9 December 2021

APDESK webinars

Webinar on application procedure for smoke flavourings primary products

Trusted science for safe food

efsa
European Food Safety Authority

Agenda

Time	Topic	Speaker
11.00-11.05	Welcome and introduction	Margherita Guidi
11.05-12.00	Lifecycle of an application Account creation and management Pre-application ID, Pre-Submission Advice and NoS New applications, renewals and modification of authorisation E-submission (demo) Portal updates and validity of applications Confidentiality in the context of smoke flavourings Public consultation RA, adoption and publication	Karine Lheureux Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Stefano Cappé Sara De Berardis Costanza Casiraghi Goran Kumric Remigio Marano Carla Martino Camilla Smeraldi Francesca Volpi

Welcome and Introduction

Who we are

Presenters of this webinar
- Karine Lheureux
- Anastasia Livanou
- Simone Gabbi

Q&A contributors:
- Stefano Cappé
- Sara De Berardis
- Costanza Casiraghi
- Goran Kumric
- Remigio Marano
- Carla Martino
- Camilla Smeraldi
- Francesca Volpi

Click to add text

Webinar moderator:
- Margherita Guidi

Goals

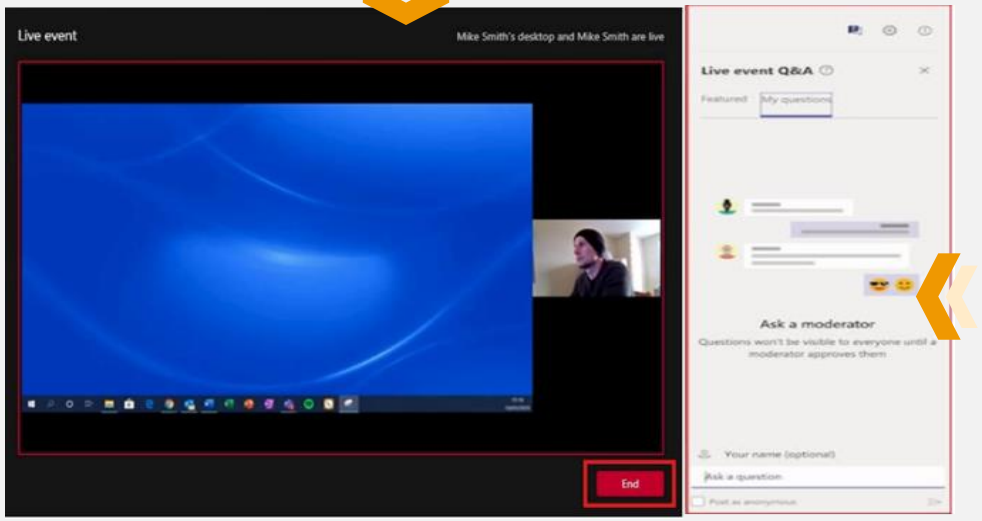
- What is the goal of this webinar? The aim is to explain the arrangements, steps and the tools of the application procedure for smoke flavourings primary products implemented by EFSA following the entry into application of the Transparency Regulation.
- Address questions encountered by applicants in recent months following 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.

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

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

European Food Safety Authority

Connect EFSA

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

eSubmission Food Chain Platform

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

Open EFSA

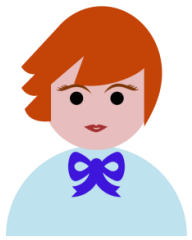
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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

Business Operator
Potential Applicant

John

Laboratories
Testing facilities

Martin

Third Parties

The public
(during PC or once studies are published)

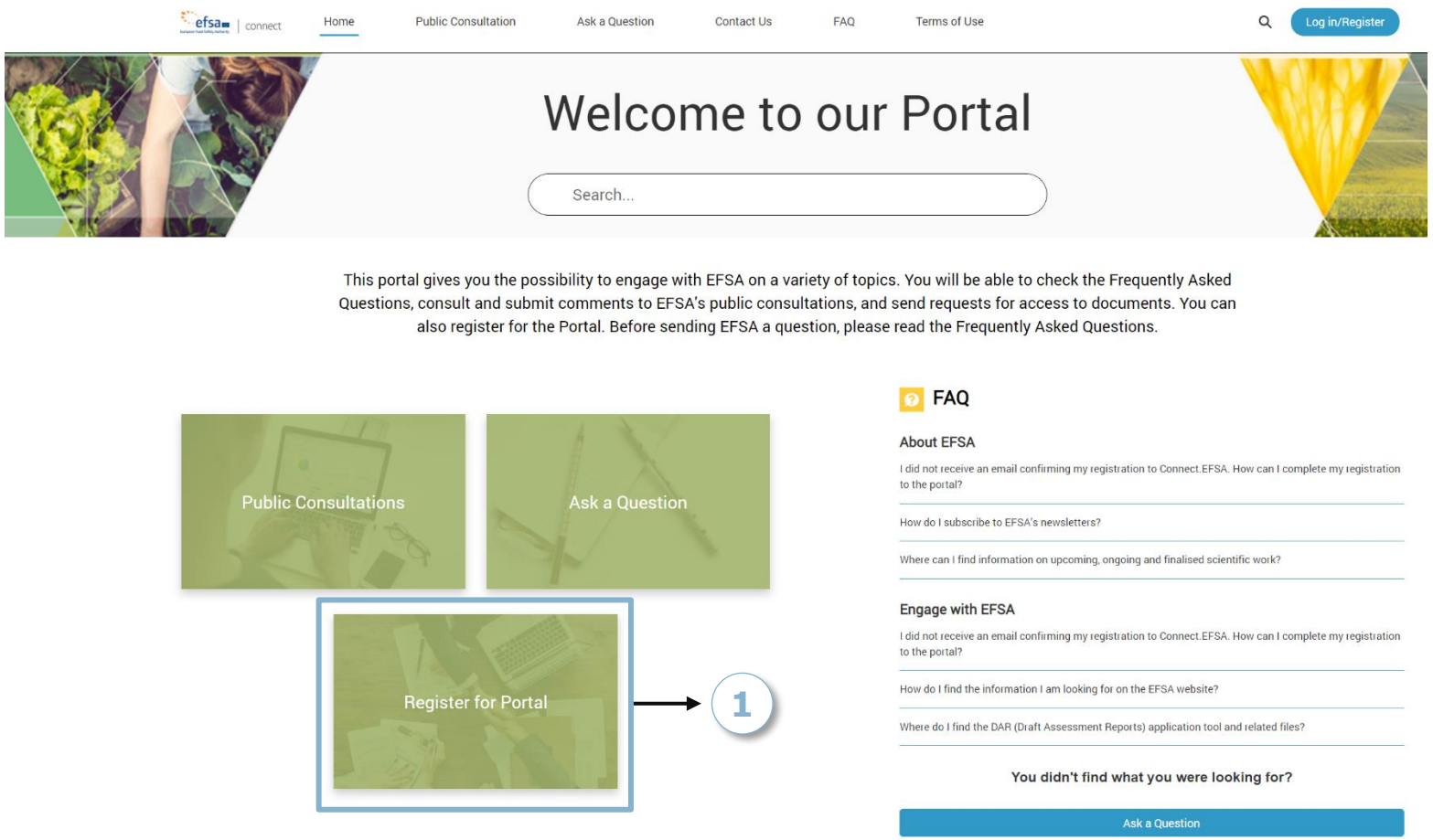
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

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

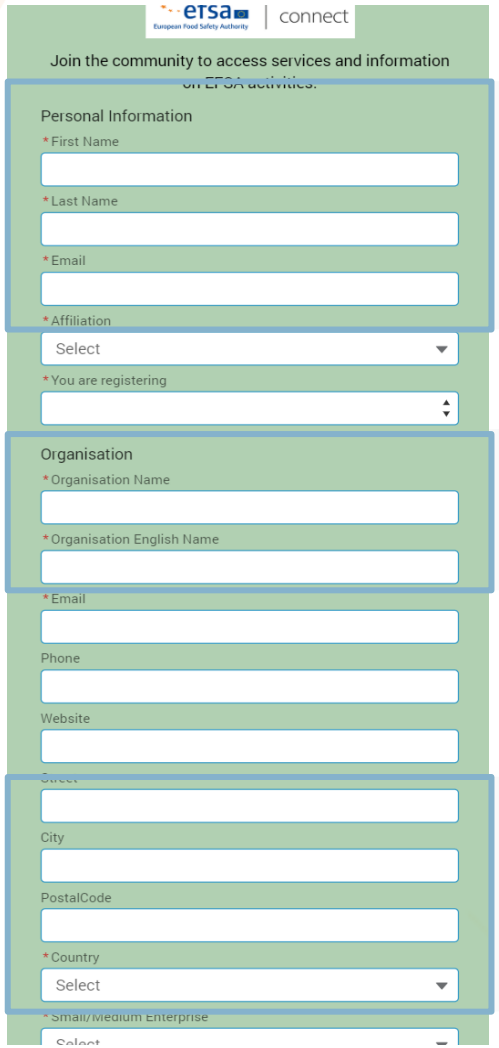
The potential applicant starts the registration in the portal.

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 – NEW since 30th April

Update from Account Registration

This feature is in place since 30/04. New video under preparation.

Organisations playing multiple roles
NEW since 30th June

Update from Account Registration

The implementation of this feature required some adjustments to the user interface.

This feature is in place from 30th June. New video under preparation.

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

Third parties

If the notification is inserted by a **consultant** (third party), the business operator (applicant) for which the consultant is working 'on behalf of' should be inserted in the field 'Business Operator'.

Valid for all pre-submission activities!

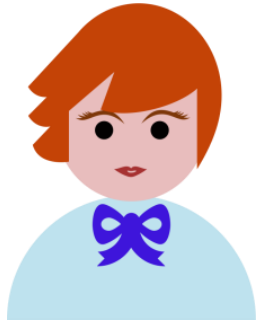
This relationship has to be previously established in the Account Management:

1. Business operator(s) selects in its "My Details" page the button "Manage Relationship" and create a new account relationship "on behalf of" with the consultant
2. The consultant can create the pre-application ID and add the business operator (the potential applicant, not the consultant!) in the 'Business Operator' field
3. If applicable, the consultant shares the pre-application ID with other business operator(s)

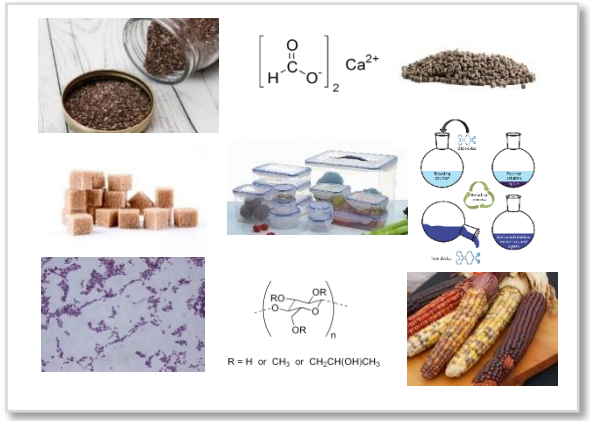
Pre-Application ID
Pre-submission advice
Notification of Studies

New applications

Pre-Application Identification



Sarah
Business Operator(s)



Subject of the application

Intended Area

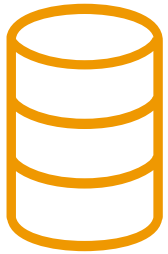
Mandate and Dossier intake
General Pre-Submission Advice

General Pre-Submission Advice

Sarah

The potential applicant gets the pre-application-ID

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



Pre-Submission Advice tool

General Pre-Submission Advice

EFSA provides advice

Step 3
Validation of application

EFSA publishes summary of Pre-Submission advice after application is declared valid

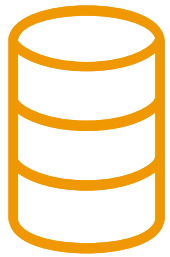
Mandate and Dossier Intake
Notification of Studies for new application

Step 1
Pre-submission phase

Sarah

The **Business Operator** gets the Pre-Application-ID

Both actors
Notify Studies
(Article 32b)



Database of Study Notifications

Step 2
Submission of application

EFSA performs the validation of the application

Step 3
Validation of application

EFSA publishes study notifications with related studies after confidentiality decision making process

Renewals

Mandate and Dossier intake
General Pre-Submission Advice

General Pre-Submission Advice

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

General Pre-Submission Advice

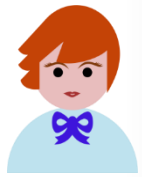
EFSA provides advice

Step 3
Validation of application

EFSA publishes summary of Pre-Submission advice after application is declared valid

Notification of Studies for renewal application

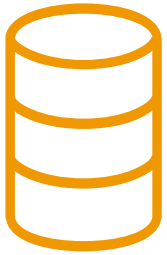
Step 1
Application renewal



Sarah

The potential applicant gets the Pre-Application-ID

The potential applicant submit the list intended studies and study design (Article 32c1)



Database of Study Notifications

Step 2
Public consultation and R-PSA

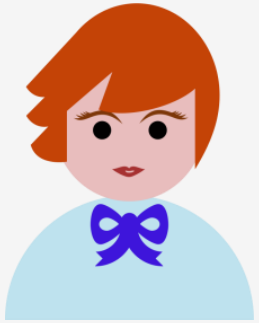
EFSA
Provides advice

Step 3
Notify studies

Sarah

The potential applicant notifies studies (Article 32b)

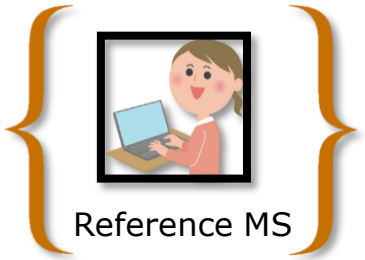
Pre-Application Identification for Renewal



Sarah

Requests
Pre-Application-ID
for Renewal

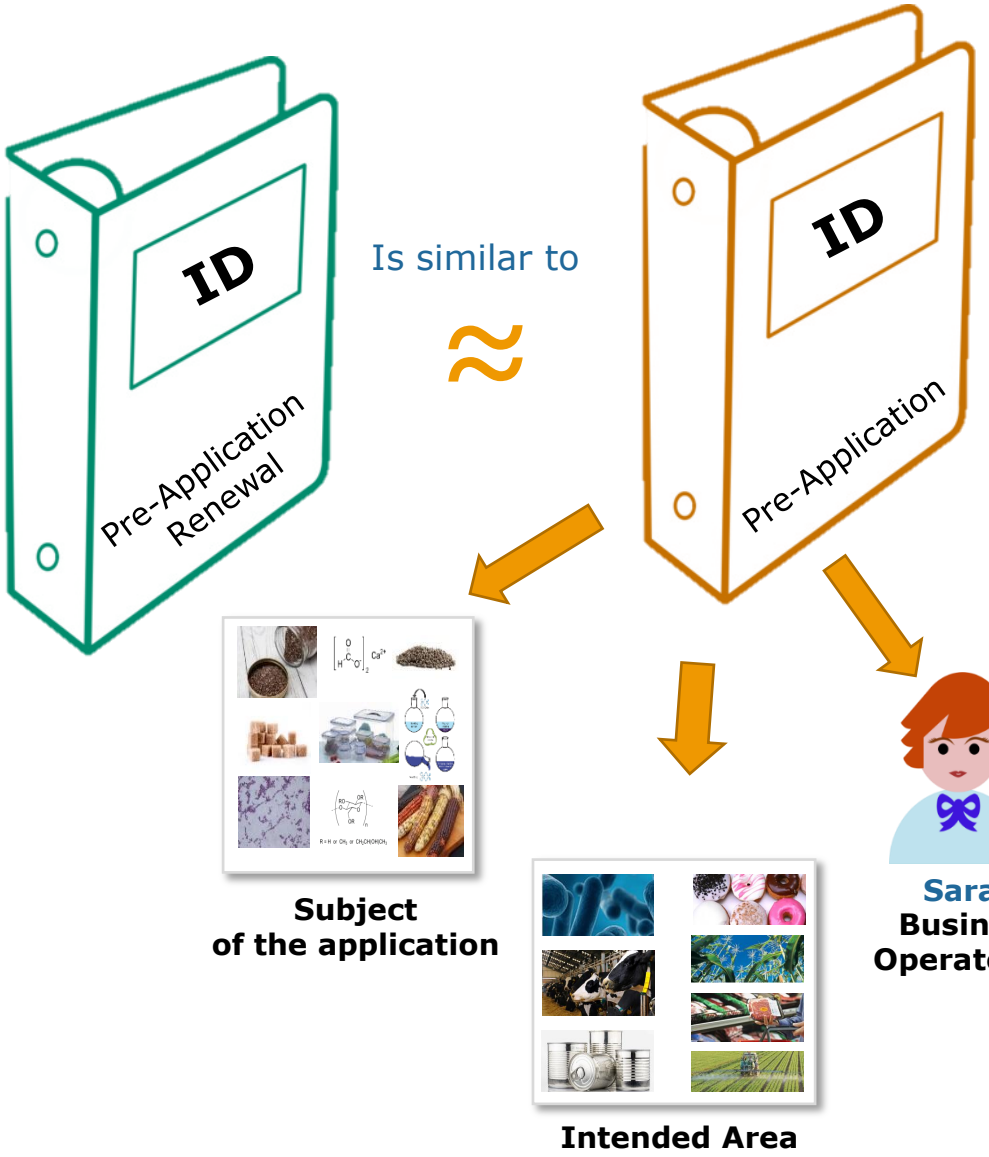
Additional features of Pre-Application Renewal



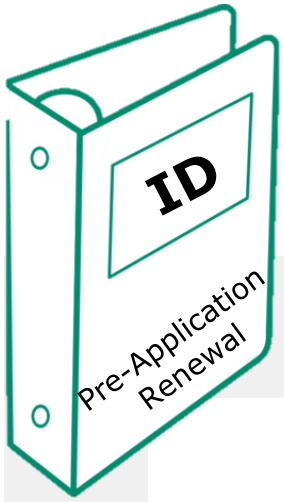
(If applicable)

Former application ID

Intended studies



Pre-Application Identification for Renewal



Submit **list of intended studies** according to 32c1

Currently not possible to notify under a pre-application-ID while Renewal Pre-Submission Advice is ongoing.

List of intended studies

Intended studies

Pre-Application ID for Renewal

This situation occured only in the first months of operation of the Transparency Regulation.
A possible NoS-DB work-around was proposed for this initial phase.

Submit **list of intended studies** according to 32c1

On completion of Renewal Pre-Submission Advice

Notify Study according to 32b

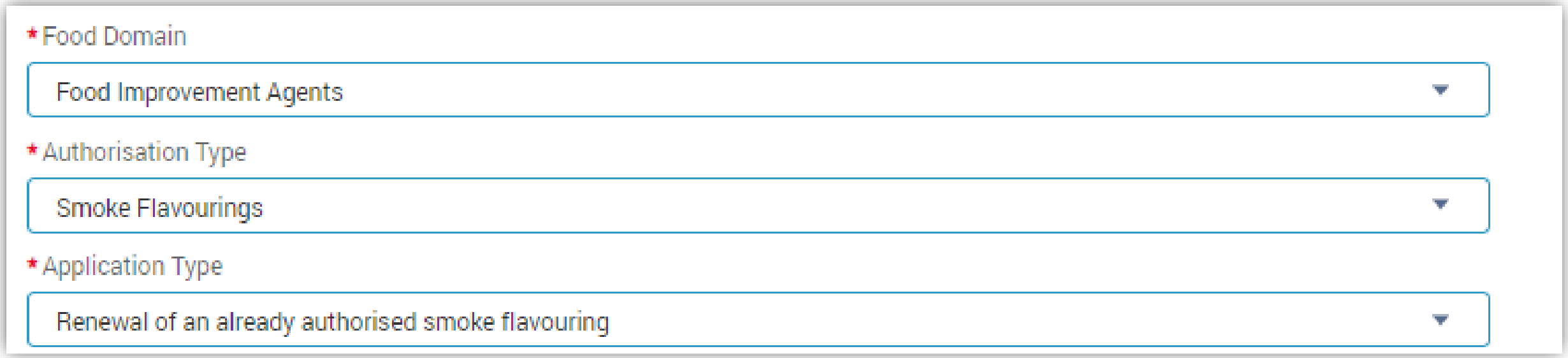
Add Study Notification to Pre-Application ID

Currently not possible to notify under a pre-application ID while Renewal Pre-Submission Advice is ongoing.

List of intended studies

Intended studies

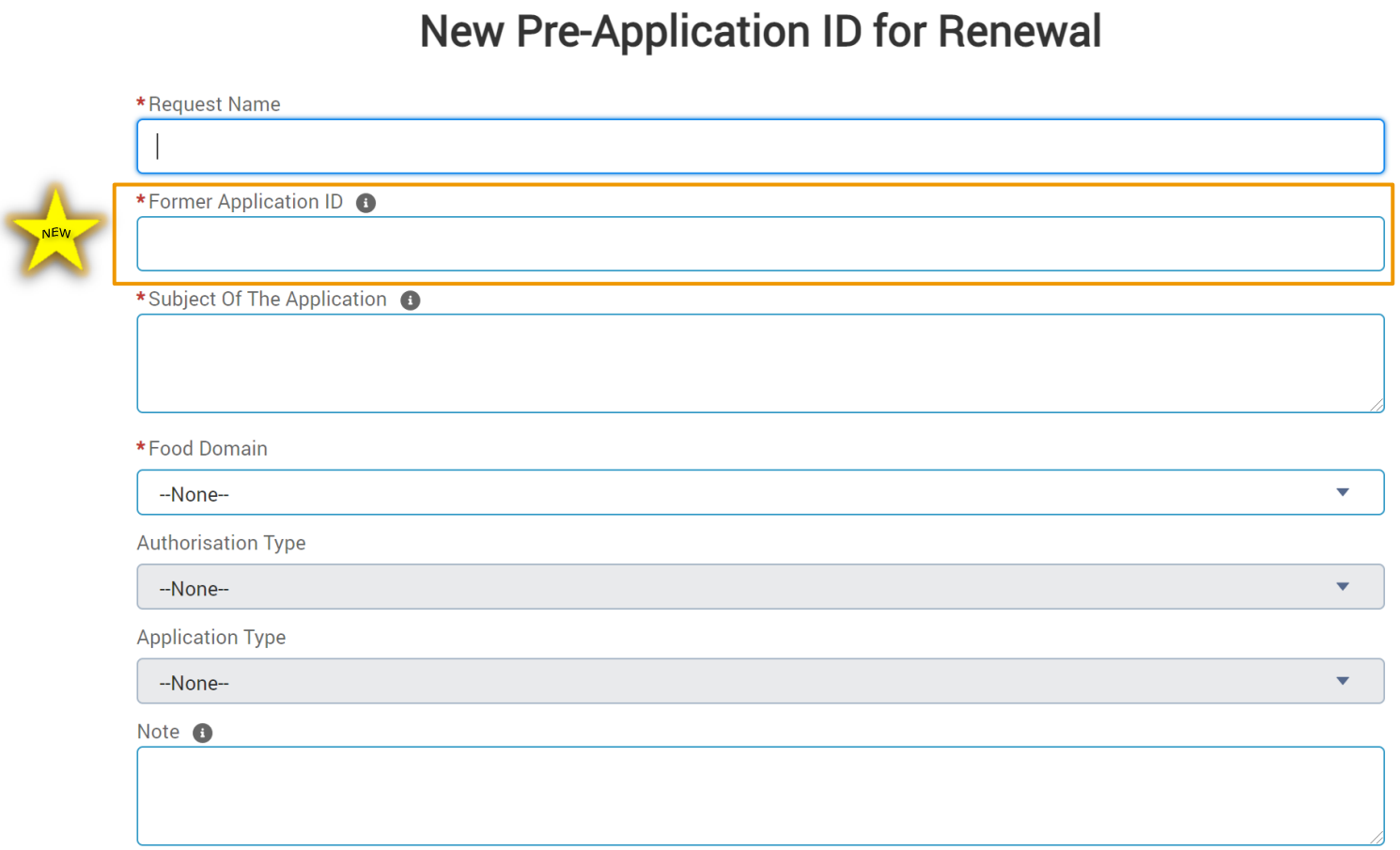
Application type – Smoke Flavourings



Even if the application covers more application types (e.g. a modification/ new use and a renewal), the RPSA will be provided only on studies intended to support the renewal.
Studies intended to support a modification of an authorisation or a new use **should not** be notified in the list of intended studies for renewals, but under Art.32b on notification of studies.

Intended Study

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: fill in intended study information

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 "To 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

Intended Studies for Renewal - Article 32c1

Legend
- Mandatory
- Optional
- Group of element

Study Title (M) – Free text: title of the study

Study Title (O) – Free text: (English name) title of the study in English language

Former application id (M)– Free text: shall contain the identifier of the application to be renewed (e.g. former EFSA question number)

Study scope (G): Section composed of multiple elements. See next slide

Study Scope - Article 32c1

Study intended area (M) – Choose from list: shall report the regulated product area of the future application that the study is meant to support

Study type (M) – Choose from list: shall report the type of the study

Study objective (M) – Free text: shall report the narrative describing the objective of the study

Test item (M) – Free text: shall report the identification of study test item.

Components (O) – if applicable: Depending on the type of test item, information on the test item **components** (for chemical productions substances and metabolites, microorganisms, GMOs) shall also be provided

Design of Study

Legend
- Mandatory
- Optional
- Group of elements

Study guideline (M) – Choose from list:
shall report the guideline or guidance document to be followed by the study

OR

Study design description (M) – Free text:
shall contain the description of the design of study including the hypothesis

Study detailed protocol (O) – Free text:
shall contain more detailed information and further elaborating methodology, statistical considerations, and organization of a study. The protocol usually gives the background and rationale for the study.

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
Public 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 reported in the summary of the renewal pre-submission advice

Renewal Pre-Submission Advice

Comments received

Step 1
Written or meeting

Where possible, EFSA shall provide RPSA in **writing**

A meeting might be organised by EFSA

Step 2
Provide the Advice

The written advice shall be provided within **30 working days** as of the closure of the PC;

The meeting shall be organised within **30 working days** as of the date of the closure of the PC

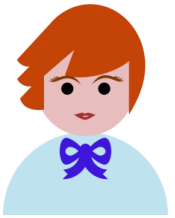
Step 3
Summary

EFSA draws up a **summary** proving an overview of the advice which includes how the **comments** were taken into account and sends it to the requester for information

Non-committal nature of R-PSA and G-PSA

Any subsequent **assessment of applications** by EFSA and the Member States

The **assessment of the** qualification of the specific regulated product under a given **regulated product area**



Sarah

The **potential applicant** shall not be bound by any 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

Portal updates and validity of application

Mandate and Dossier Intake

- **New applications:** Member State Authority forward Application to EFSA
- **Renewals:** European Commission forward Application to EFSA

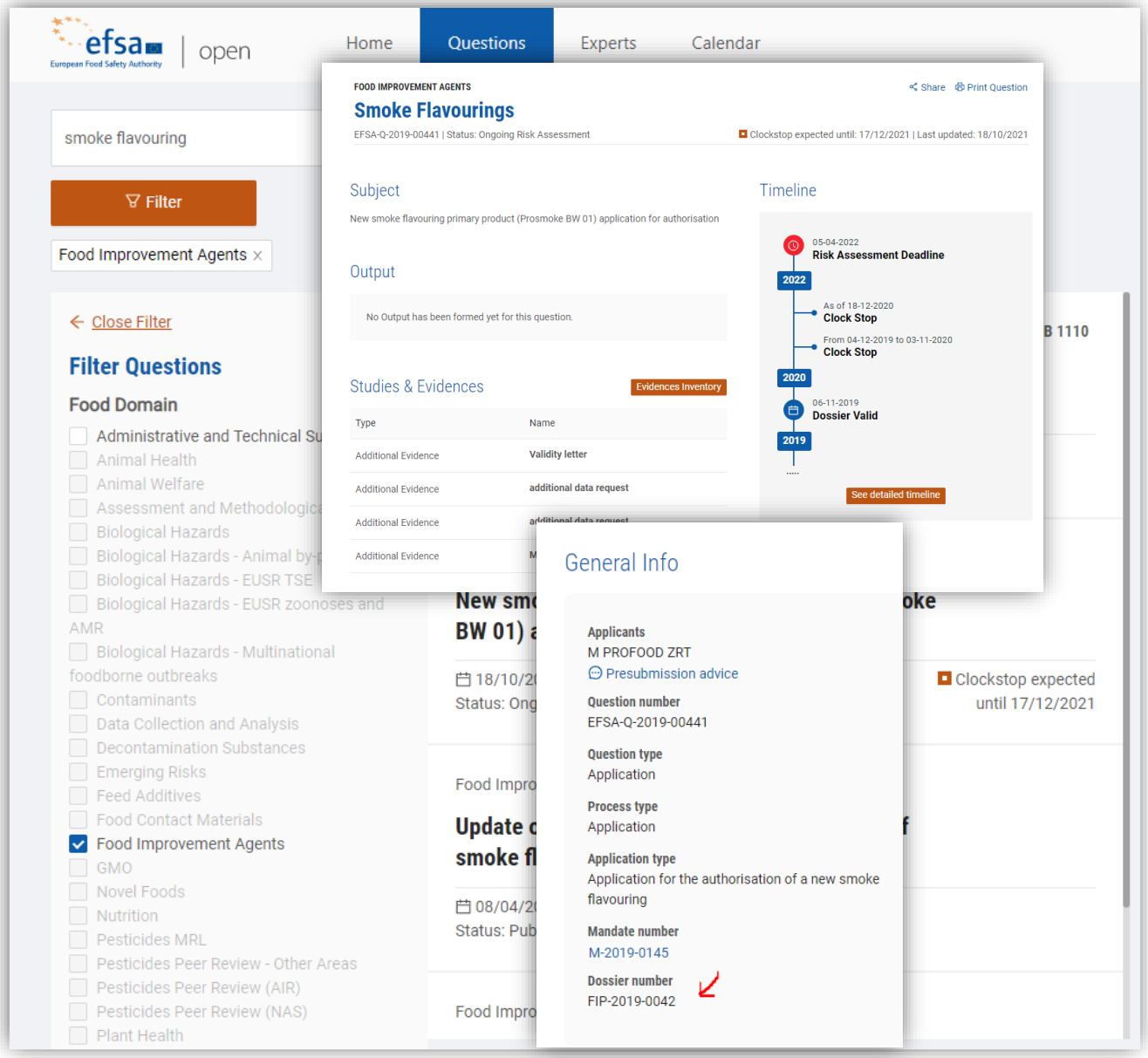
- Application registered - Question # (dossier + mandate)
- Visible in Open.EFSA Portal

- EFSA performs Validity check (+ NoS check)
- Request for Information (RFI): received & replied via ESFC

- EFSA declares the application Valid for risk assessment

- EFSA publishes non confidential valid dossier (+ summary Pre-submission advice)

- Assessment of confidentiality requests



Confidentiality in the context of smoke flavourings

Smoke Flavouring 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 178/2002 and Article 15 of Regulation 2065/2003 and sectoral acts

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 GFL, Article 15 of Regulation 2065/2003 as amended by the TR and sectoral acts

Transparency Regulation principles

Proactive Disclosure

Art 38 of Reg 178/2002 + Article 7 Reg 2065/2003
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

Art 39-39e of Reg 178/2002 + Art 15 of Reg 2065/2003
Confidential status:

- Only for items included in the closed positive list of the PAs` Annex
- Only if substantive and procedural requirements are met

Underlying principles

- Proactive disclosure of application dossiers
- Confidentiality as exception to transparency
- Burden of proof on applicants
- Non-disclosure of information claimed confidential pending decision-making

Who is an applicant?

1. **Any natural or legal person submitting an application or notification** under Union Law

2. Any natural or legal person **submitting scientific data and information for evaluation** to the Authority **pursuant to** established **sectoral Union law procedures**

3. Where permitted under sectoral Union law procedures and/or in the absence thereof, any natural or legal person **submitting voluntarily to the Authority upon which the Authority is expected to base its scientific outputs** within the meaning of Article 38(1)(d) of the GFL

4. Any natural or legal person **who has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output** and therefore having a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested as laid down in the Annex.

Not EC, EP, other Union institutions, bodies, offices or agencies, Union Member States or third countries' public authorities.

Procedural requirements

- Submission through ESFC for applications or Portalino for follow up to inconclusive opinions and data supporting general 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:

d. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 2065/2003	
Legal basis under which the request may be submitted	**Items that may be claimed confidential**
Article 15(1) of Regulation (EC) No 2065/2003 (making reference to Article 39 of Regulation (EC) No 178/2002)	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 or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
Article 15(1) of Regulation (EC) No 2065/2003 making reference to Article 39e(1) of Regulation (EC) No 178/2002	any other personal data except for (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) the 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 subject matter.
Article 39e(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.

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.

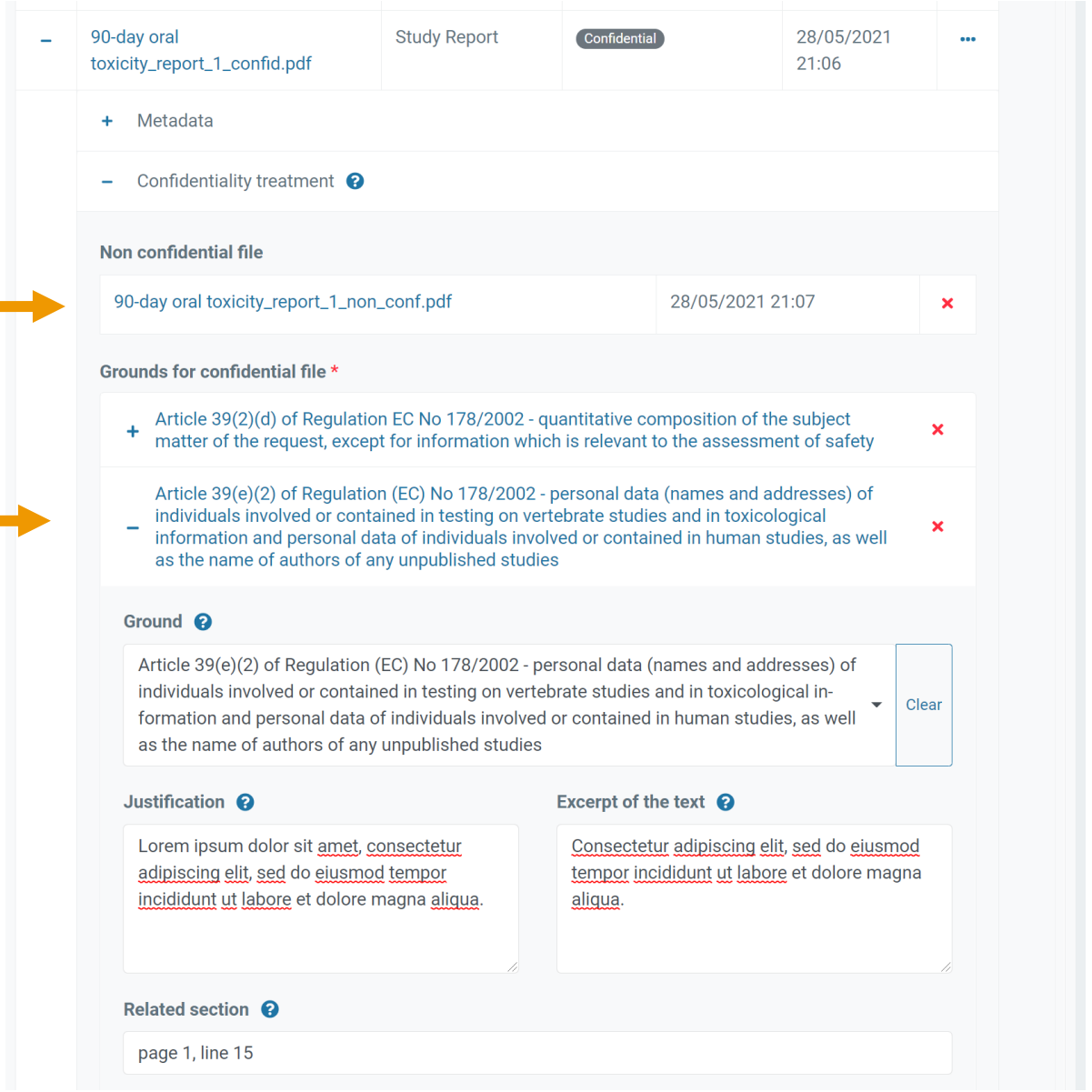
Legal Ground: GFL Art 39e(2 & 3)

Substantive requirements

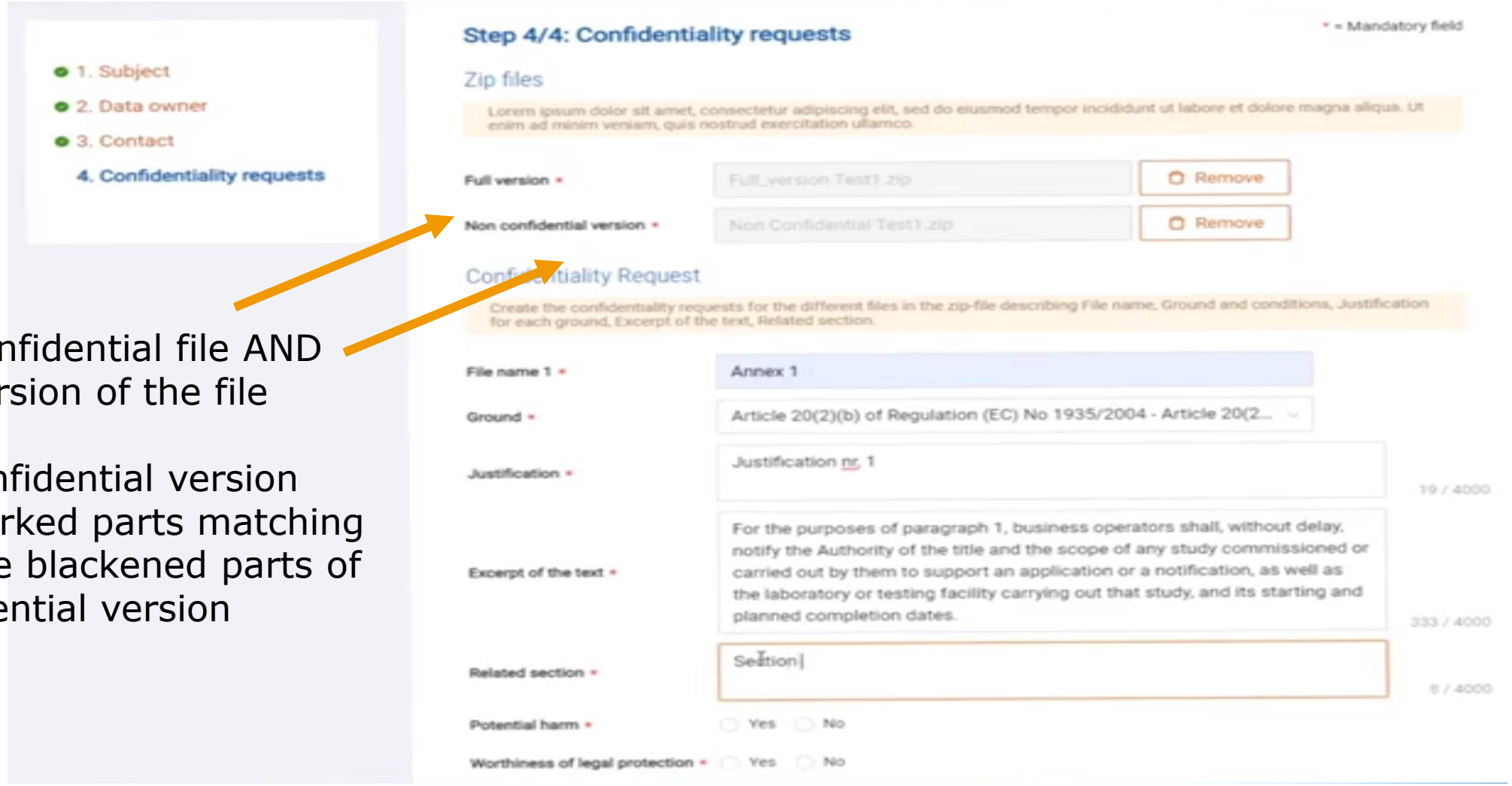
- Identifying clearly the information claimed confidential, with references
- Indicating the legal basis (grounds)
- Explaining why the item should be kept confidential:
  - Information not publicly available
  - Potential harm to a significant degree
    - Information acquired legitimately
    - Negligible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

ESFC - Building a Confidentiality Request

- Provide non-confidential file
- Define your request:
  - Legal ground
  - Justification
  - Excerpt
  - Location in file
- Add requests, as required



Portalino – building confidentiality requests (1)

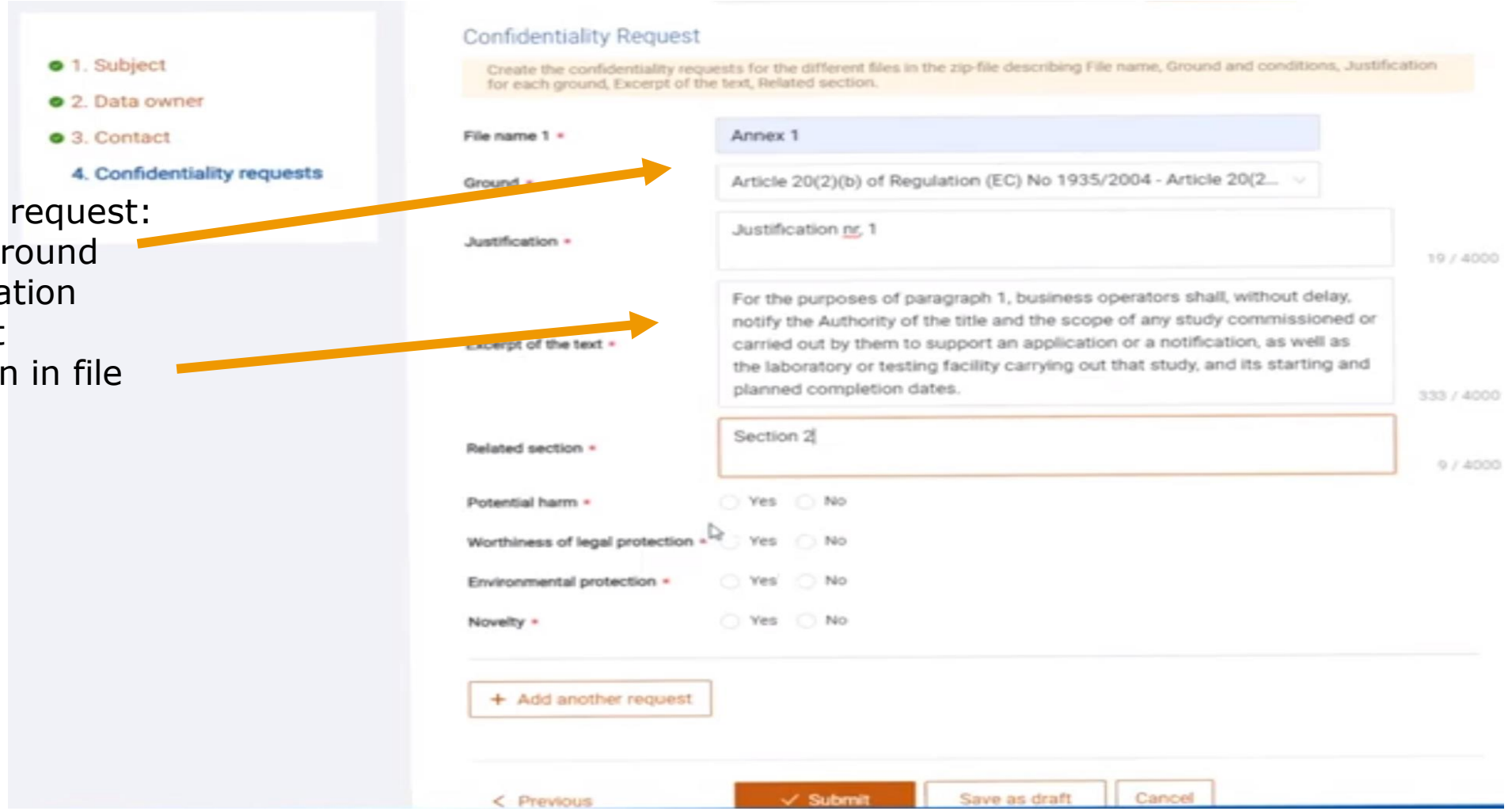


Provide non-confidential file AND Confidential version of the file

Ensure that confidential version includes earmarked parts matching exactly with the blackened parts of the non-confidential version

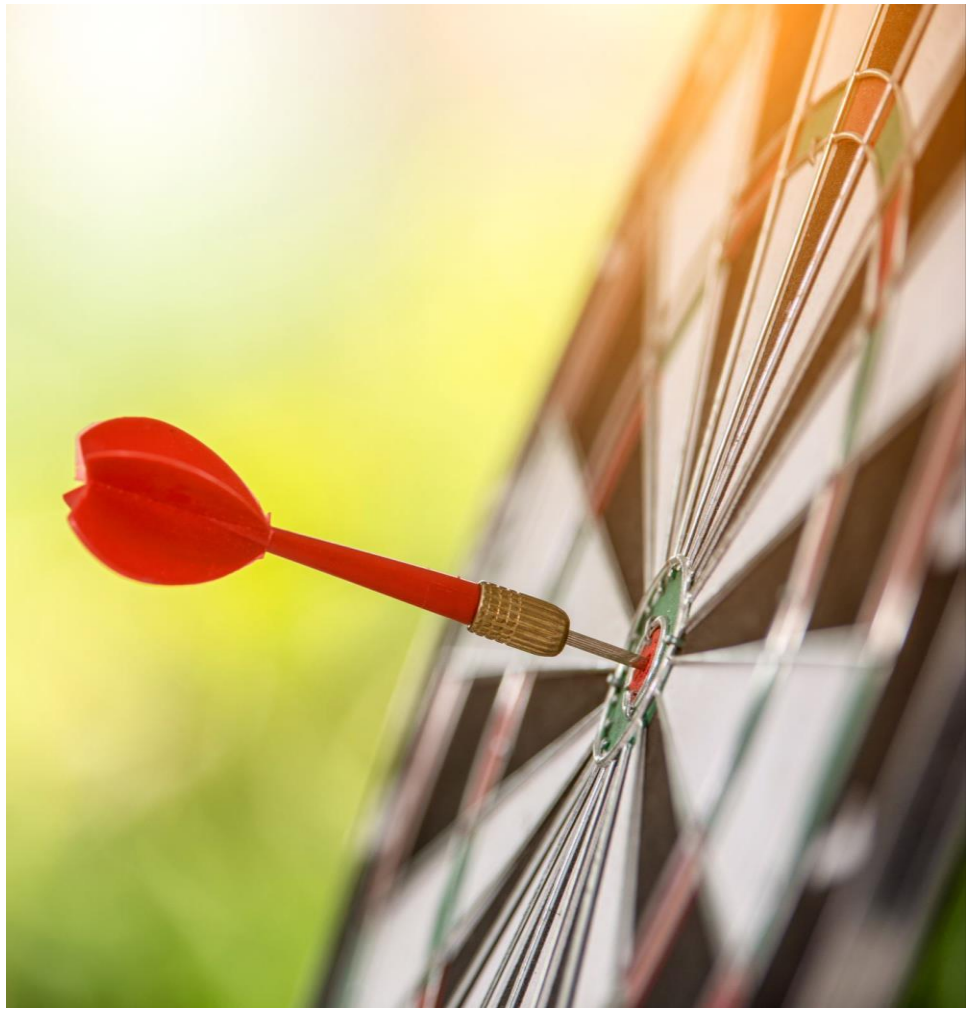
Portalino – building confidentiality requests (2)

- Define 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
- ✓ Only one confidentiality request per document per legal ground is submitted
- ✓ Avoiding duplications
- ✓ No confidentiality requests on publicly available info
- ✓ Submitting a justification per confidentiality request
- ✓ Justification to comply with Articles 9 and 10 of EFSA's Practical Arrangements concerning transparency and confidentiality



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 output identifies foreseeable effects on human health, animal health or the environment *(Art 39c GFL)*

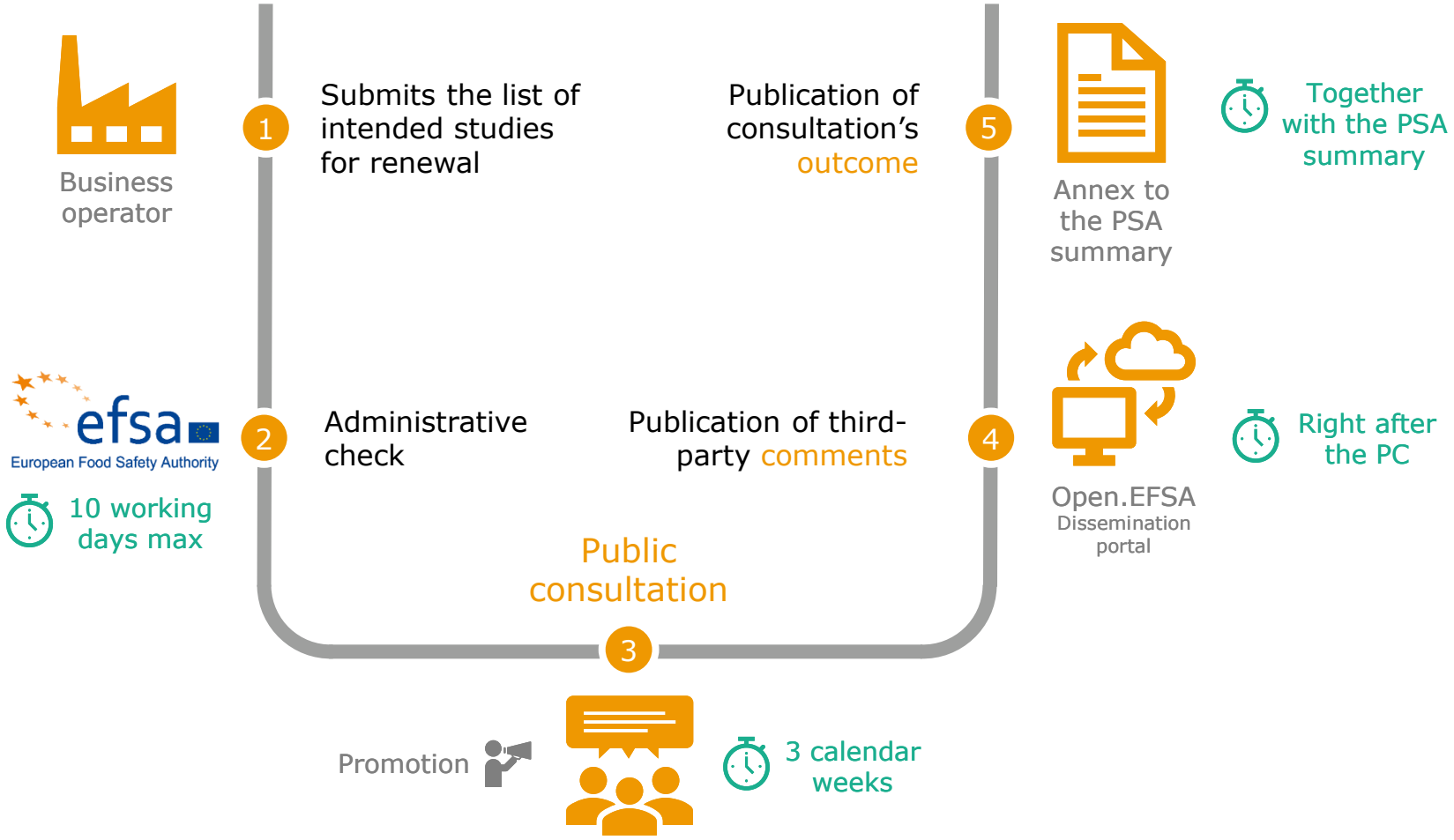
Public Consultation

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

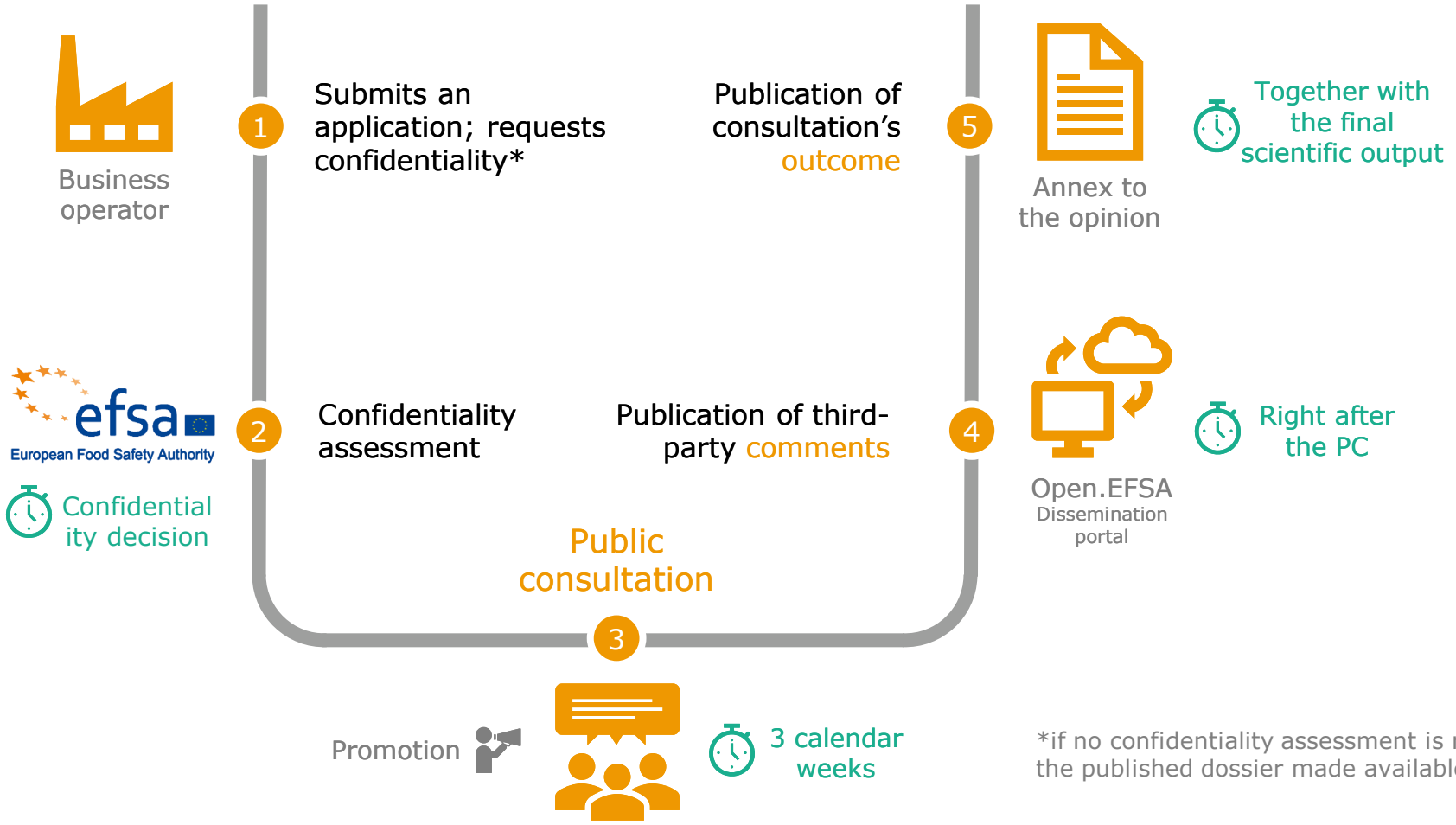


Aim:
Inform the elaboration of the renewal pre-submission advice to a potential applicant

When:
Pre-application phase (ahead of renewal)

Overview of the process

PC on the non-confidential version of a validated application



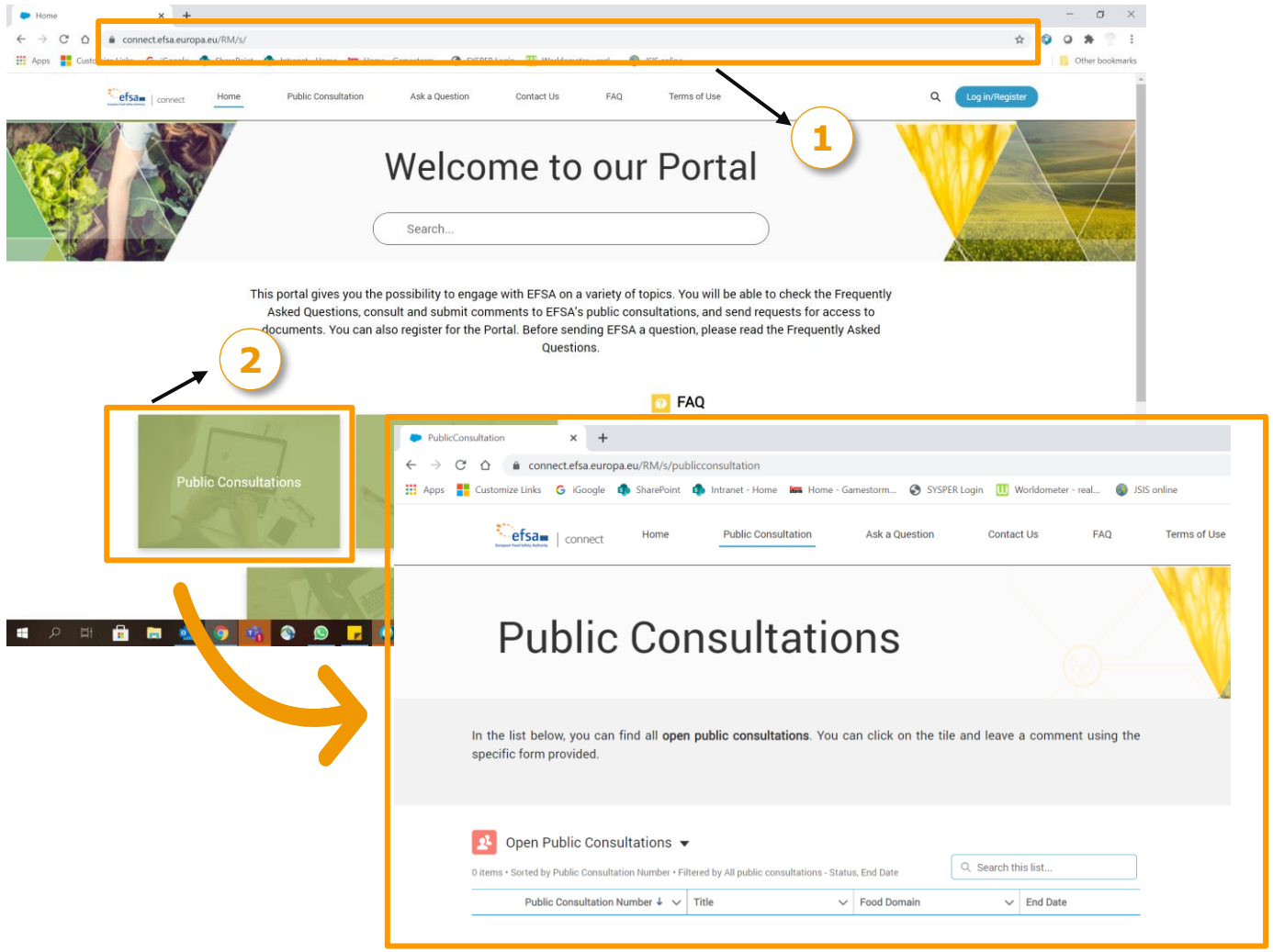
Aim:
Collect new or additional evidence/data/information to assess an application

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

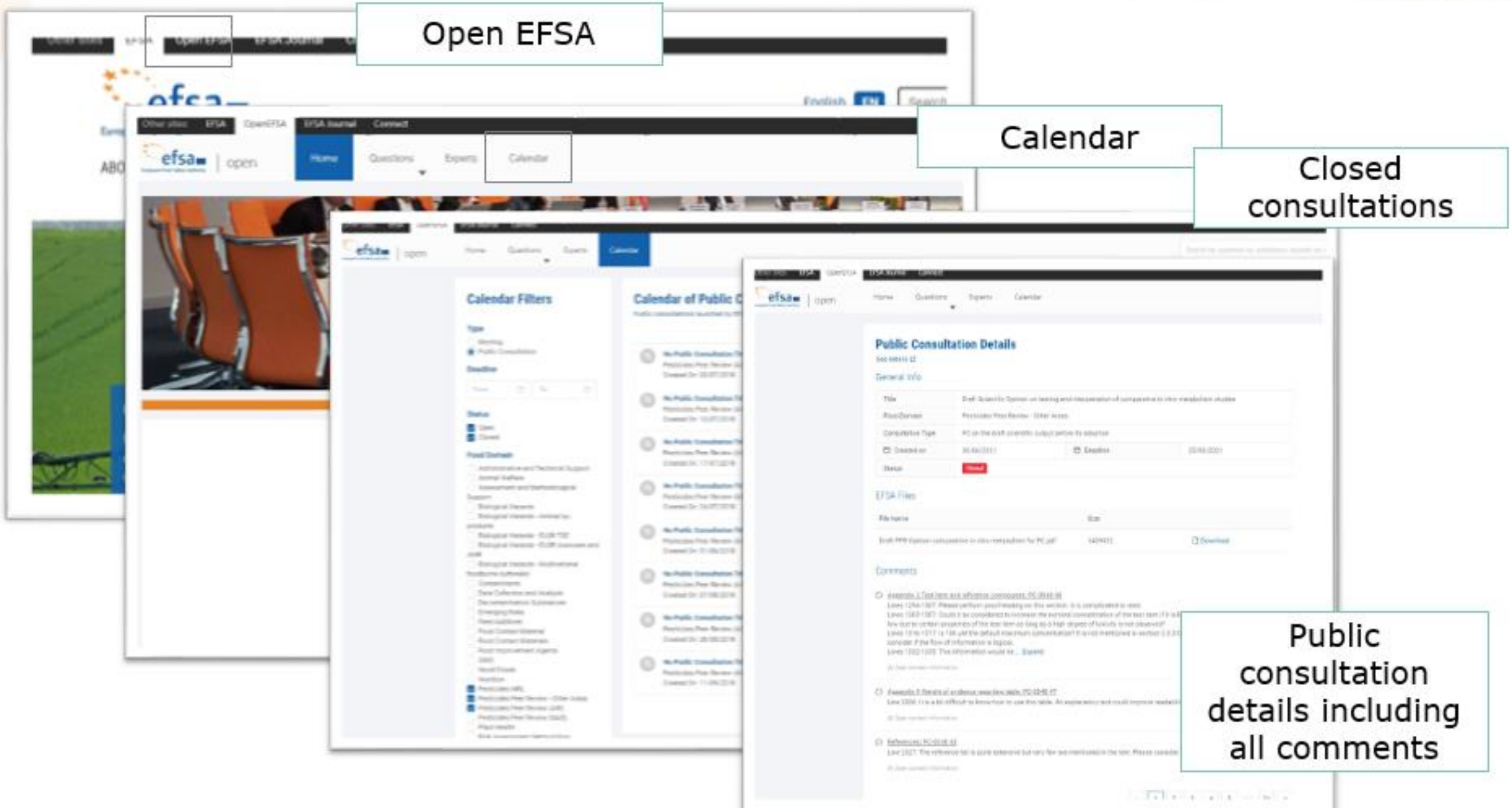


How to access the portal

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

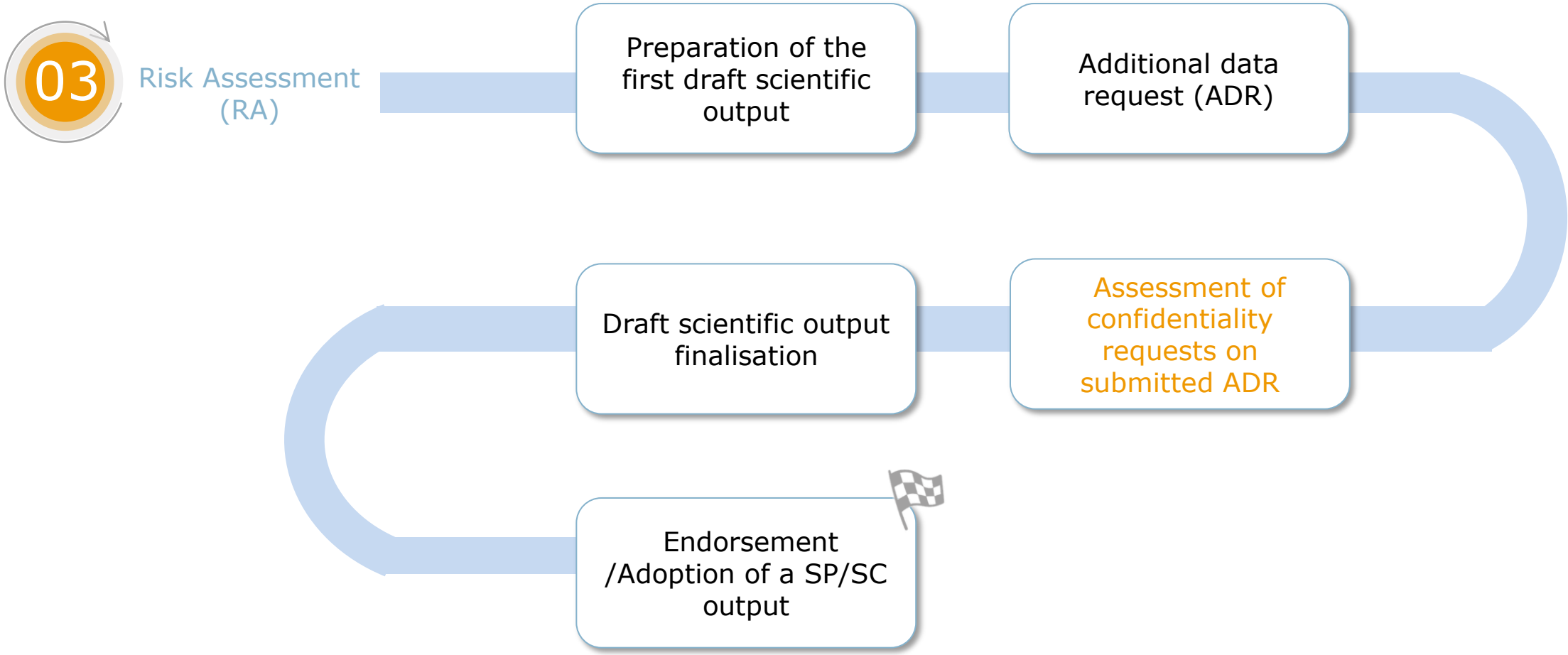
The portal will be easily accessible from the EFSA website

Open EFSA - Publishing of comments



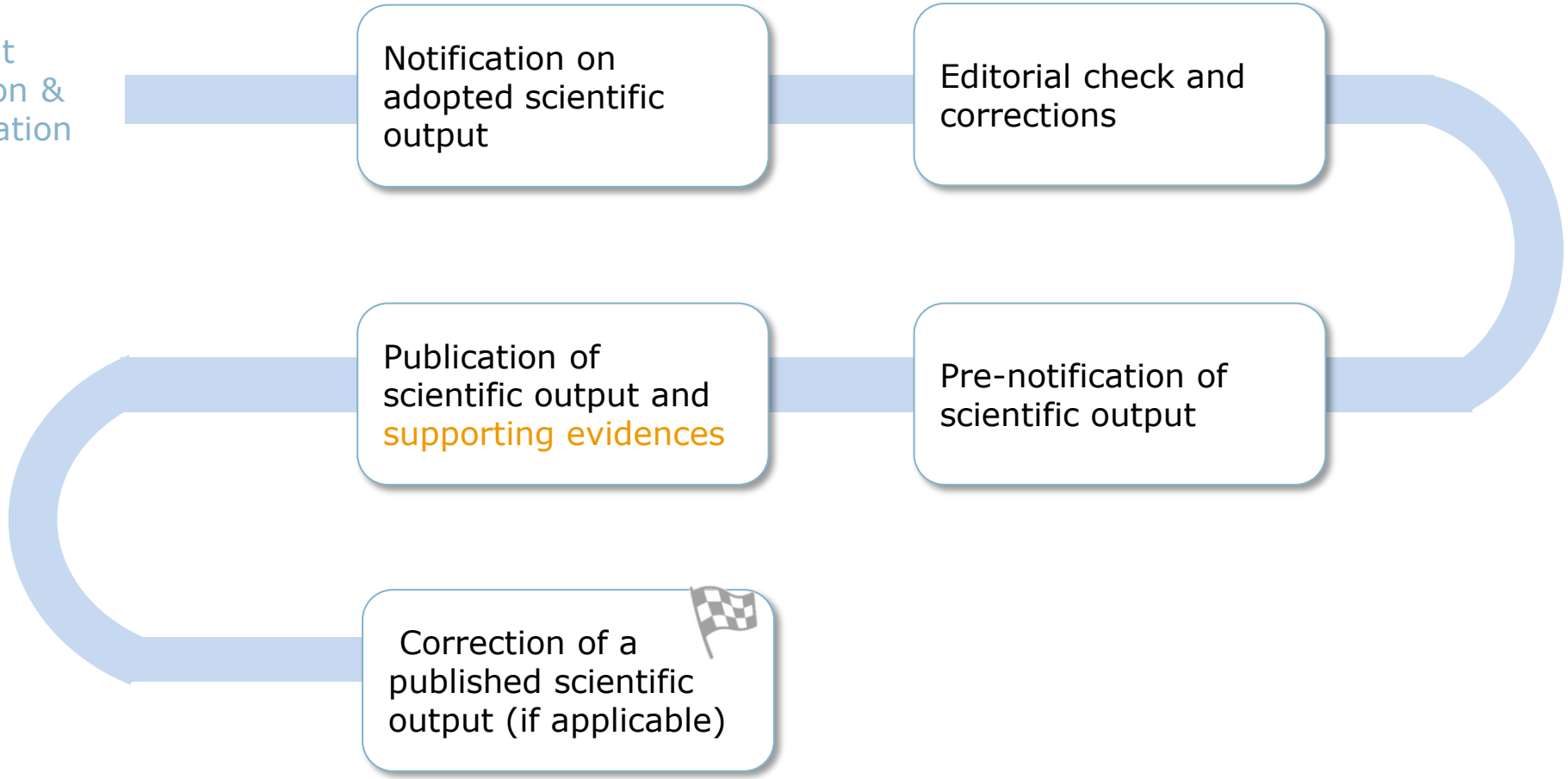
Risk Assessment, Adoption and Publication

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
- Consolidated version Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives
- Practical arrangements: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
- PAs on transparency and confidentiality: Practical Arrangements concerning transparency and confidentiality
- Q&A on Practical arrangements: https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

Guidance/training material:

- Smoke flavourings primary products applications: regulations and guidance web section
  - Updated administrative guidance for the preparation of applications on smoke flavourings primary products (EFSA, 2021)
  - Updated Scientific Guidance for the preparation of applications on smoke flavouring primary products (EFSA FAF Panel, 2021)
- 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 (NEW since 01 July)
  User Guide - Pre-application ID (NEW since 01 July)

Questions & answers session

Trusted science for safe food

efsa
European Food Safety Authority

Join our new LinkedIn group:

"EFSA support to applicants"

A space where you will find:

- Information and support materials
- Updates on the developments and progresses of IT tools and platforms
- Alerts on new training material and upcoming events
- Answers to the most frequently asked questions
- Clarification from 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)

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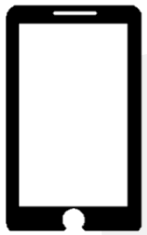

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Thank you for attending our webinar

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