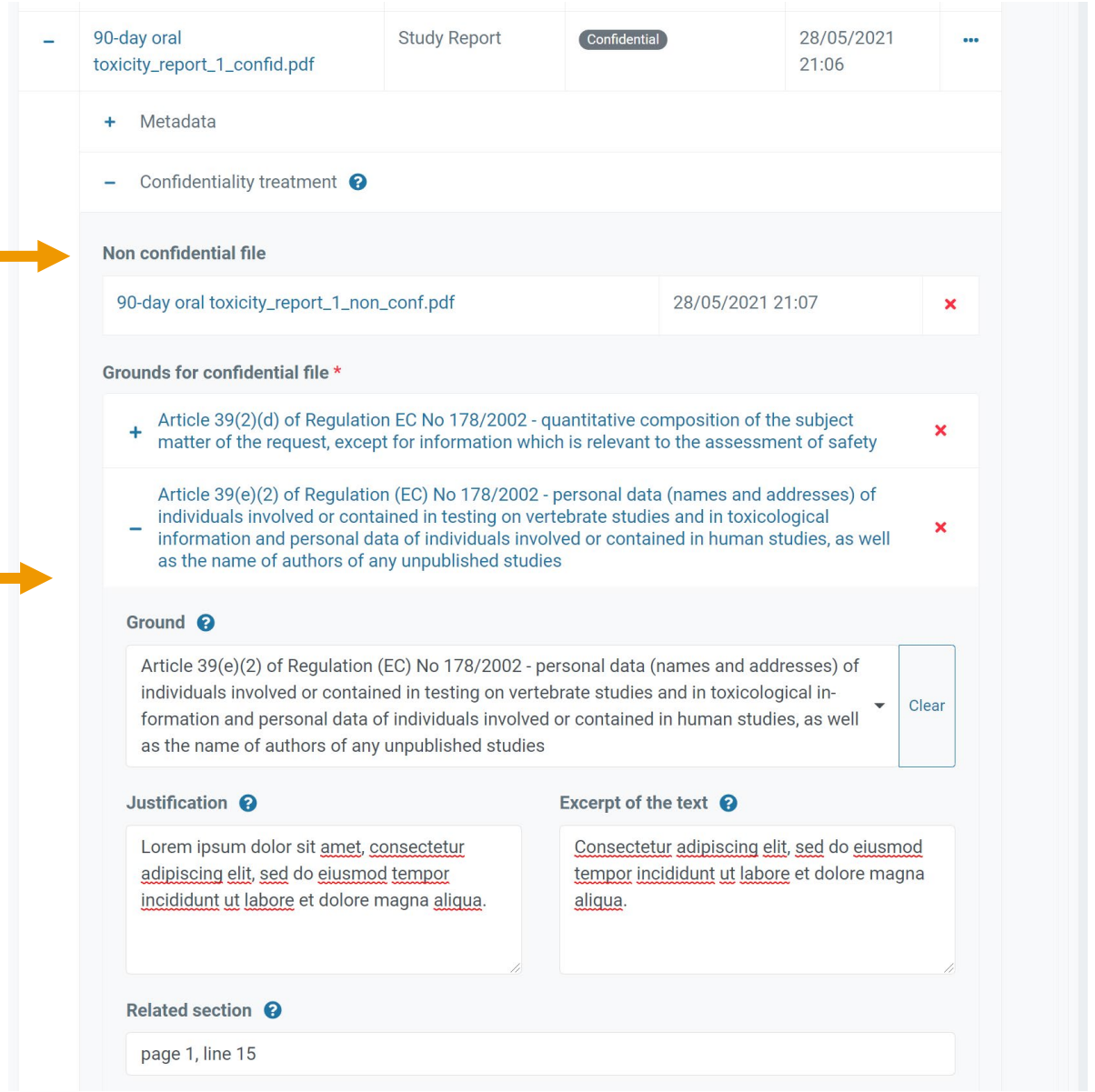
- Identifying clearly the information claimed confidential, with references
- Indicating the legal basis (grounds)
- Explaining why the item should be kept confidential:
  - Information not publicly available
  - Potential harm to a significant degree
    - Information acquired legitimately
    - Negligible harm – rebuttable presumption
    - Novelty – rebuttable presumption
  - Clarification on whether information claimed confidential falls under "environmental information" (Art 2 of Aarhus Regulation)

ESFC - Building a Confidentiality Request

- 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

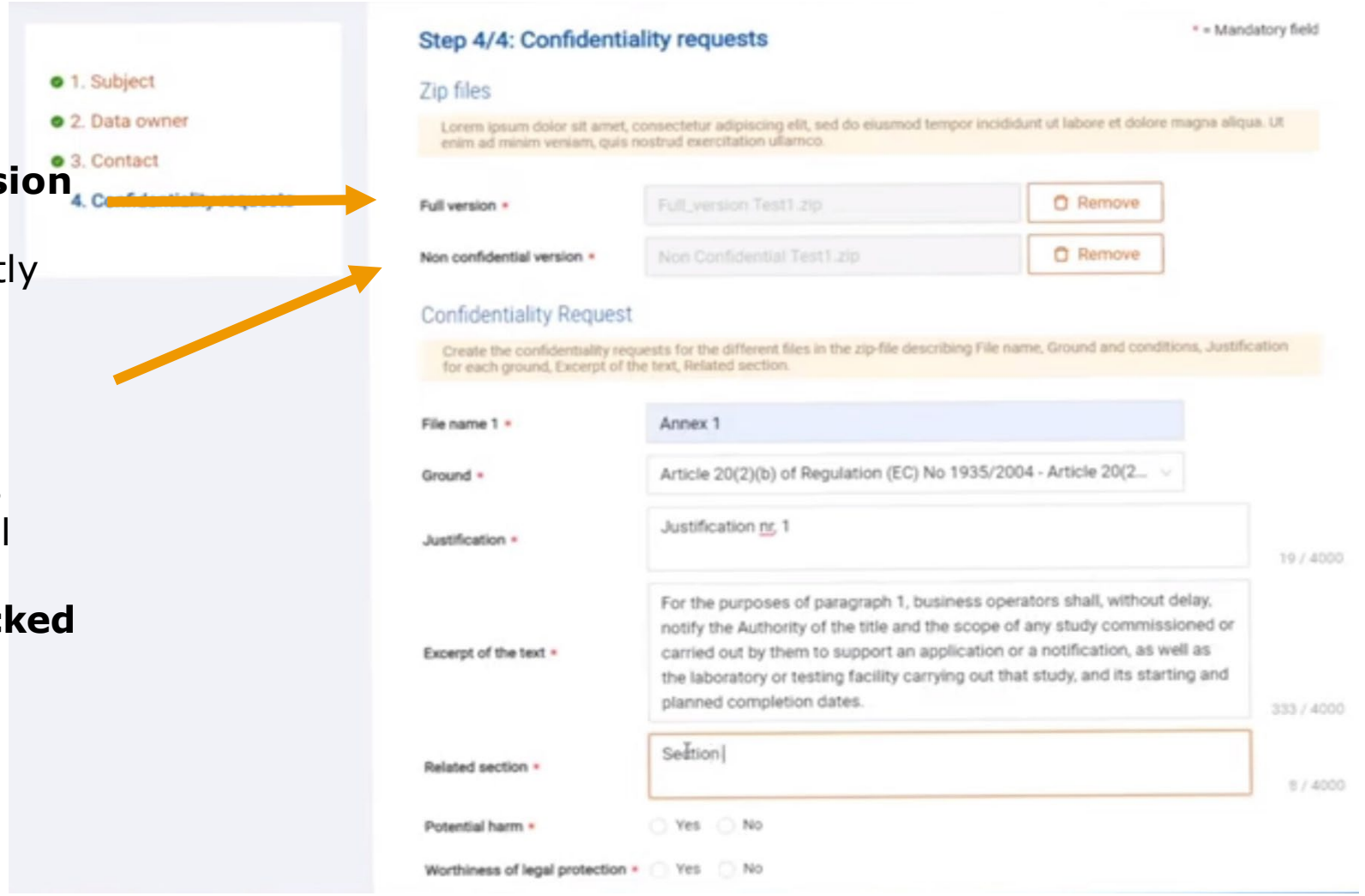


Portalino – building confidentiality requests (1)

- Provide non-confidential file AND confidential version of the file

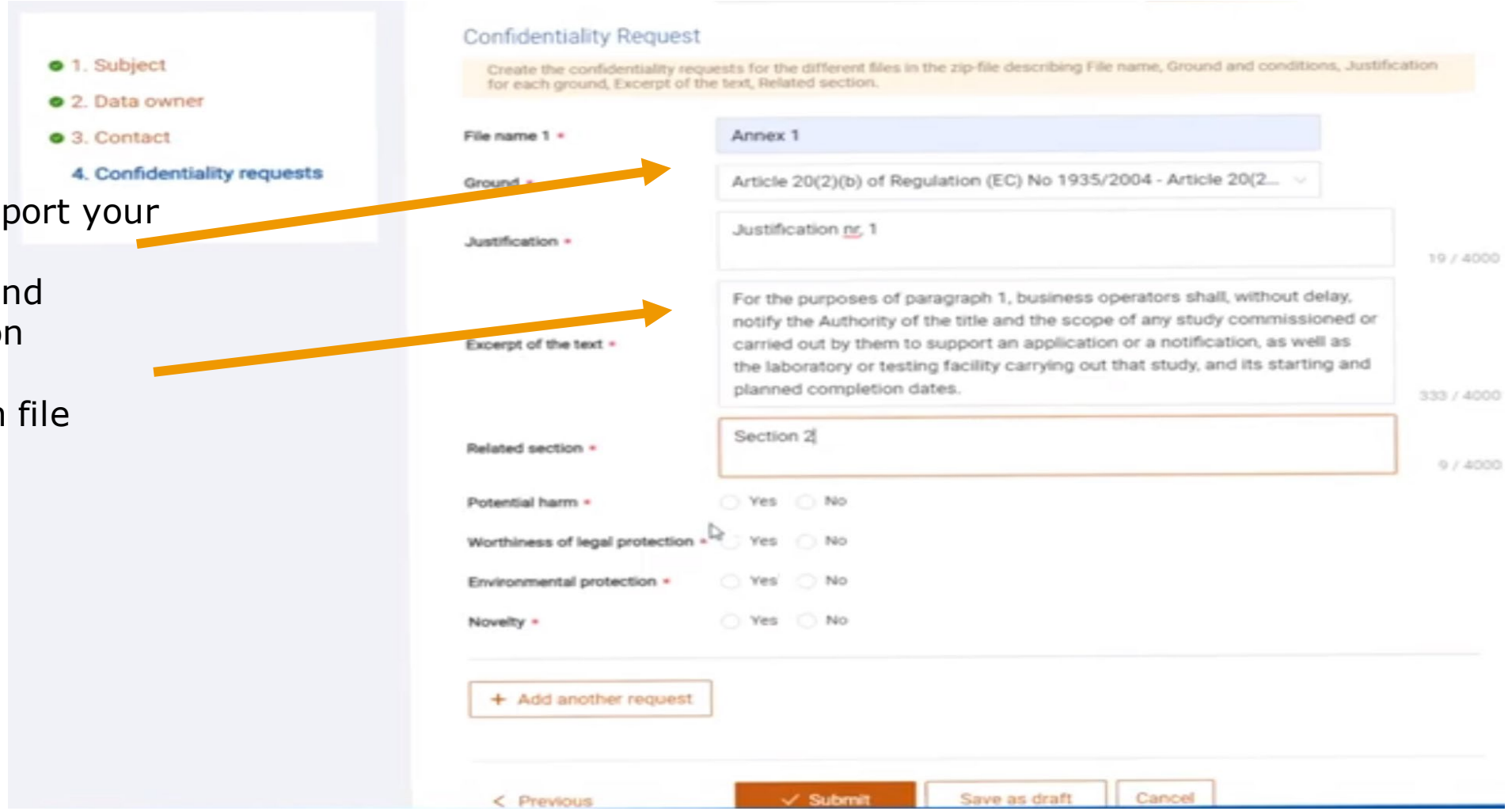
- Ensure that the **confidential version** of the document i**ncludes earmarked parts** matching exactly the blackened parts of the non-confidential version

- Ensure that information claimed confidential is redacted by using a redaction tool which ensures that the **redacted information is irreversibly blocked out.**



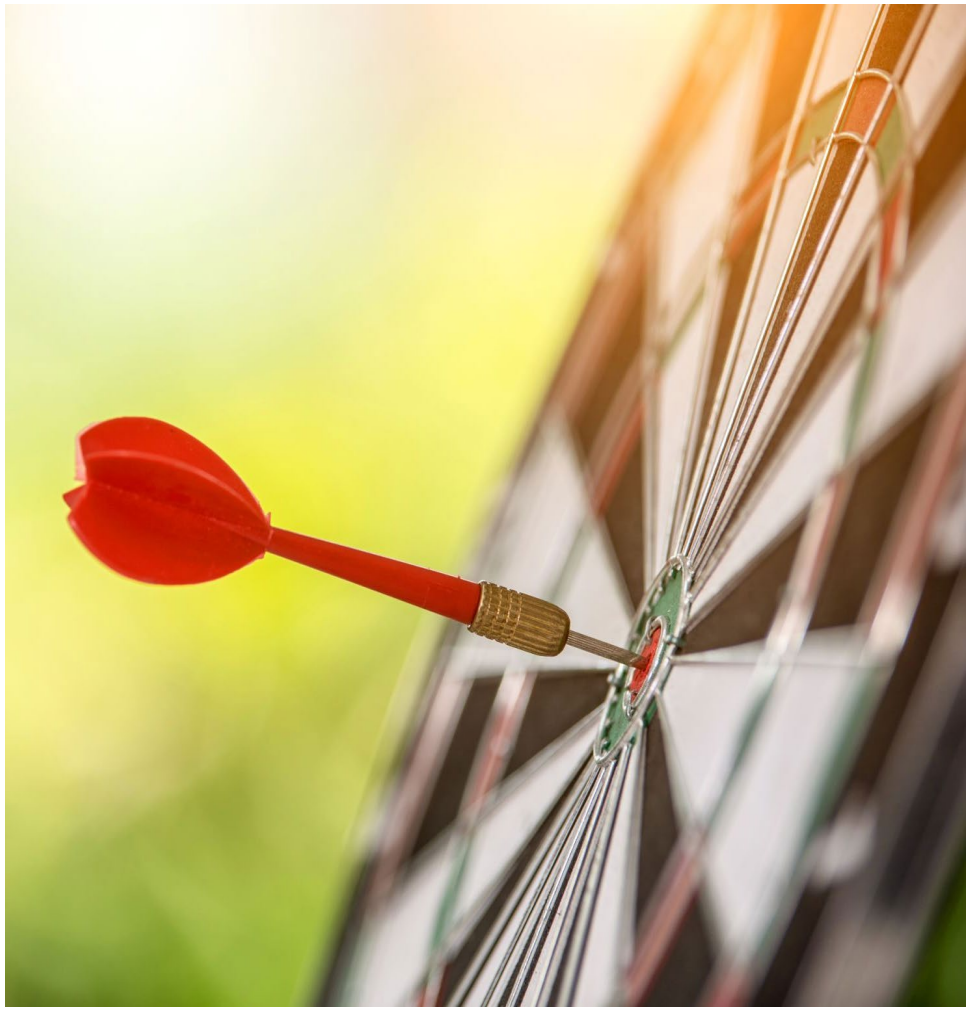
Portalino – building confidentiality requests (2)

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



Practical Tips

- ✓ 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

Notification of the final decision to the applicant via ESFC or email confidentialityrequestassessment@efsa.Europa.eu

Possibility to file confirmatory application via tool or email to

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)*

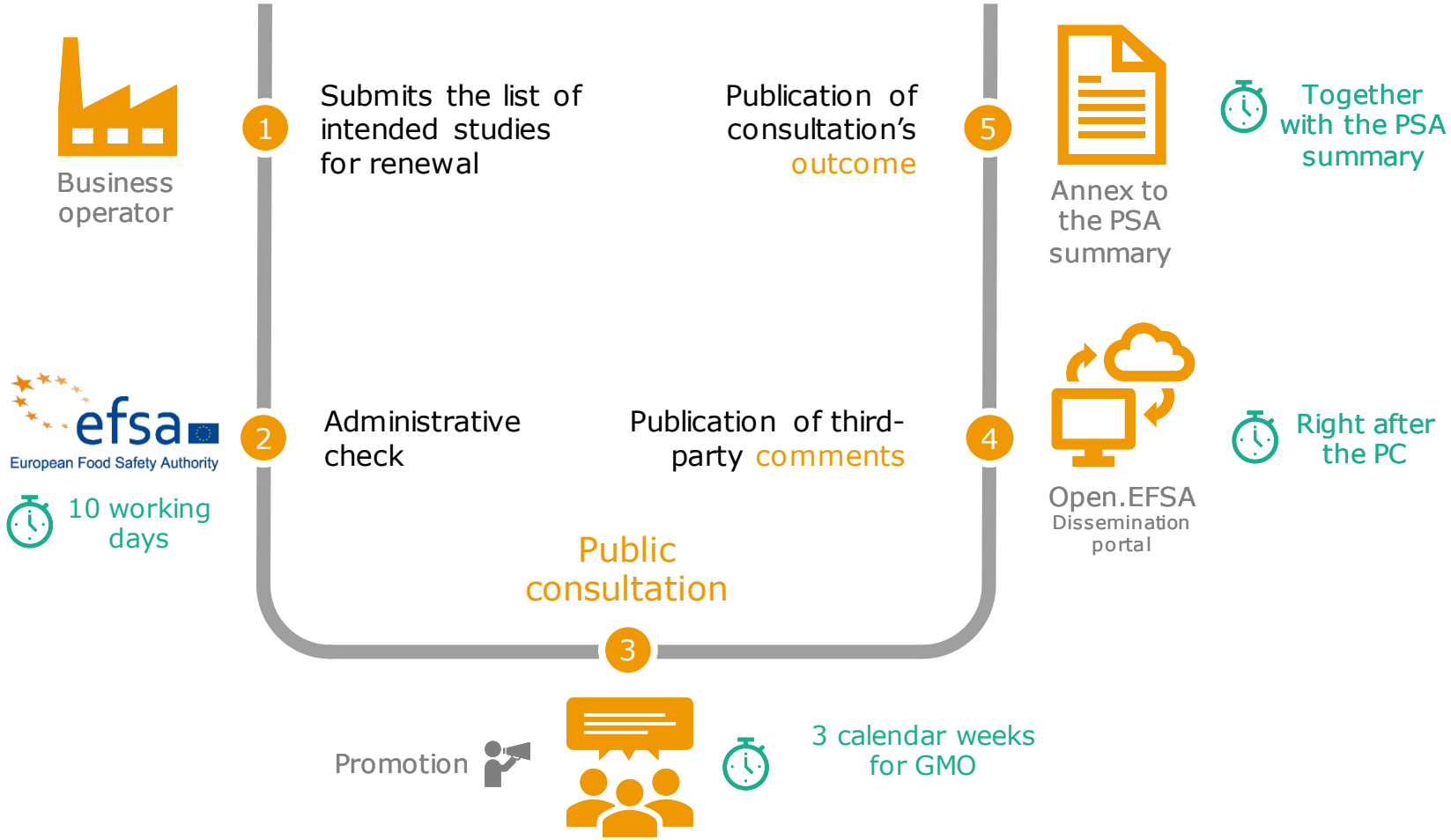
Public Consultations

EFSA's (main) types of PCs

- 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**

Overview of the process

PC on the list of intended studies for application renewal

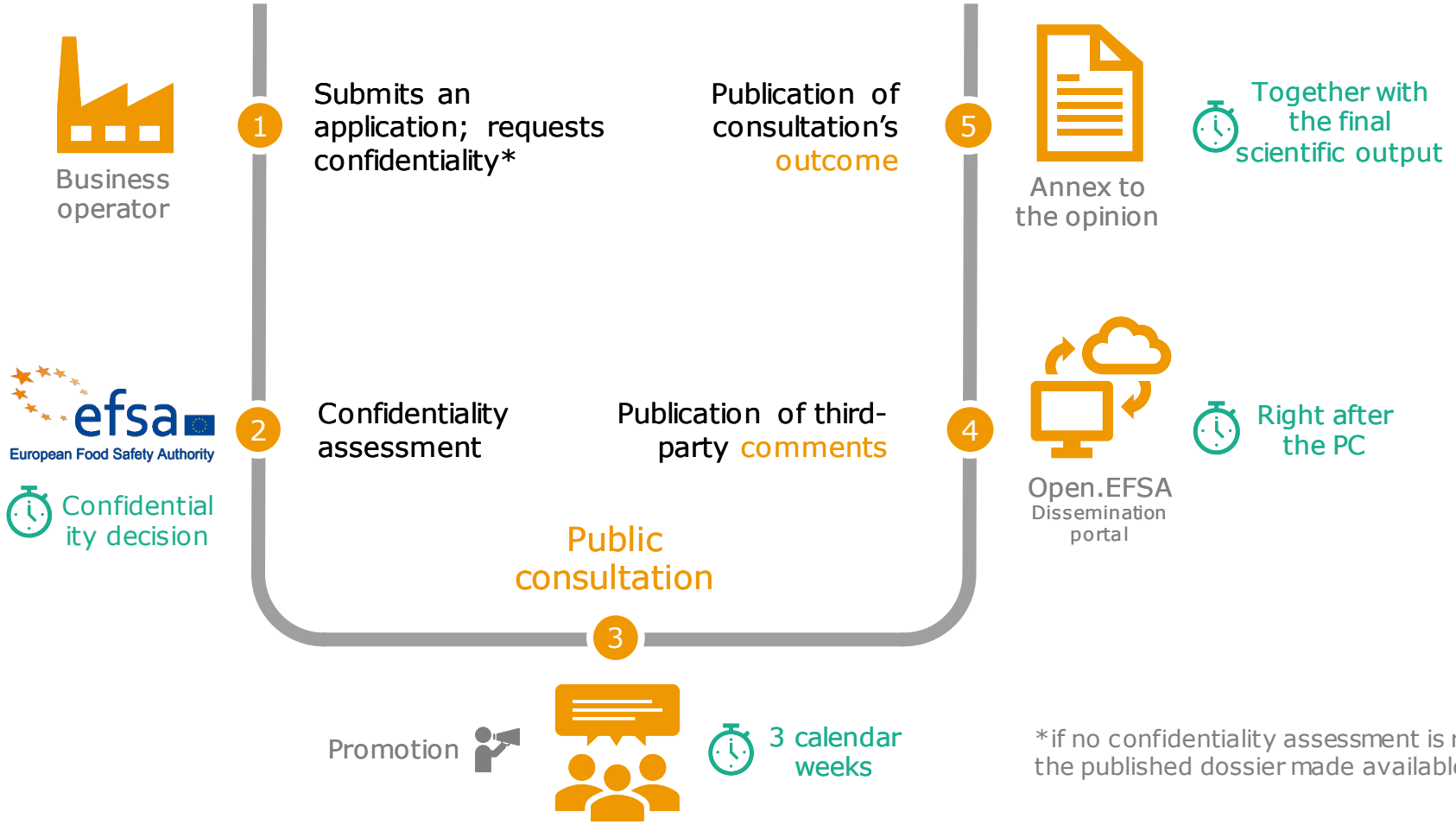


Aim:
Inform the elaboration of the renewal pre-submission advice to a potential applicant

When:
Pre-application phase (ahead of renewal)

Overview of the process

PC on the non-confidential version of a validated application



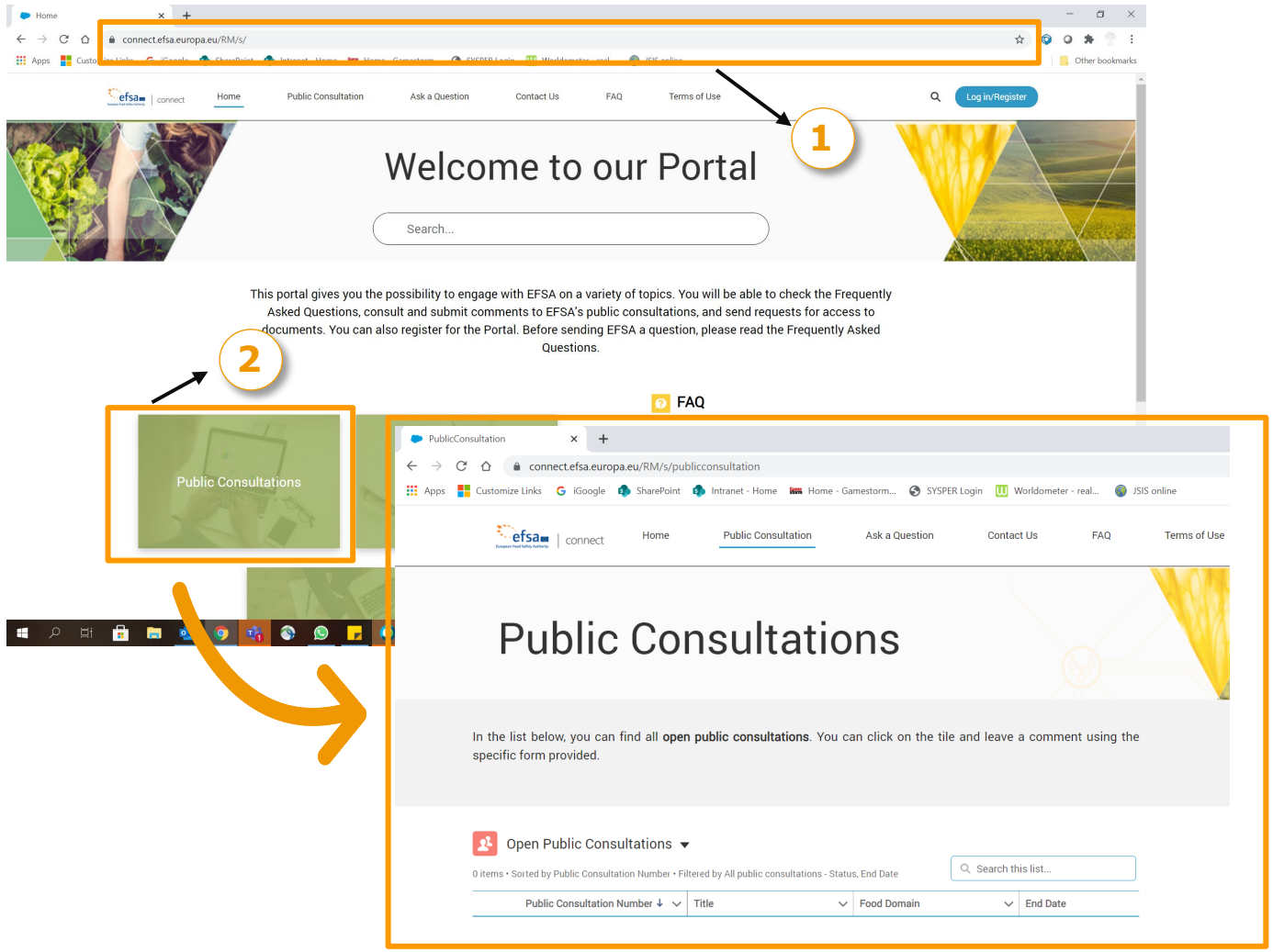
Aim:
Collect new or additional evidence/data/information to assess an application

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

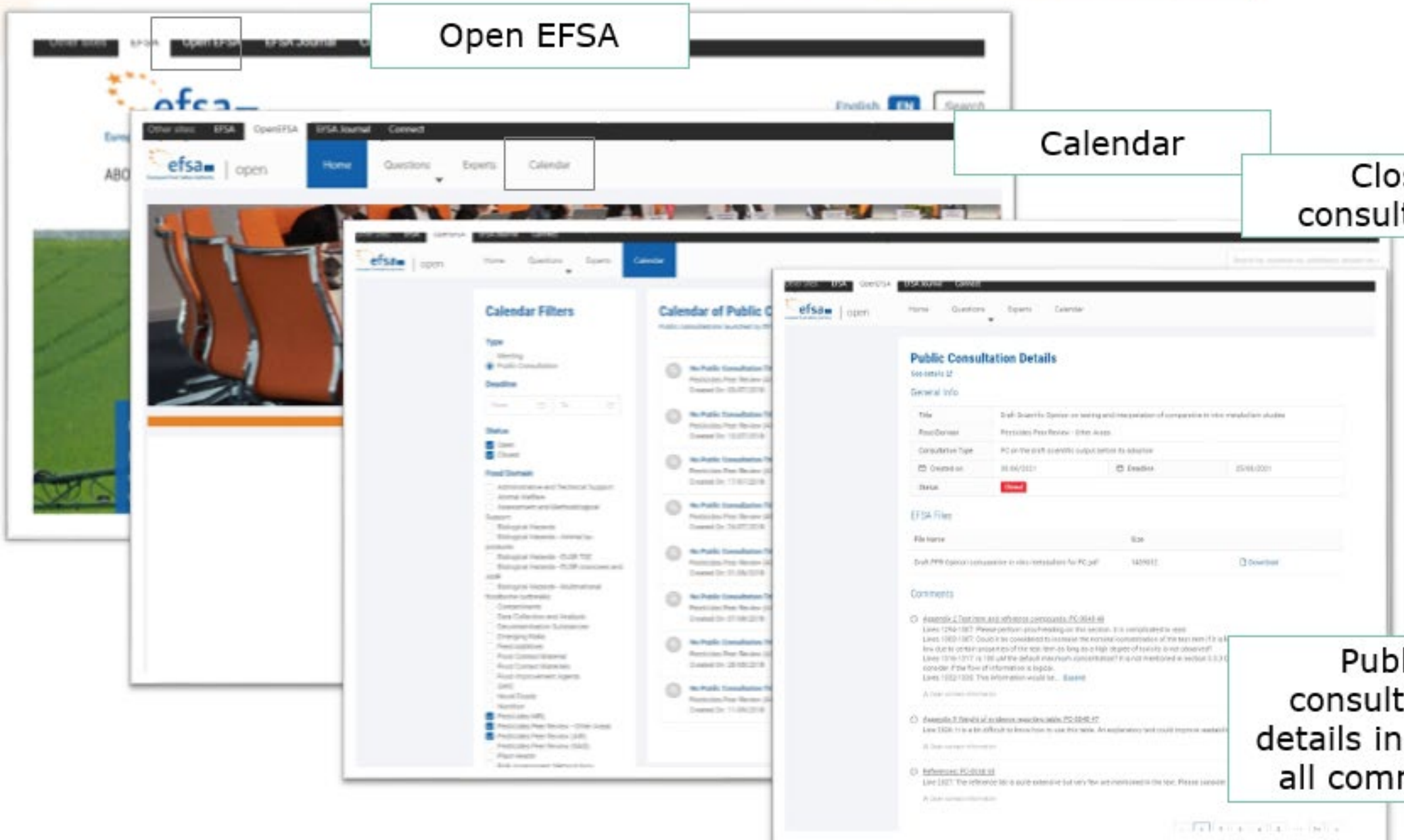


How to access the portal

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

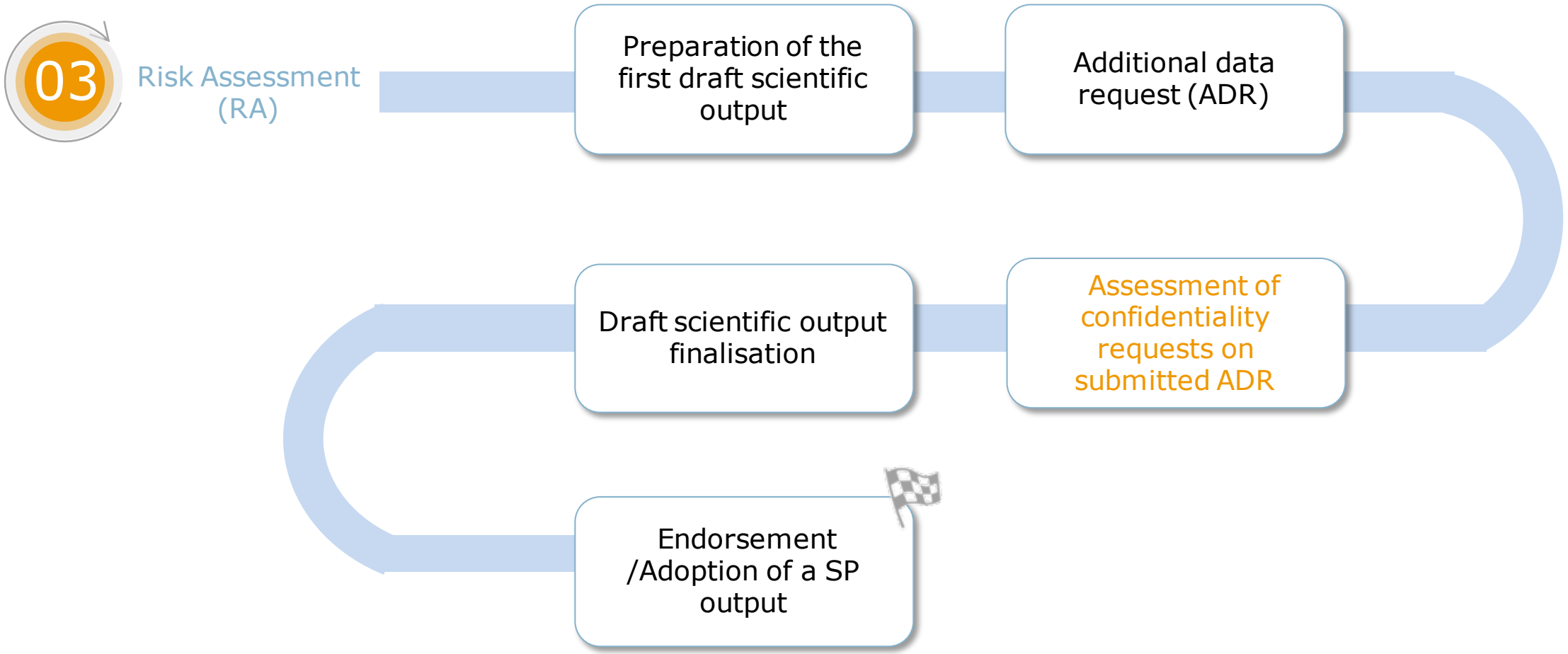
The portal is easily accessible from the EFSA website

Open EFSA - Publishing of comments



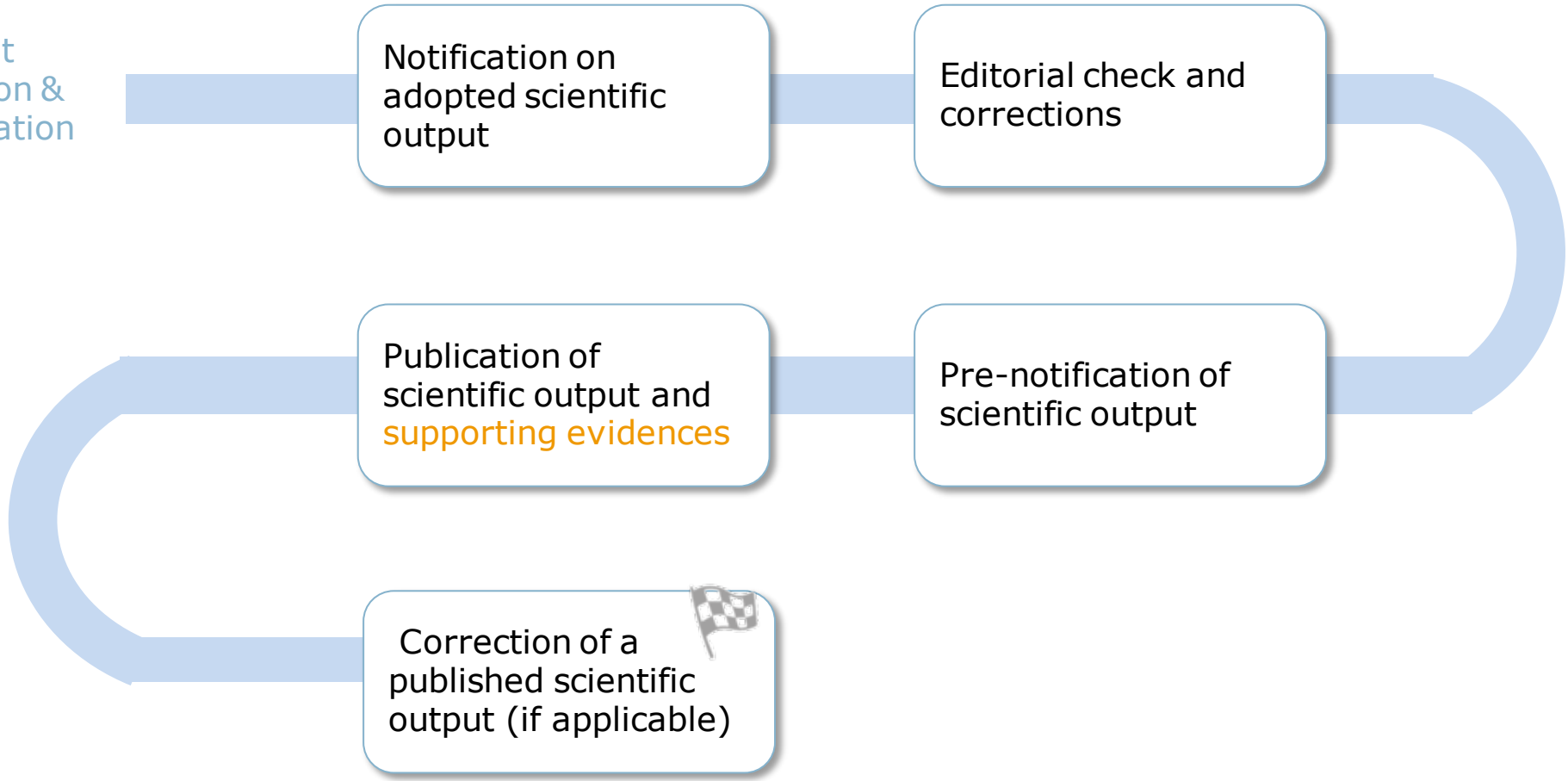
Risk Assessment, Adoption and Publication

Risk Assessment Phase



Output Publication & Dissemination phase

04 Output Publication & Dissemination



Useful information

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
- 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

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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

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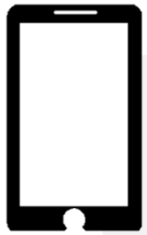

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