Webinar on the application procedure for food contact materials

25 November 2021

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 E-submission (demo) Portal updates and validity of applications Confidentiality in the context of FCM Public consultation RA, adoption and publication FAQ from FCM applicants	Karine Lheureux Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Stefano Cappé Sara De Berardis Simone Gabbi Goran Kumric Karine Lheureux Anastasia Livaniou Remigio Marano 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
- Goran Kumric
- Remigio Marano
- Francesca Volpi

Webinar moderator:
- Margherita Guidi

Goals

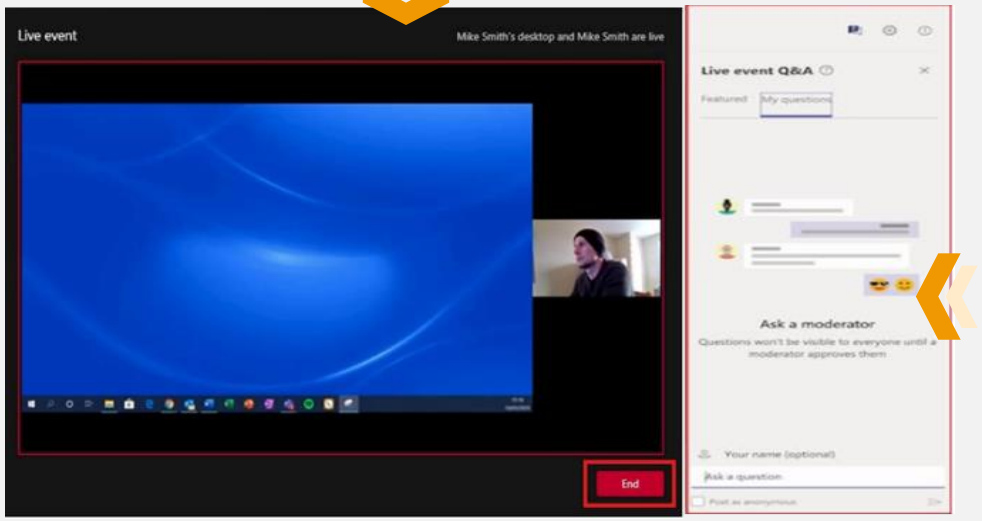
- What is the goal of this webinar? The aim is to explain the arrangements, steps and the tools of the application procedure for FCM implemented by EFSA following the entry into application of the Transparency Regulation.
- Address questions encountered by applicants in recent months following the entry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

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

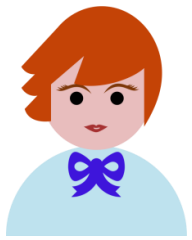
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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)

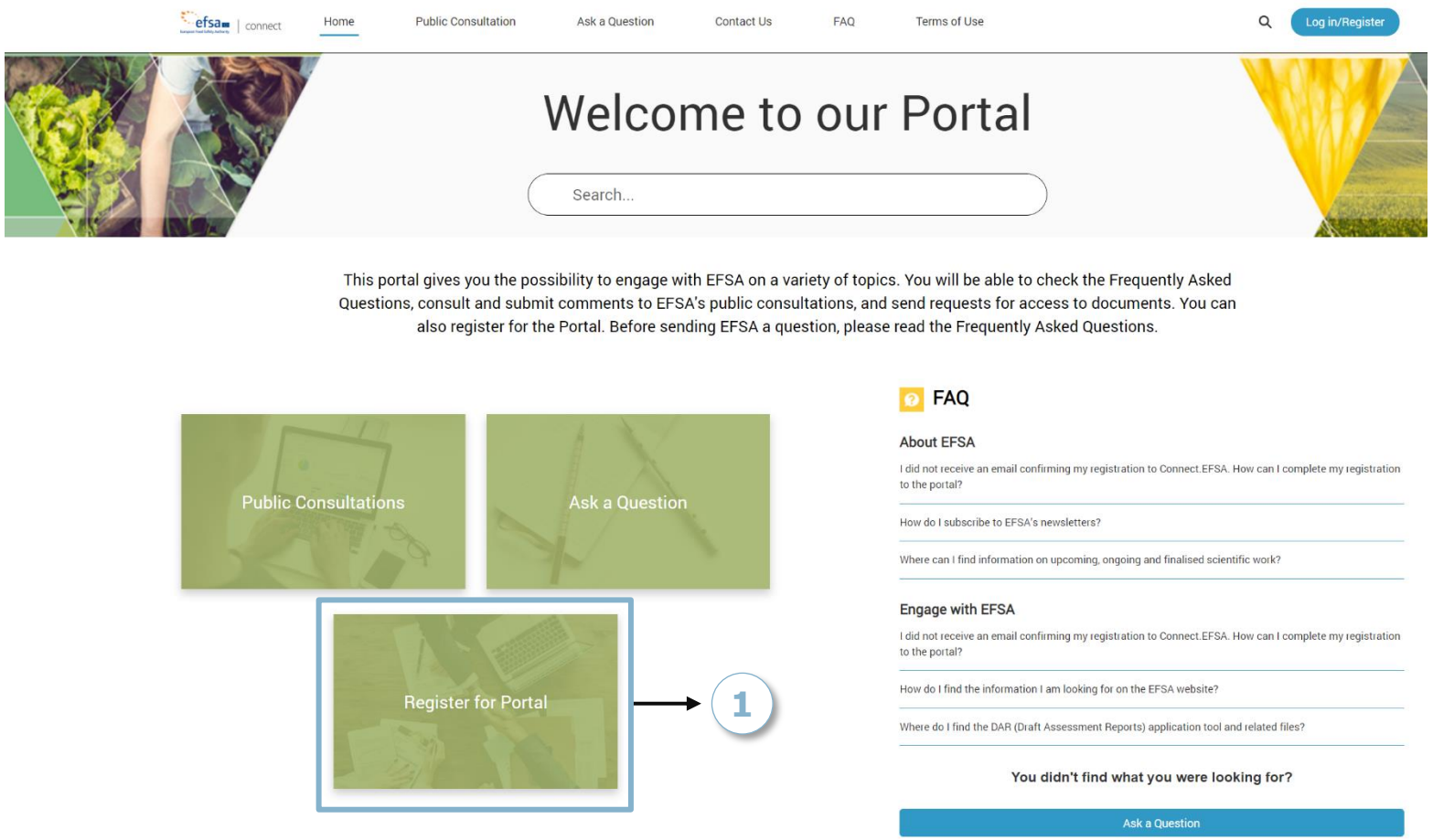
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

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

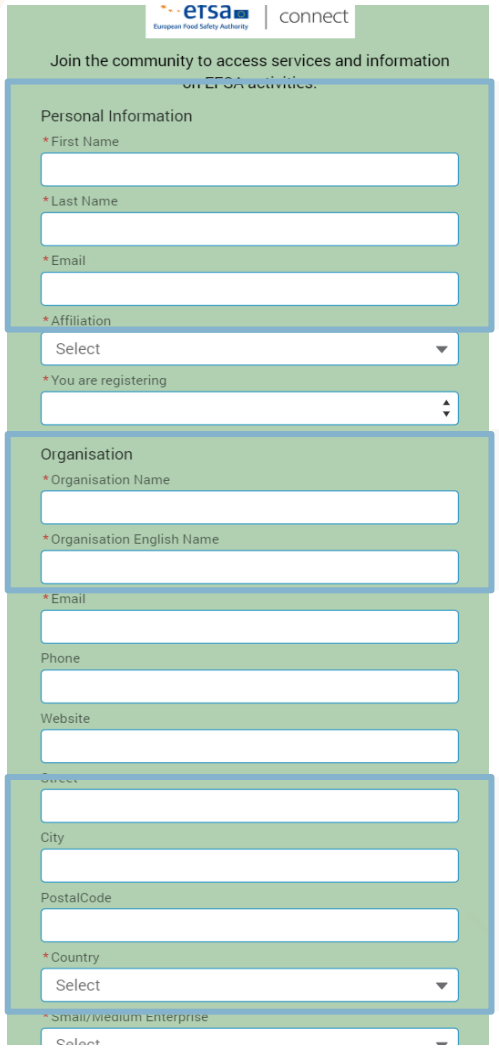
The potential applicant starts the registration in the portal.

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!

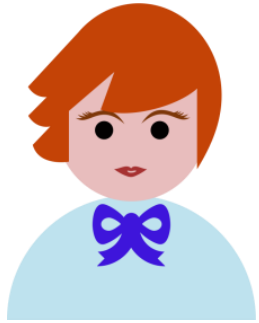
This relationship has to be previously established in the Account Management:

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)

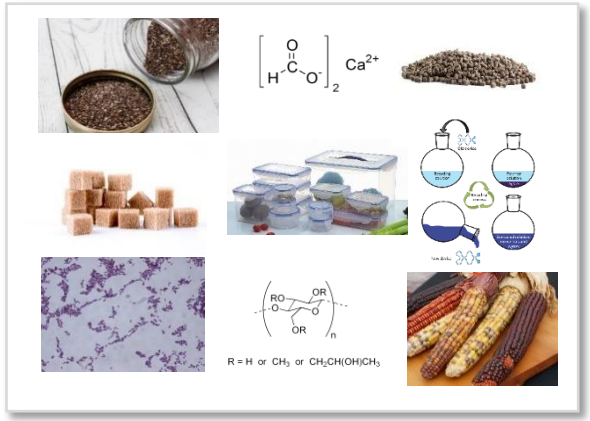
Pre-Application ID
Pre-submission advice
Notification of Studies

New applications

Pre-Application Identification



Sarah
Business Operator(s)



Subject of the application

Intended Area

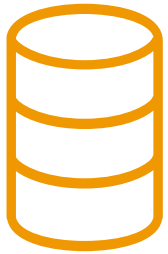
Mandate and Dossier intake
General Pre-Submission Advice

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

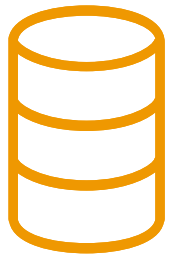
Mandate and Dossier Intake
Notification of Studies for new application

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

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, modif., renewal)

- **Food Contact Materials**: Substances, Active & Intelligent materials, Recycling processes
- **Food Improvement Agents**: Food Additives, Food Enzymes, Food Flavourings, Smoke Flavourings
- **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

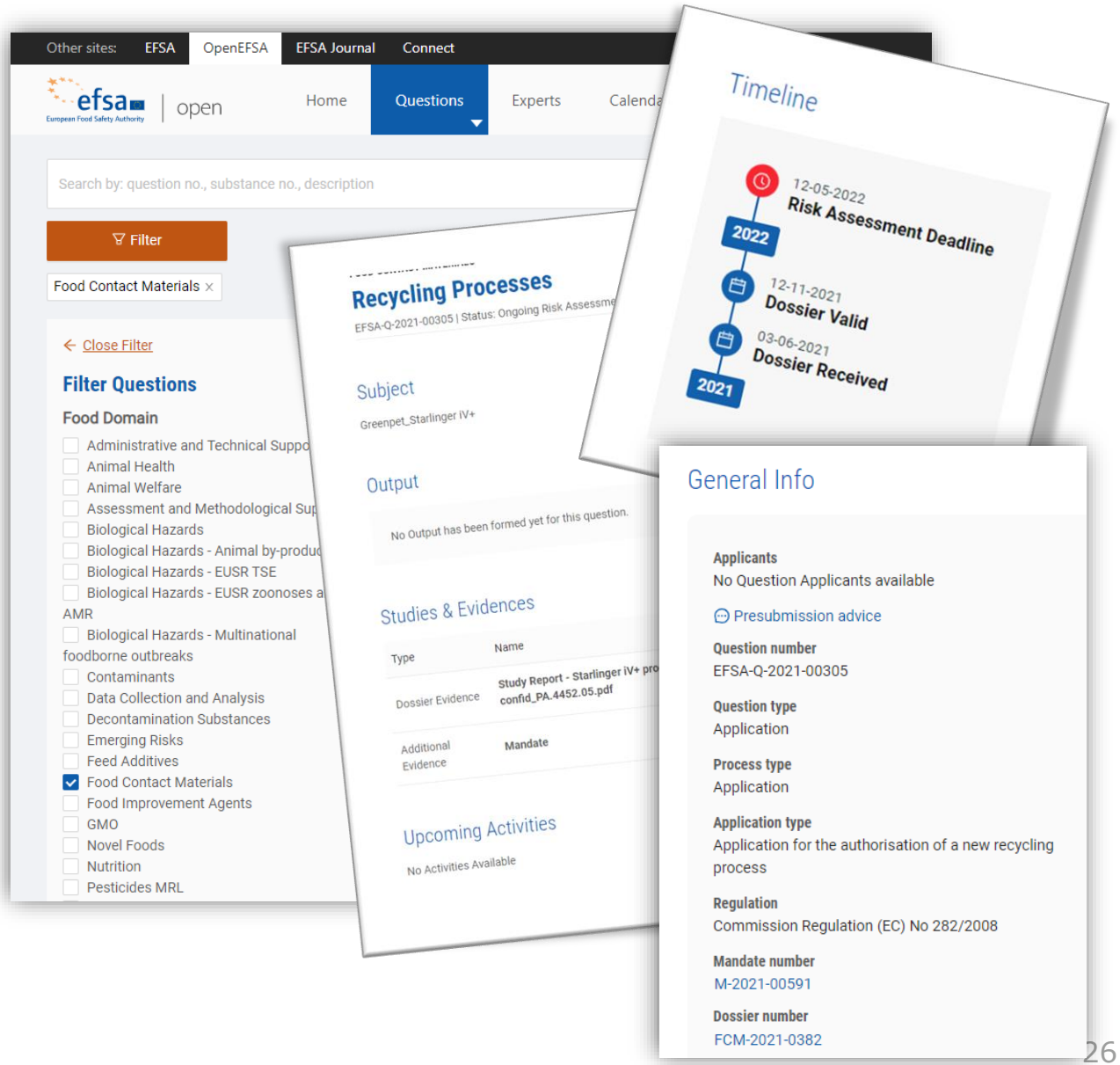
Video Tutorials
Hyperlink

User Guide
Hyperlink

Portal updates and validity of application

Mandate and Dossier Intake

- Member State Authority forwards Application to EFSA
- Application registered - Question # (dossier + mandate)
- Q# visible in Open.EFSA Portal (subject, mandate, timeline)
- EFSA performs Completeness check (+ NoS check)
- Request for Information (RFI): received, and replied to, via ESFC (incl. data)
- 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 food contact materials

Food Contact Material Applications

Application submitted before 27/03/2021

Application submitted on/after 27/03/2021

Pre-TR GFL applies

- Confidentiality requests assessed in accordance with Article 39 of the GFL and Article 20 of Regulation 1935/2004 & sectoral acts

GFL as amended by TR applies

- Practical Arrangements concerning transparency and confidentiality apply
- Confidentiality requests assessed in accordance with Articles 39-39e of the amended GFL and Article 20 of Regulation 1935/2004 as amended by the TR

Transparency Regulation principles

Proactive Disclosure

Art 38 of TR + Article 19 Reg 1935/2004
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 TR + Art 20 of Reg 1935/2004
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/notification 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
- 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:

e. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 1935/2004	
Legal basis under which the request may be submitted	**Items that may be claimed confidential**
Article 20(2)(a) of Regulation (EC) No 1935/2004	any information provided in detailed descriptions of starting substances and mixtures used to manufacture the substance subject to the authorisation, the composition of mixtures, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those mixtures, materials or articles, impurities, and migration testing results, except for information which is relevant to the assessment of safety;
Article 20(2)(b) of Regulation (EC) No 1935/2004	the trademark under which the substance shall be marketed as well as the trade name of the mixtures, material or articles in which it shall be used, where applicable;
Article 20(2)(c) of Regulation (EC) No 1935/2004	any other information deemed confidential within the specific procedural rules referred to in point (n) of Article 5(1) of Regulation (EC) No 1935/2004;
Article 20(2) of Regulation (EC) No 1935/2004 (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 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)

!

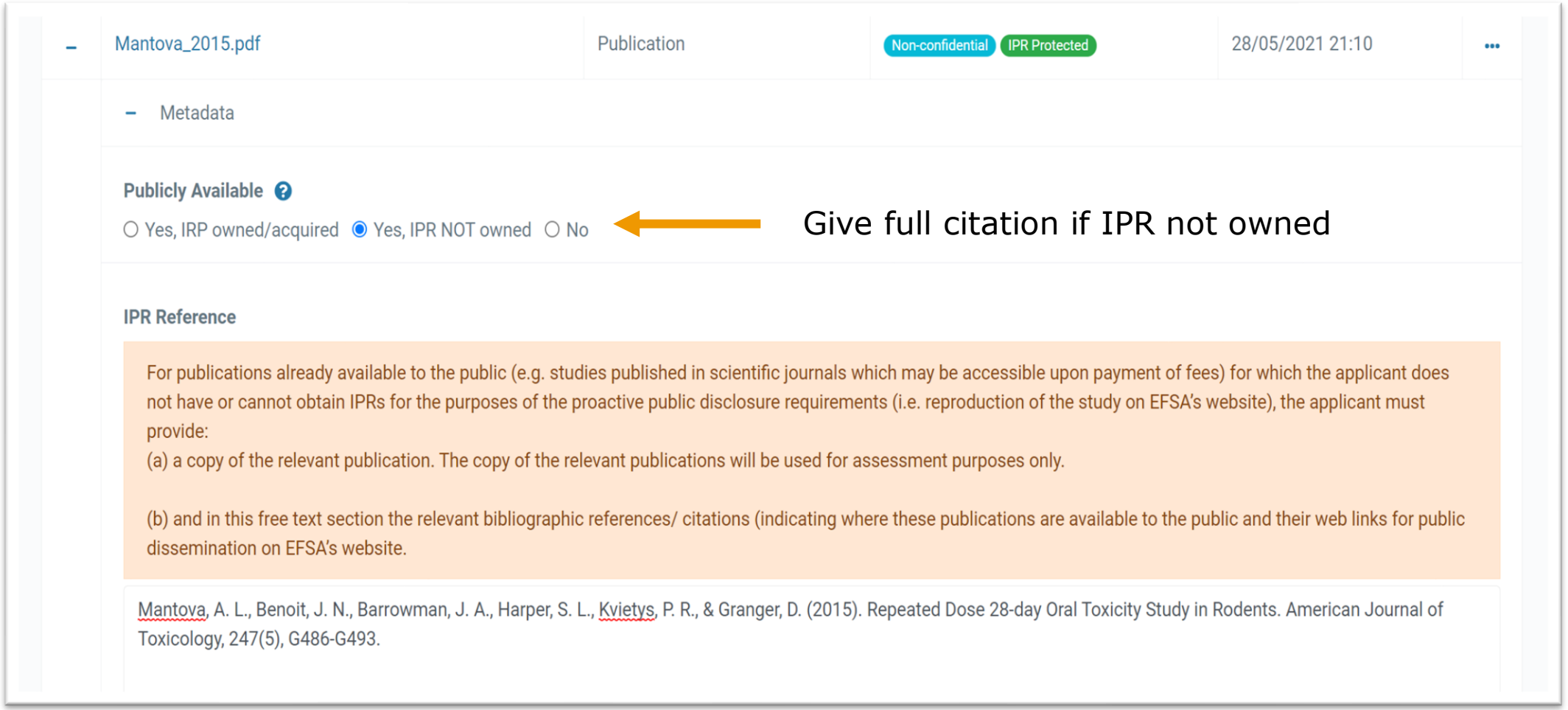
Submit confidentiality requests for other personal data to be withheld from disclosure, **including** names and addresses of NATURAL PERSONS involved in testing on vertebrate animals or in obtaining toxicological information.

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

Substantive requirements

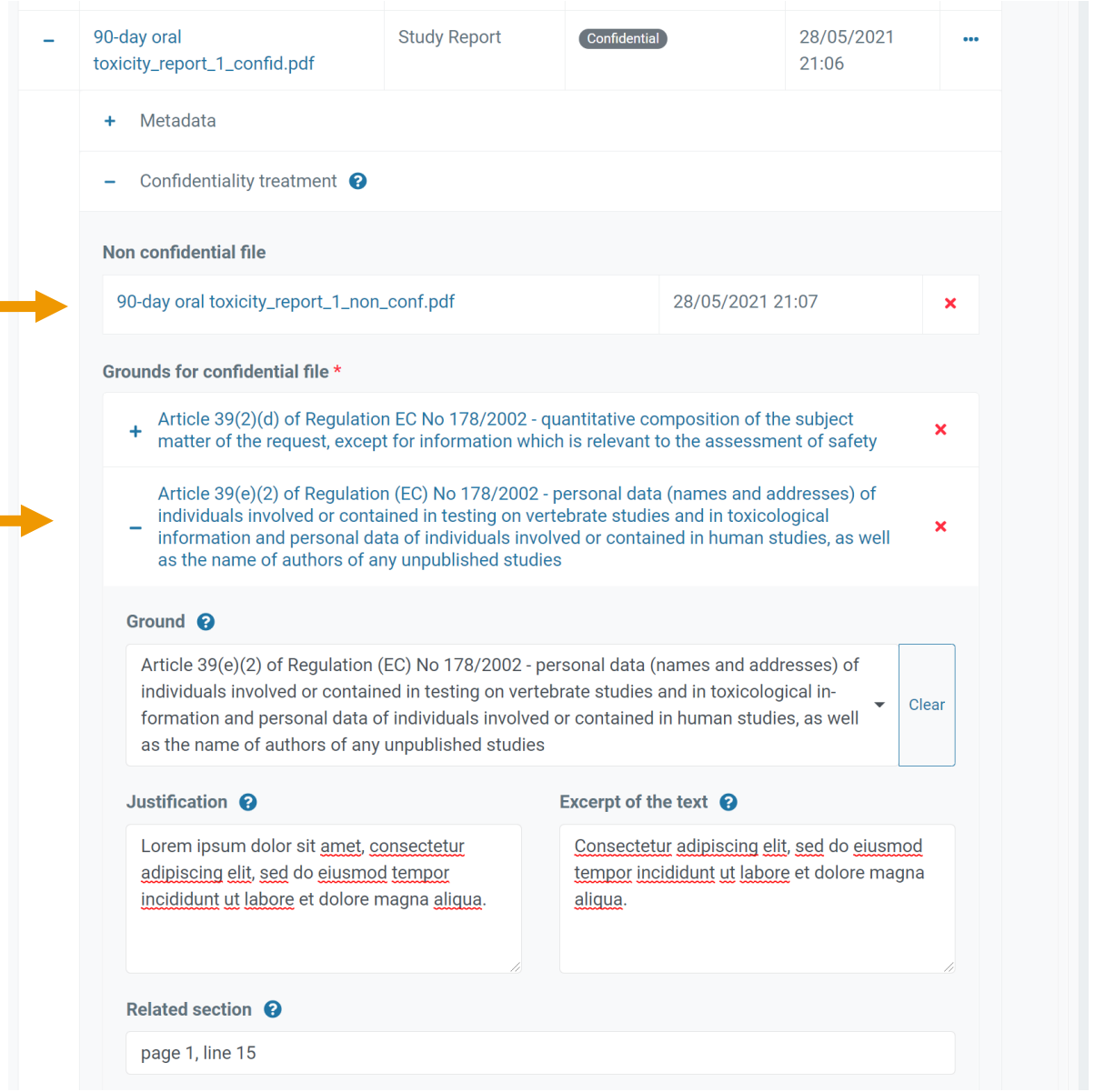
- Identifying clearly the information claimed confidential, with references
- Indicating the legal basis (grounds)
- Explaining why the item should be kept confidential:
  - Information not publicly available
  - Potential harm to a significant degree
    - Information acquired legitimately
    - Negligible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

Published studies



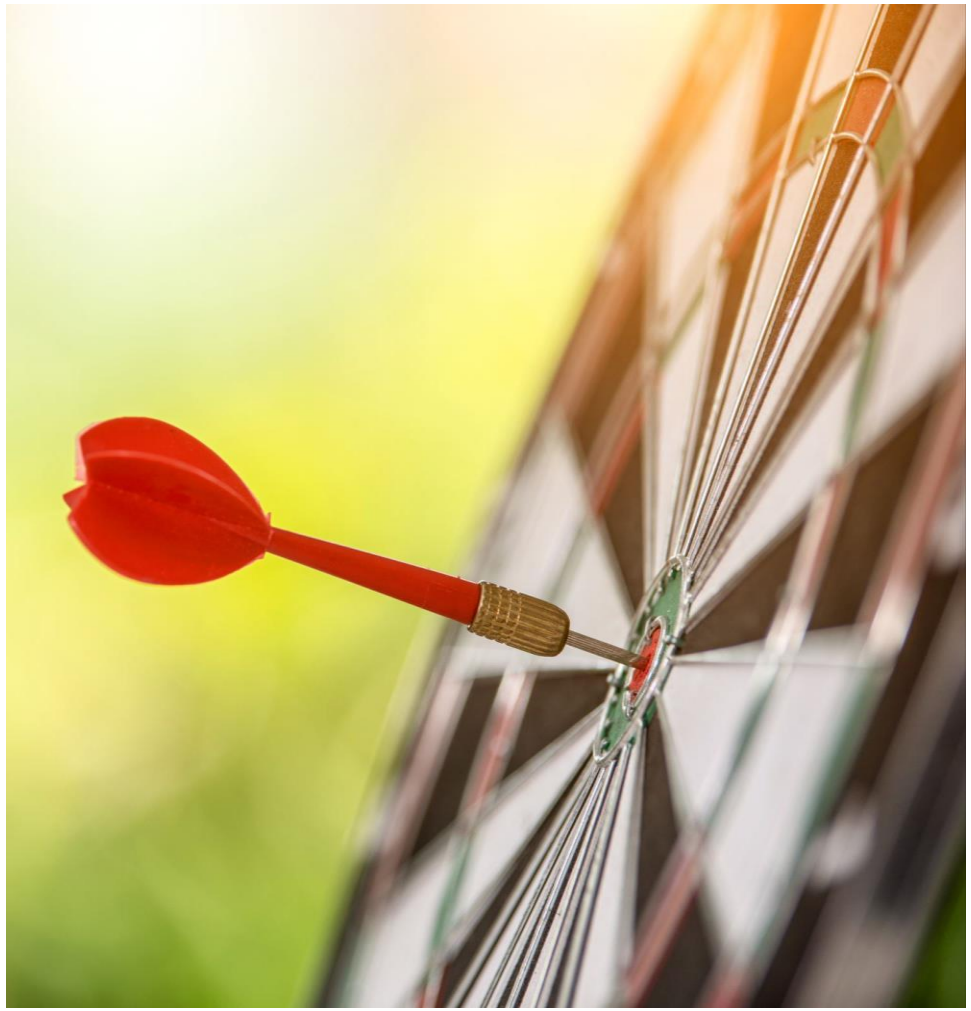
Building a Confidentiality Request

- Provide non-confidential file
- Define your request:
  - Legal ground
  - Justification
  - Excerpt
  - Location in file
- Add requests, as required
- Ensure that earmarked parts of the confidential version match exactly with the blackened parts of the non-confidential version



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)*

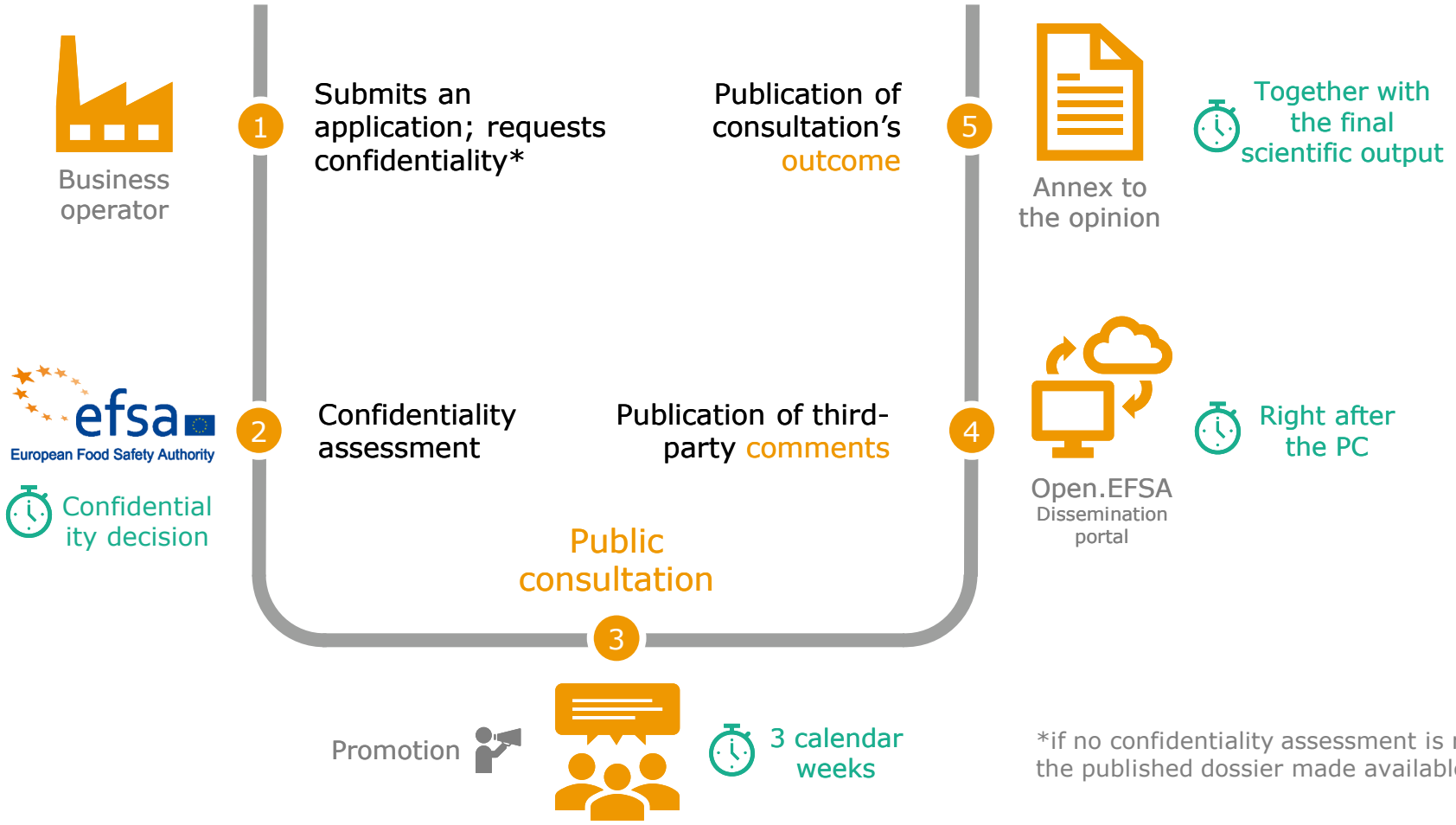
Public Consultation

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 non-confidential version of a validated application



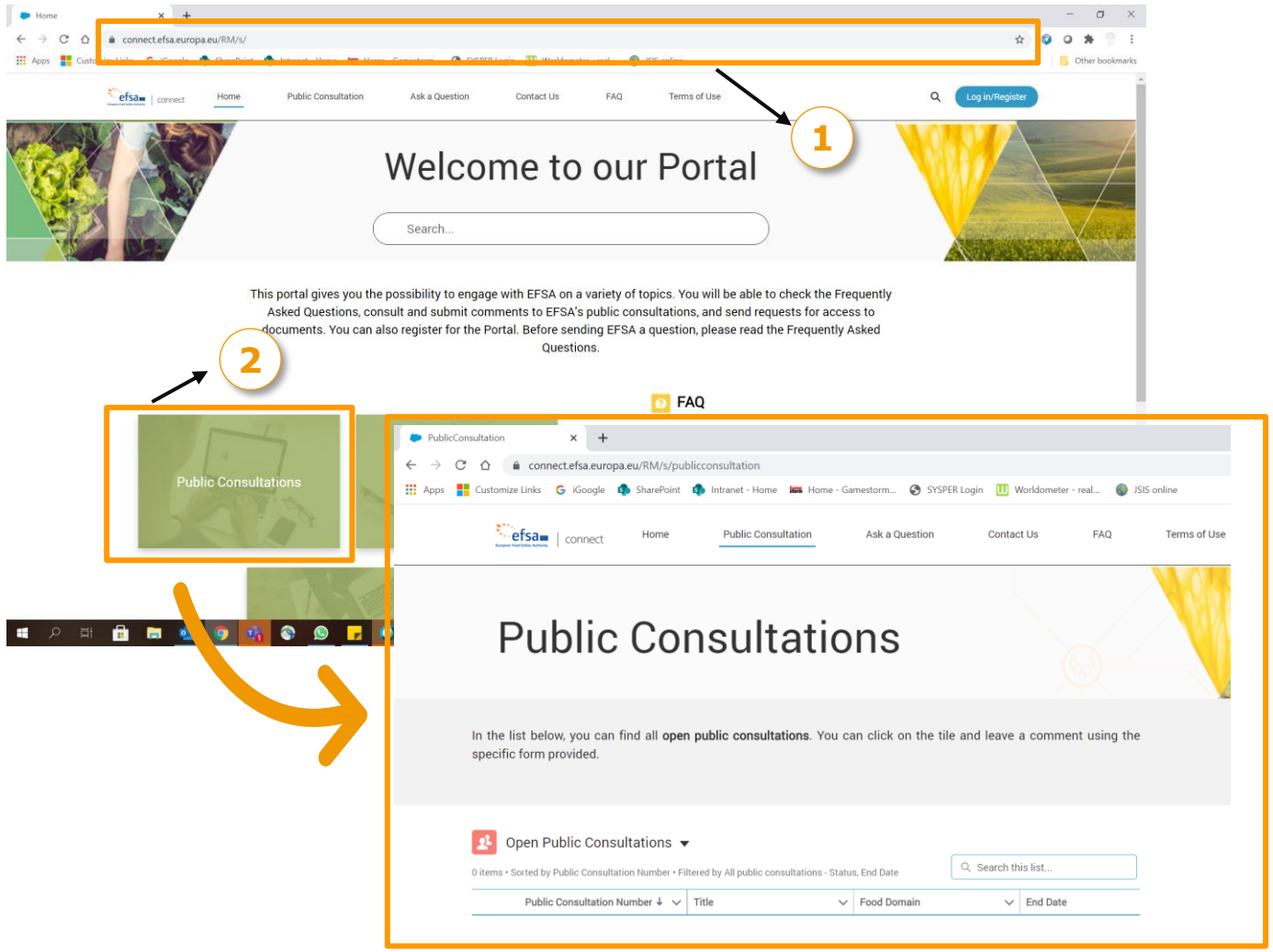
Aim:
Collect new or additional evidence/data/information to assess an application

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



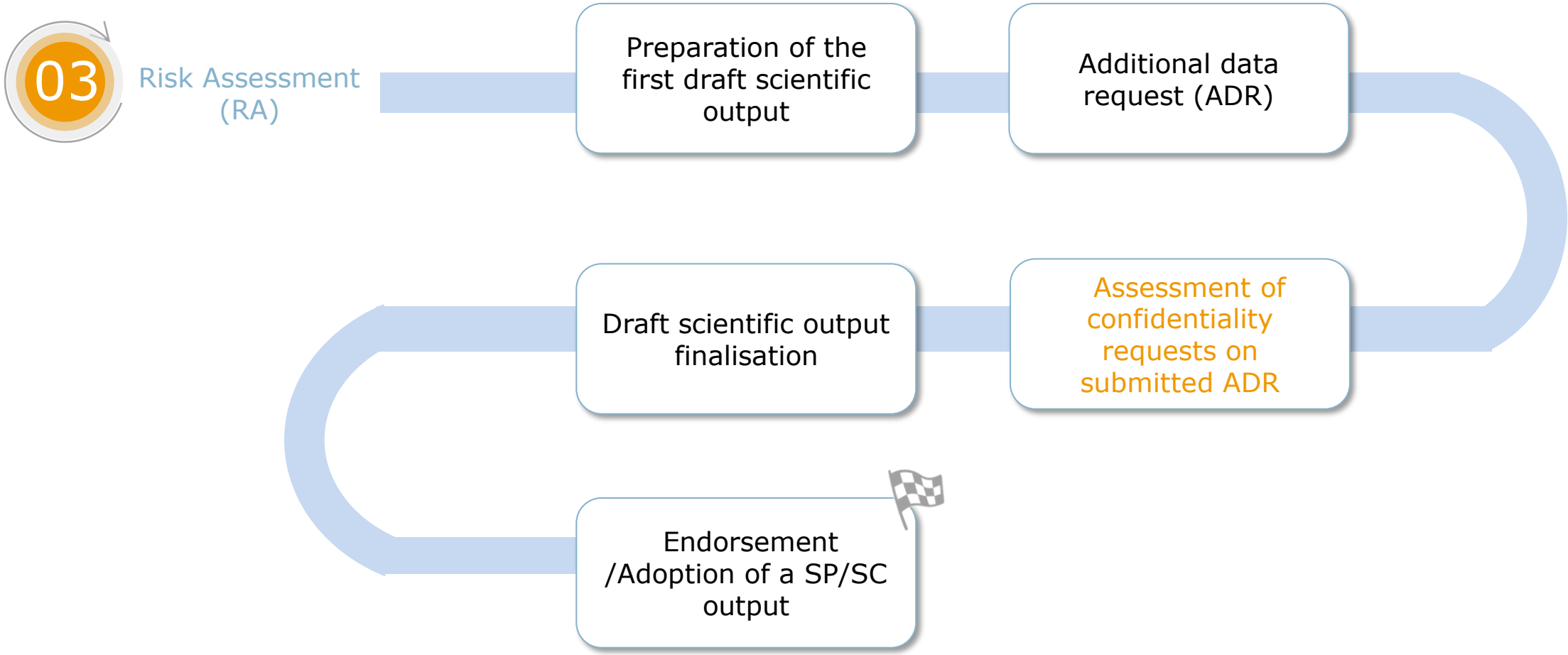
How to access the portal

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

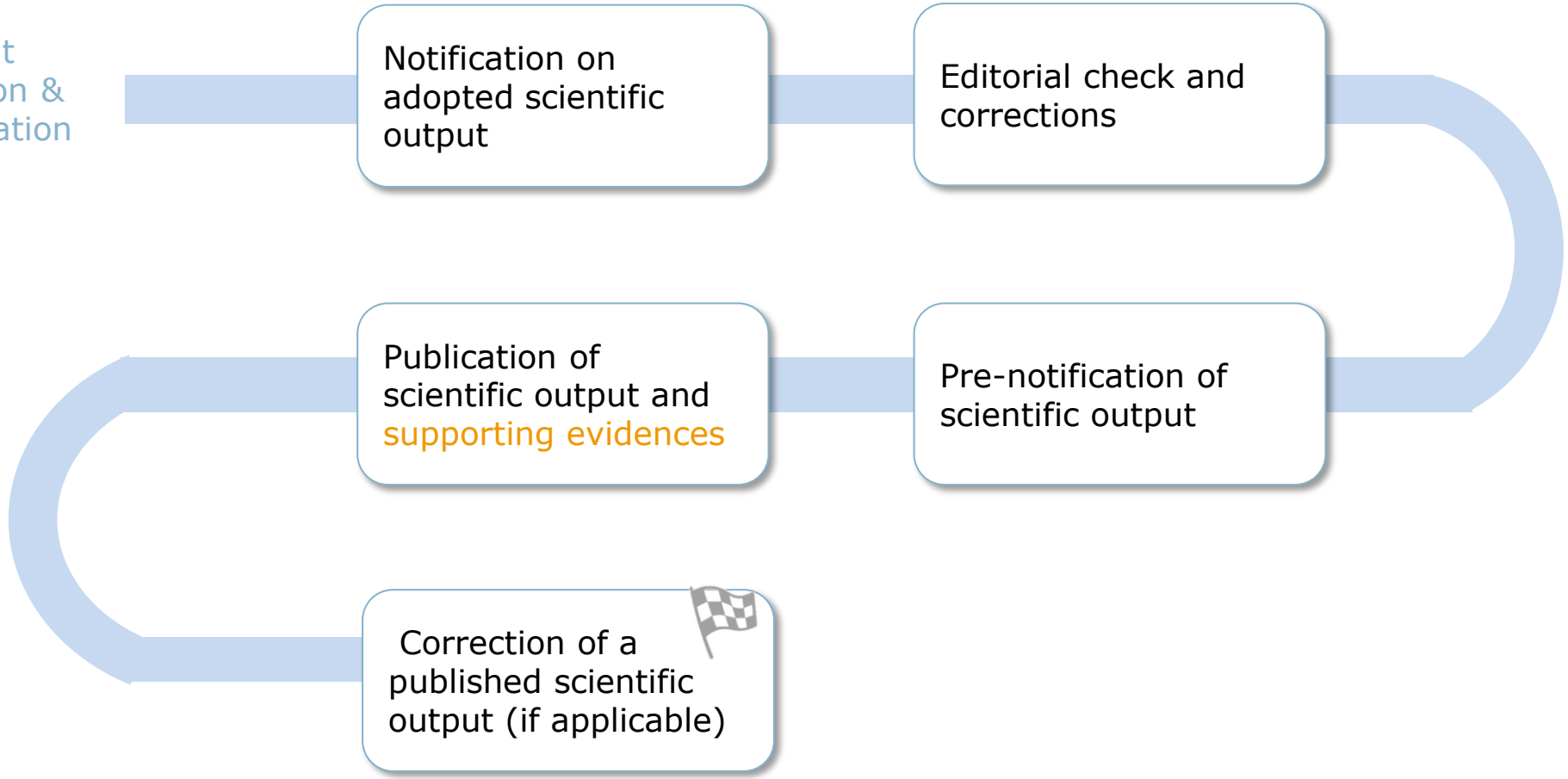
Risk Assessment, Adoption and Publication

Risk Assessment Phase

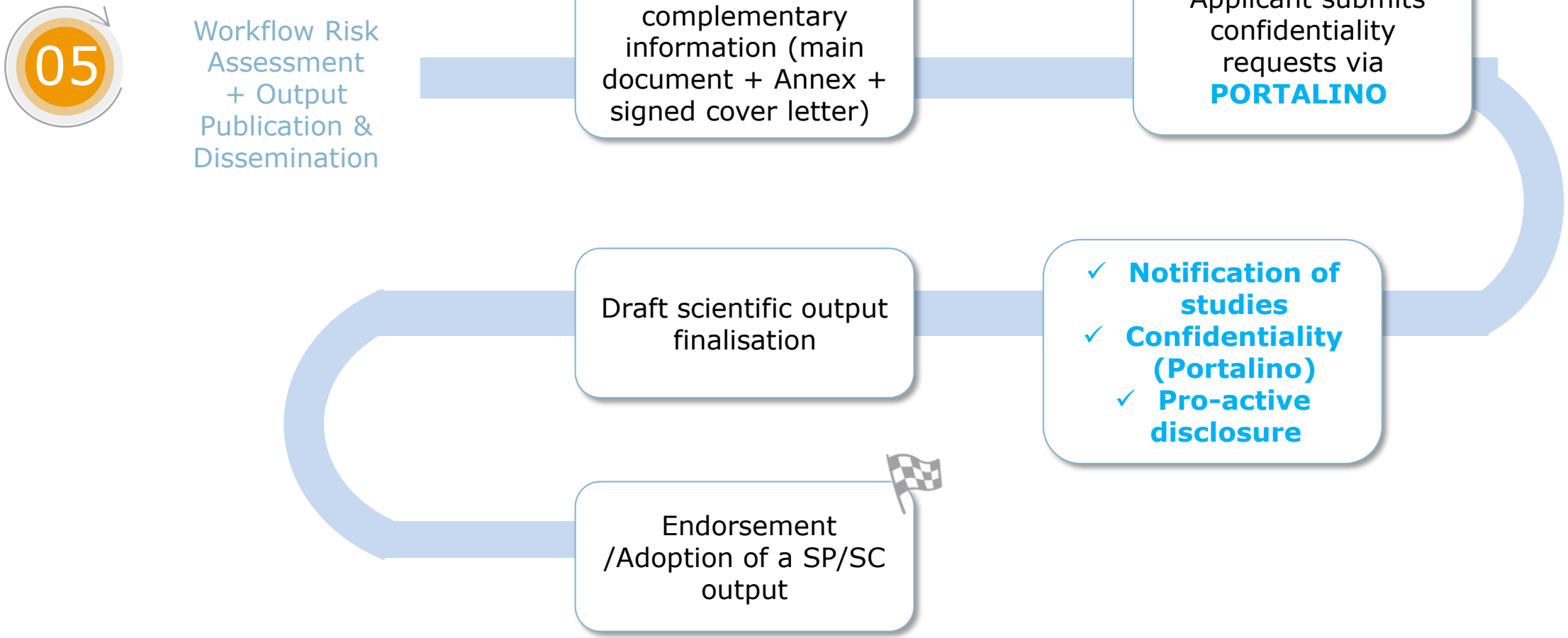


Output Publication & Dissemination phase

04 Output Publication & Dissemination



EFSA inconclusive scientific output



Administrative guidance for the preparation of applications on additives for use in animal nutrition - chapter 2.12: https://www.efsa.europa.eu/en/supporting/pub/en-6508

Useful information

Legal documents:

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- Consolidated version Regulation (EC) 1935/2004 on Food Contact Materials
- 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 aggangements: https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

Guidance/training material:

- Updated administrative guidance for the preparation of applications on substances to be used in plastic food contact materials
- Food contact materials applications: regulations and guidance web section
- Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles
- 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)

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

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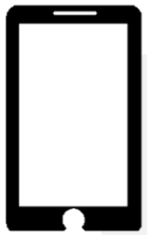

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