25 January 2022

EFSA webinar series

Webinar on application procedure for health claims

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 NoS Applications and modification of authorisation E-submission (demo) Portal updates and validity of applications Confidentiality in the context of health claims Public consultation RA, adoption and publication	Bénédicte Vagenende Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Stefano Cappé Sara De Berardis Leng Heng Janusz Ciok Goran Kumric Francesca Volpi Anastasia Livaniou Simone Gabbi

Welcome and Introduction

Who we are

Presenters of this webinar
- Bénédicte Vagenende
- Anastasia Livanou
- Simone Gabbi

Q&A contributors:
- Stefano Cappé
- Sara De Berardis
- Leng Heng
- Janusz Ciok
- Francesca Volpi

Webinar moderator:
- Goran Kumric

Goals

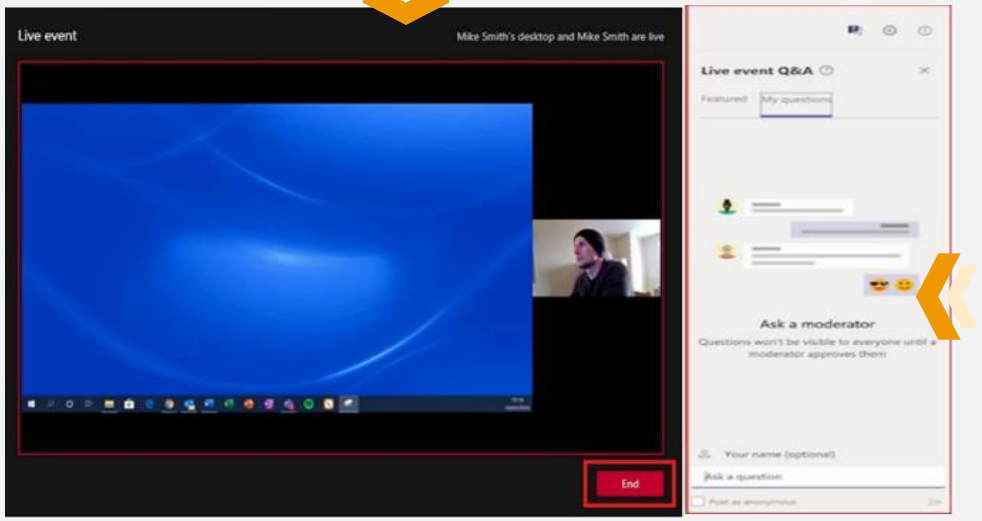
- What is the goal of this webinar? The aim is to explain the arrangements, steps and the tools of the application procedure for health claims implemented by EFSA following the entry into force of the Transparency Regulation.
- Applicable to health claim applications submitted pursuant to Articles 13.5, 14 and 19 of Regulation (EC) No 1924/2006
- 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

Click to add text
Click to add text
Click to add text
Click to add text

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

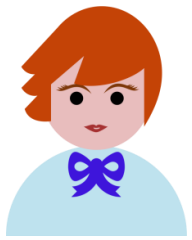
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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)

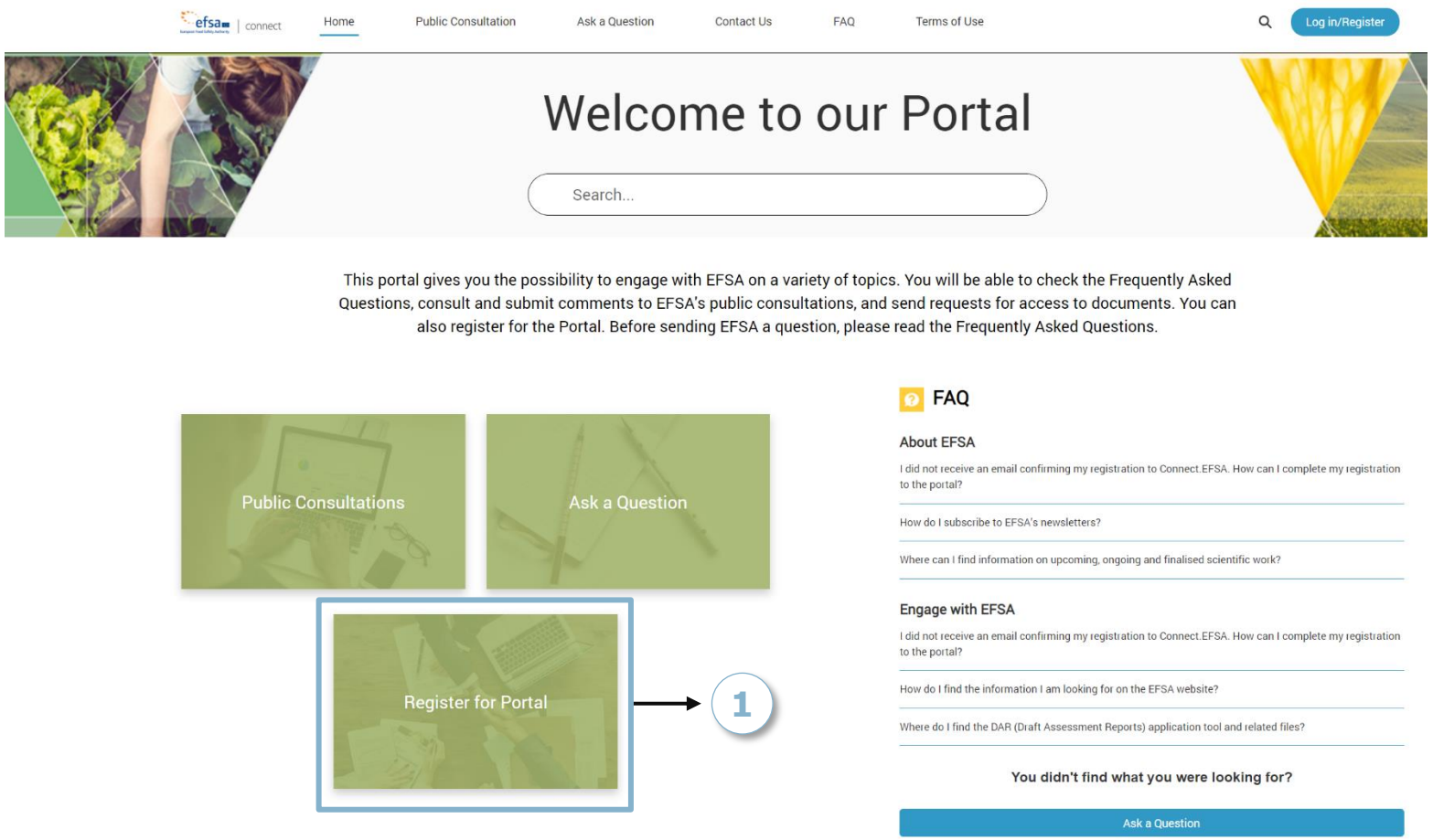
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

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

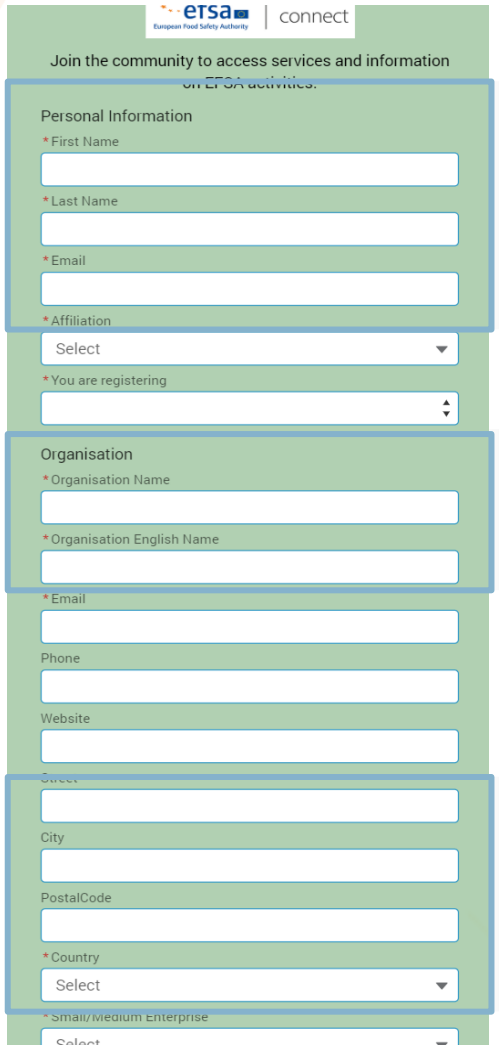
The potential applicant starts the registration in the portal.

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.

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.

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'.

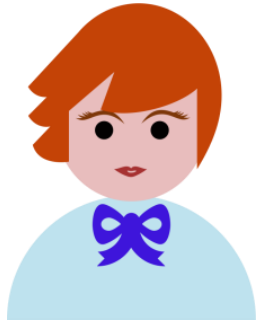
Valid for all pre-submission activities!

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

Pre-Application Identification



Sarah
Business Operator(s)

Subject of the application

Intended Area

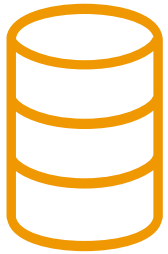
Mandate and Dossier intake
General Pre-Submission Advice

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

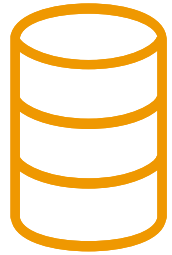
Mandate and Dossier Intake
Notification of Studies for new application

Step 1
Pre-submission phase

Sarah

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

Both Business Operator and Laboratory
Notify Studies (Article 32b)



Database of Study Notifications

Step 2
Submission of application

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

Step 3
Validation of application

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

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

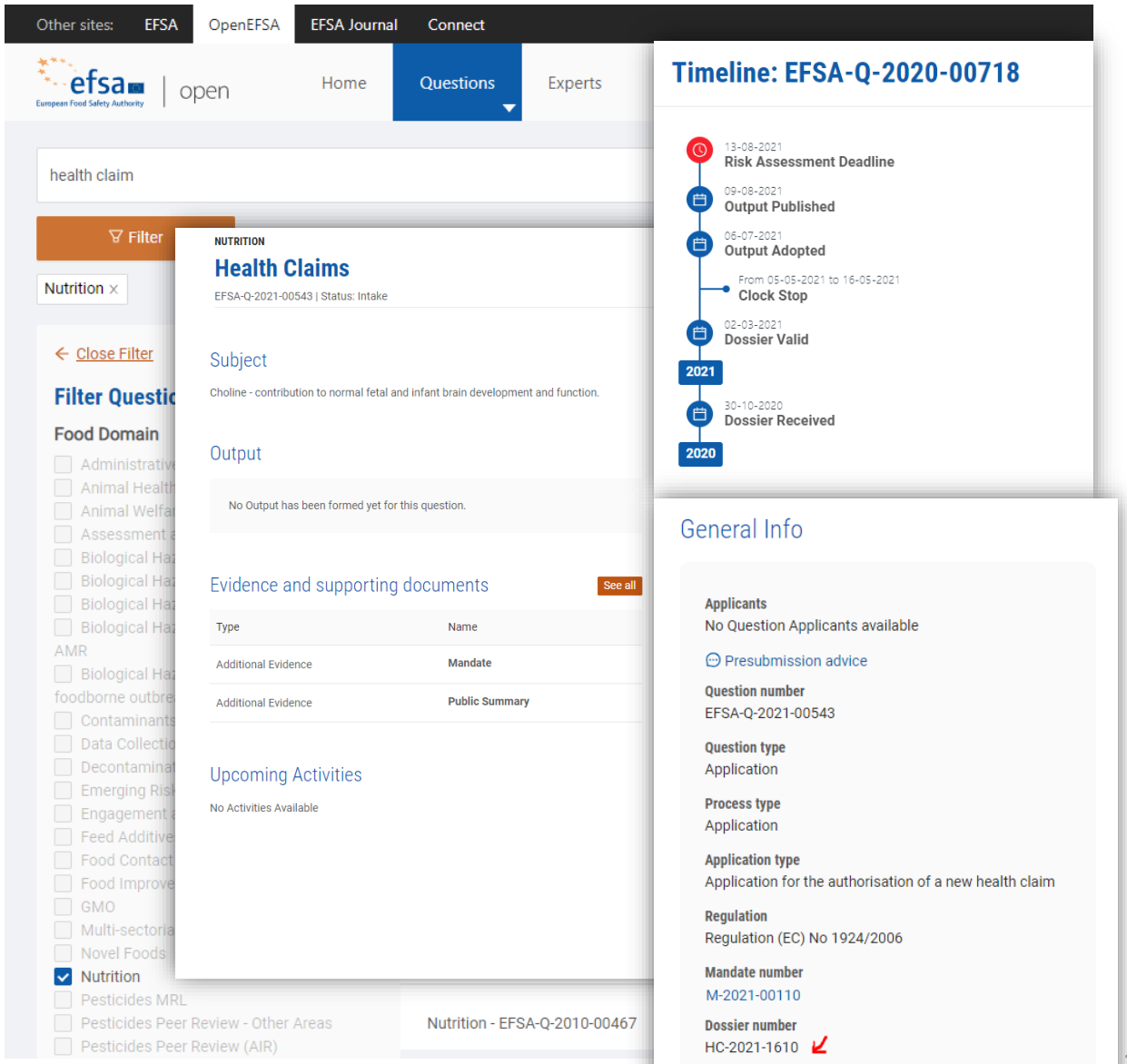
Video Tutorials
Hyperlink

User Guide
Hyperlink

Portal updates and validity of application

Mandate and Dossier Intake

- Member State (MS) Authority requests EFSA the NoS extraction and performs the NoS check
- MS forwards application to EFSA
- Application registered - Question # (dossier + mandate)
- Visible in Open.EFSA Portal
- EFSA performs Completeness check
- Request for Information (RFI): received & replied via ESFC
- MS declares application valid for risk assessment
- EFSA publishes non confidential valid dossier
  (+ summary general pre-submission advice)
- Risk Assessment & Assessment of confidentiality requests



Confidentiality in the context of health claims

Health claims Applications

Application submitted before 27/03/2021

Pre-Transparency Regulation Regulation 178/2002 applies

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

Application submitted on/after 27/03/2021

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

Art 38(1) 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

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 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 – for health claims:

- 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, e**xcept 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;
- **quantitative composition** of the subject matter of the request, **except for** information which is relevant to the assessment of safety

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

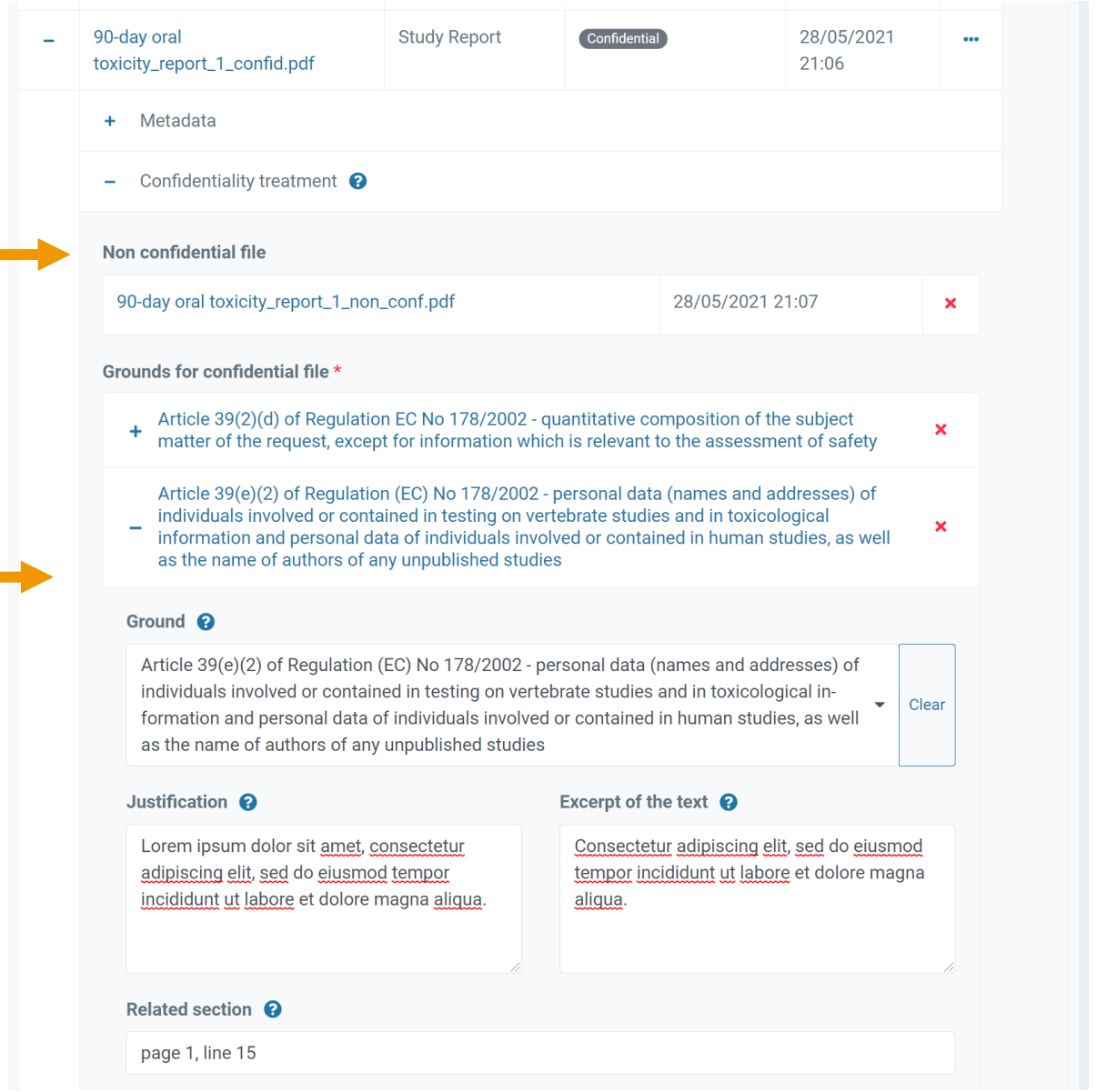
- Identifying clearly the information claimed confidential, with references
- Indicating the legal basis (grounds)
- Explaining why the item should be kept confidential:
  - Information not publicly available
  - Potential harm to a significant degree
    - Information acquired legitimately
    - Negligible 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

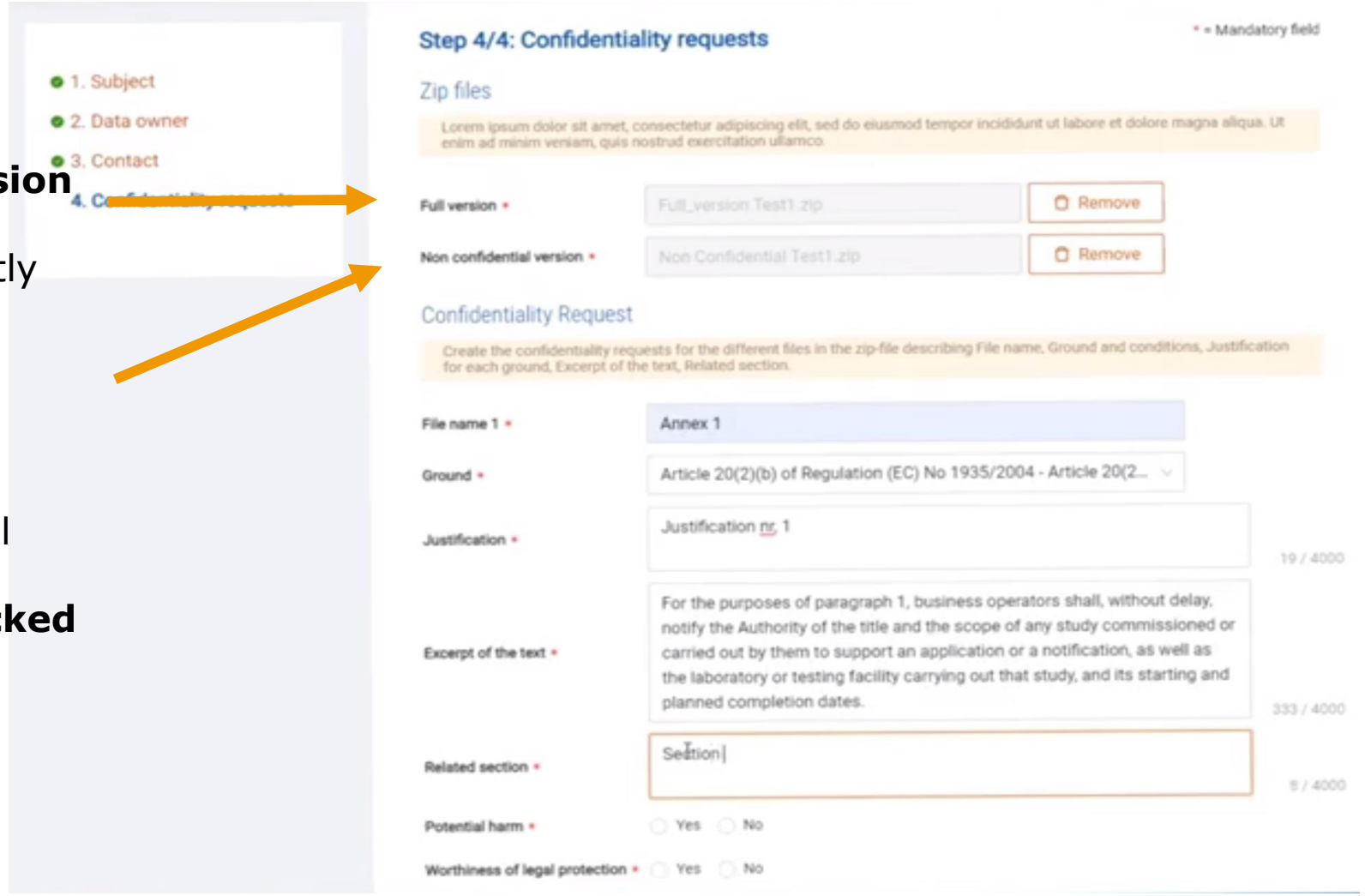


Portalino – building confidentiality requests (1)

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

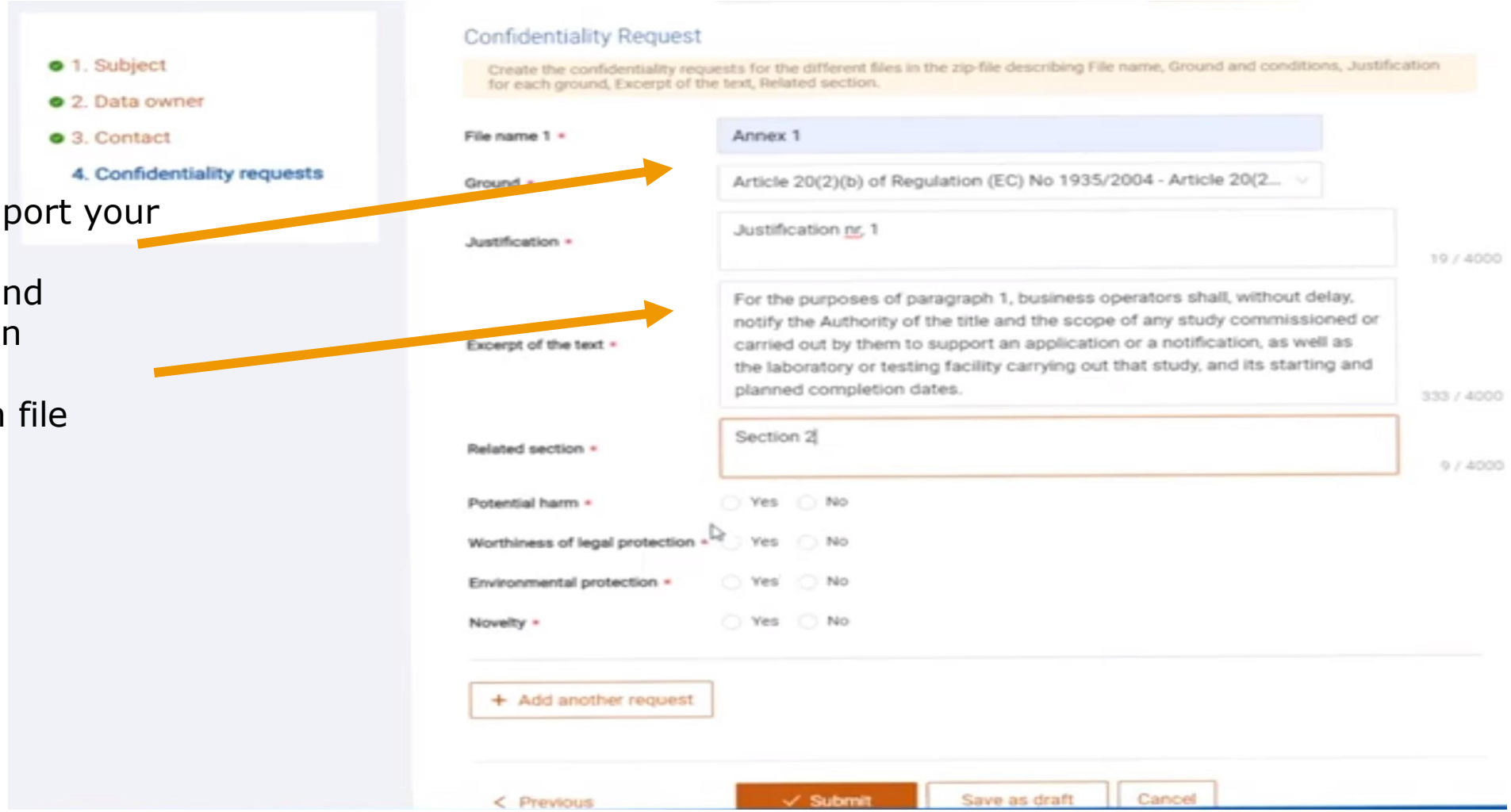
- Ensure that the **confidential version** of the document i**ncludes earmarked parts** matching exactly the blackened parts of the non-confidential version

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



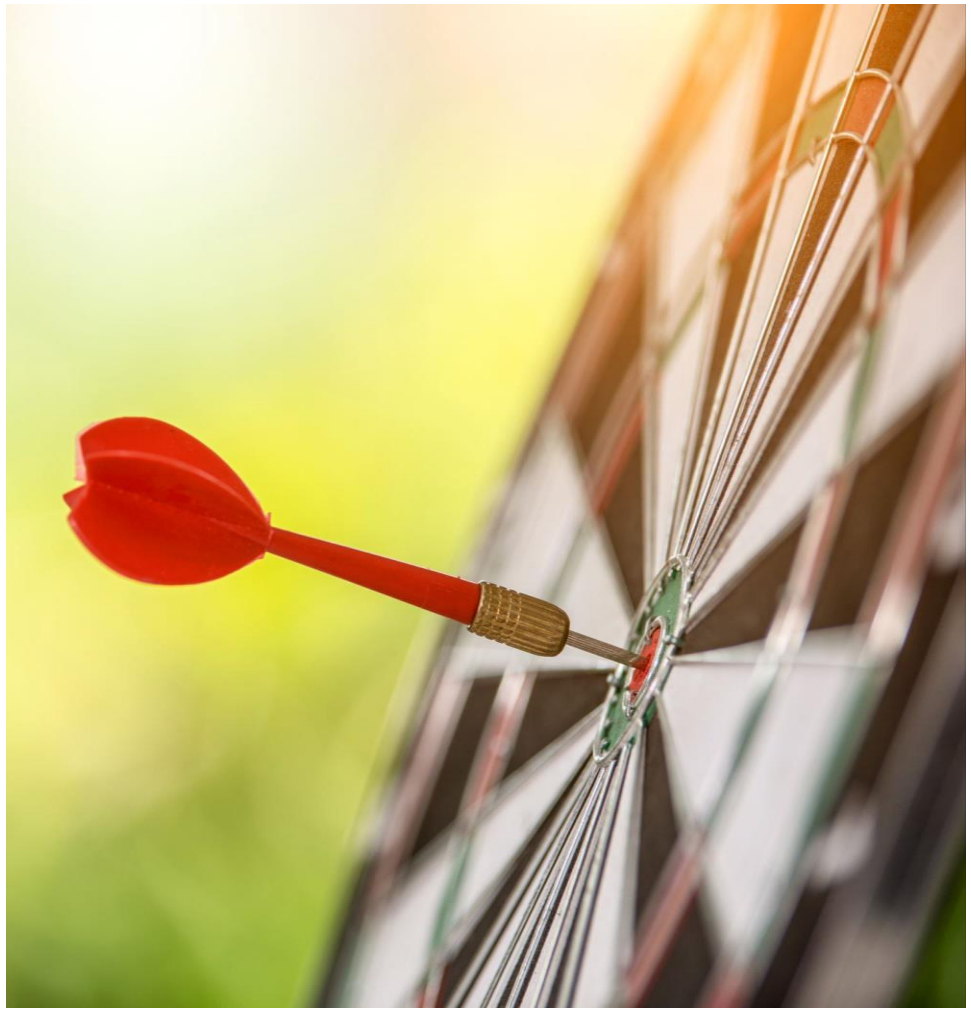
Portalino – building confidentiality requests (2)

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

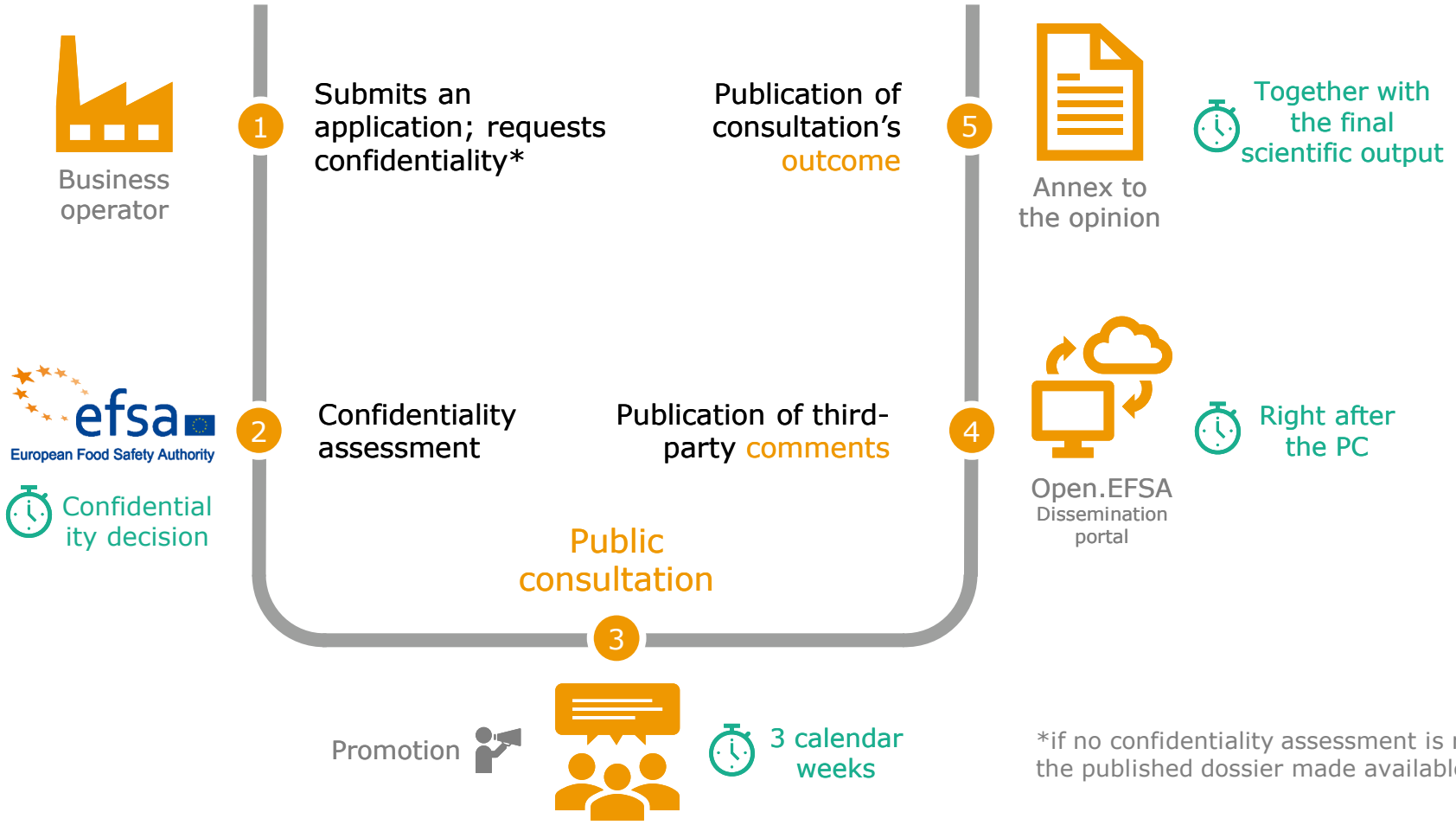
Public Consultation

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 non-confidential version of a validated application



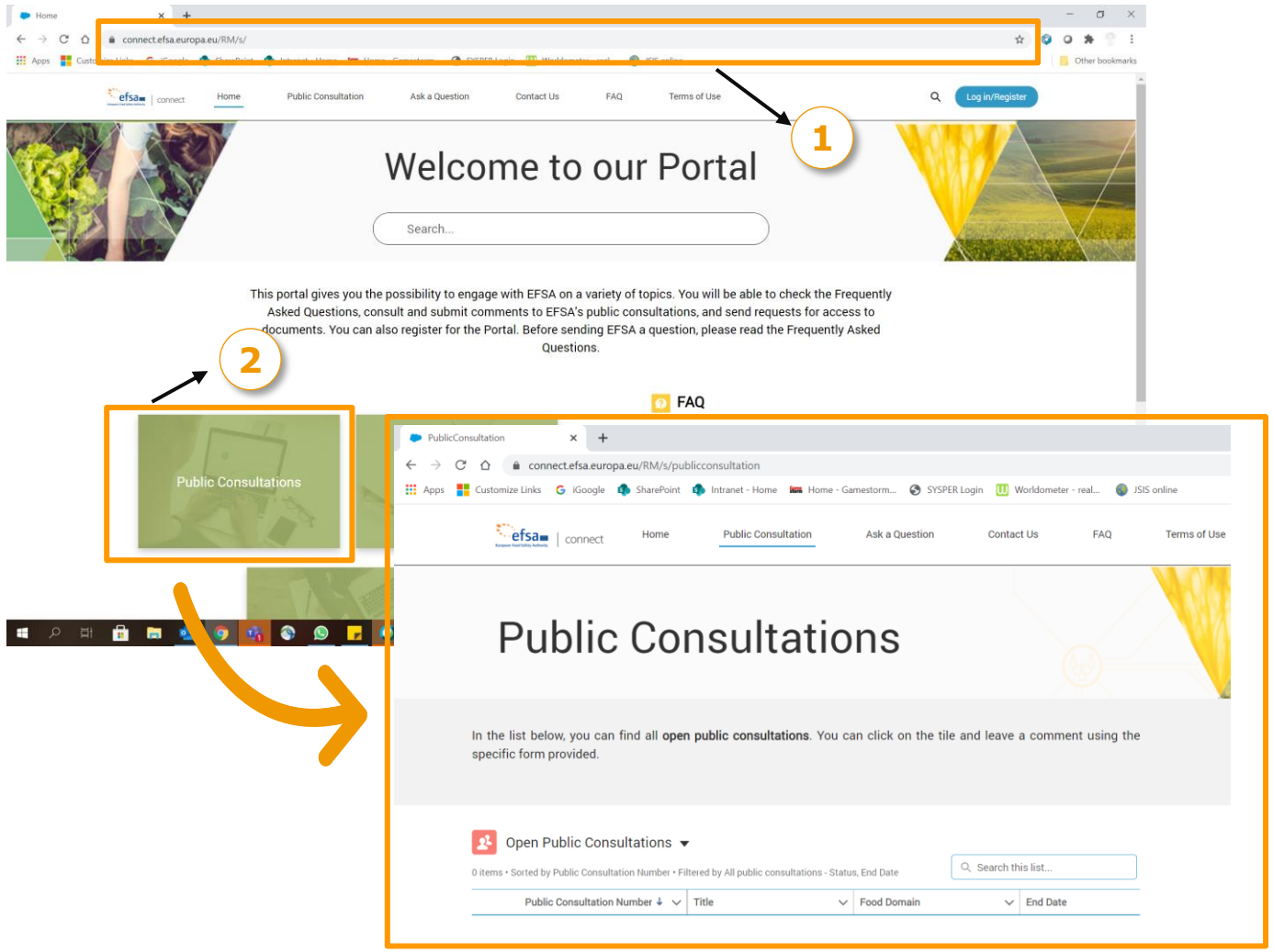
Aim:
Collect new or additional evidence/data/information to assess an application

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

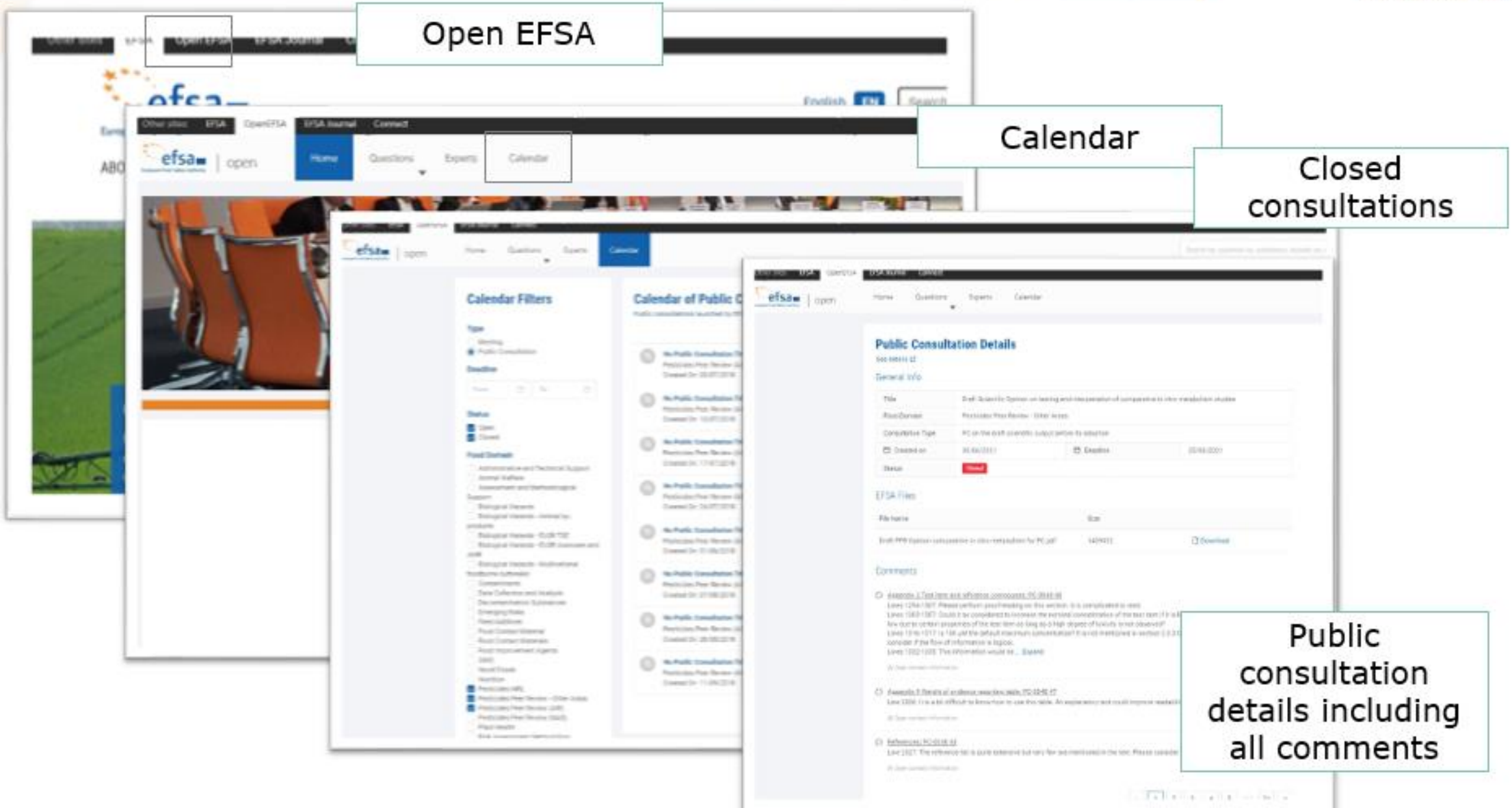


How to access the portal

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

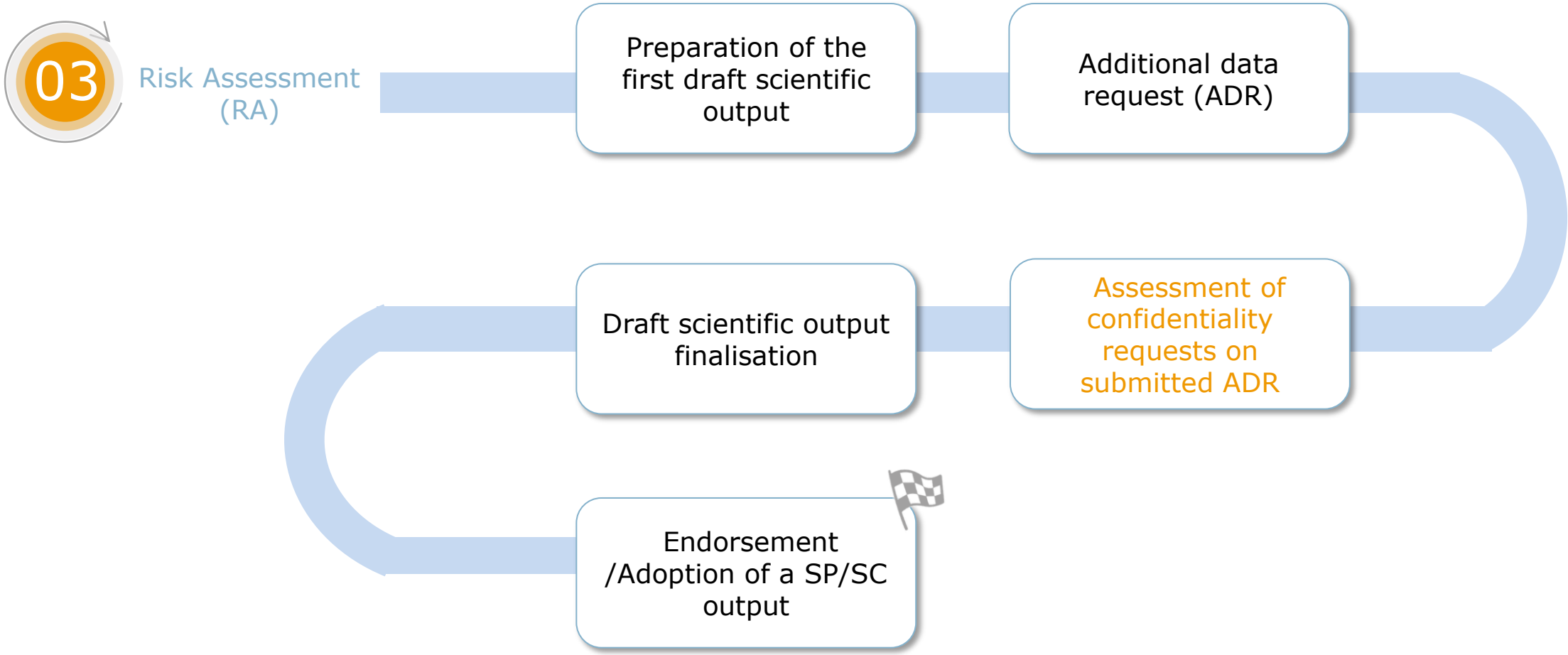
The portal is easily accessible from the EFSA website

Open EFSA - Publishing of comments



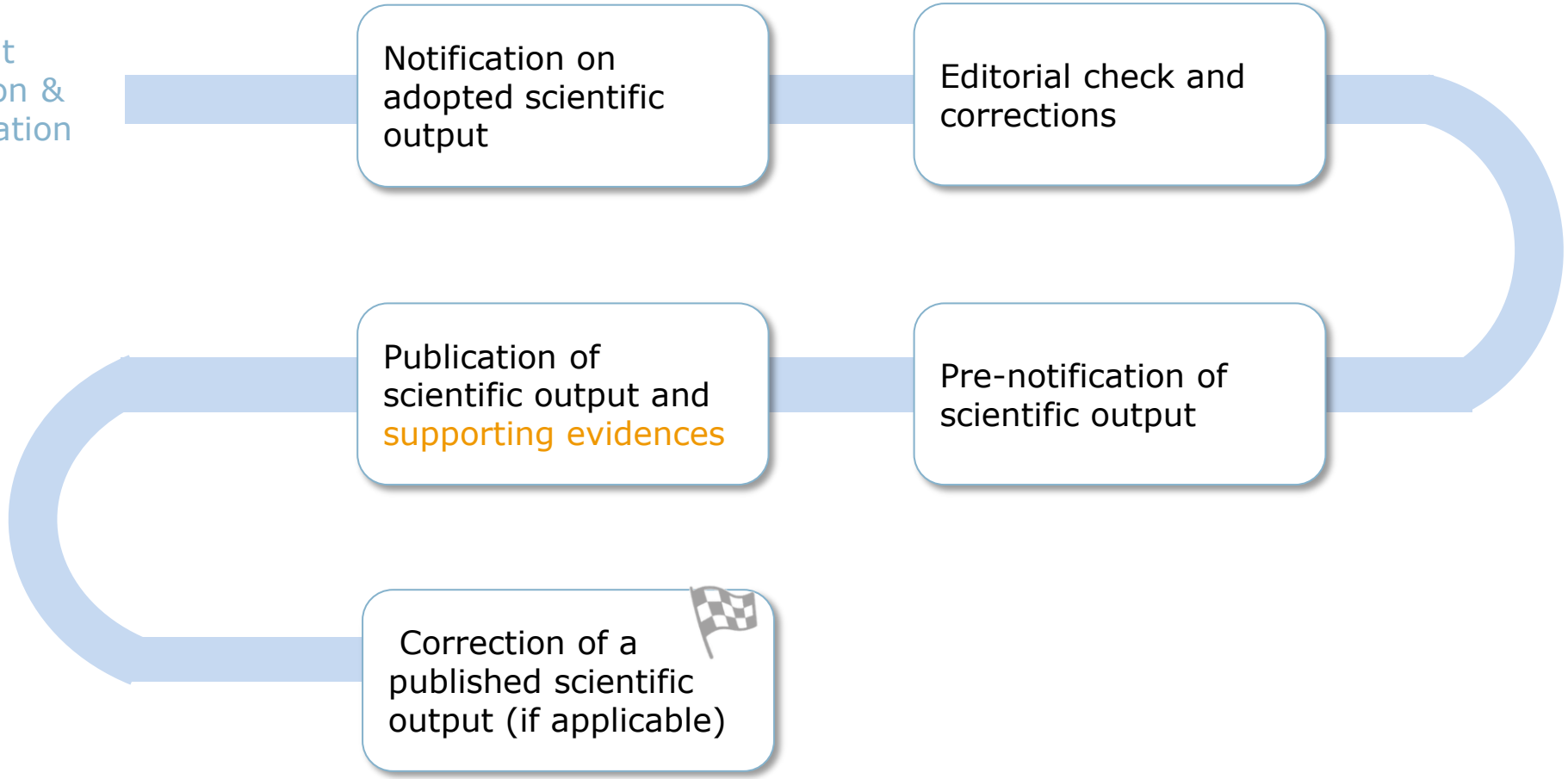
Risk Assessment, Adoption and Publication

Risk Assessment Phase



Output Publication & Dissemination phase

04 Output Publication & Dissemination



FAQs from Heath Claims applicants

Question and answer (1)

While the details of the notified study can only be viewed publicly once the actual application (e.g. health claim application) has been submitted and marked as valid, what about the publication of the study details alone: are they published before?

- **No information on the studies notified pursuant to Article 32b(2) and (3) of the General Food Law is made public before the corresponding application is considered valid** according to Article 6(1) point f of the EFSA Practical Arrangements concerning transparency and confidentiality.
- **The information notified is published in OpenEFSA after validation** and once a final decision on confidentiality requests becomes applicable.

50

Question and answer (2)

Where can I find the health claim applications that have been submitted before 2021?

In the register of questions, only recent applications are visible.

- **Information on questions that were already closed at the date of 21 January 2021 can be retrieved in the following static reports** available at: https://www.efsa.europa.eu/en/register-of-questions.
- Only applications that were still ongoing at the date of 21 January 2021 were migrated to the new OpenEFSA portal (https://open.efsa.europa.eu/).

Question and answer (3)

If I want to initially conduct a research study for research purposes only, but eventually use it for future health claim application, what should I do in case of a change of strategy?

- **The inclusion in the application of a study which has not been previously notified needs in any case to be justified by the applicant.**
- It is not necessary to notify EFSA studies not conducted for the purpose of supporting an application (e.g. studies conducted for research purpose only)
- With regard to **studies initially conducted for a purpose other than supporting an application** in relation to which Union law contains provisions for EFSA to provide a scientific output, it should be noted that **the verification of compliance with study notifications is carried out following the receipt of the application**.

As described in Question 34 of Section B of the Questions and Answers on the EFSA Practical Arrangements, **only studies commissioned or carried out by business operators to support an application** in relation to which Union law contains provisions for EFSA to provide a scientific output **are subject to the notification of study obligations** (Articles 32b of the General Food Law)

Question and answer (4)

Where can I find the status "pending" or "on hold" for botanical claims?

- **This information is not displayed in OpenEFSA**
- **They are listed in: Questions on hold Botanical claims, and at the Commission webpage** (identified by claim ID number) available here: https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/resources/docs/claims_pending.pdf

Please visit also:
General function" health claims under Article 13

Available at:
https://www.efsa.europa.eu/en/topics/topic/general-function-health-claims-under-article-13

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:

- Health Claims: guidance web section
  - General scientific guidance for stakeholders on health claim applications (Revision 1)
  - Scientific and technical guidance for the preparation and presentation of a health claim application(revision 3)
- 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 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

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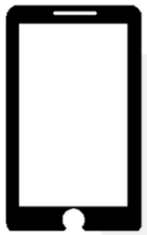

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