Application procedure for Food Enzymes, Food Flavourings and Food Additives

4 June 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 Pre-application ID NoS E-submission (demo) Appearance on the portal and validity step Confidentiality Public consultation RA, adoption and publication	Karine Lheureux Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Karine Lheureux Anastasia Livaniou Simone Gabbi Remigio Marano Stefano Cappé Francesca Volpi Goran Kumric

Welcome and Introduction

Who we are

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

Q&A contributors:
- Remigio Marano
- Stefano Cappé
- Francesca Volpi
- Goran Kumric

Webinar moderator:
- Margherita Guidi

Goals

Explain the steps and tools of the application procedure for food enzymes, food flavourings and food additives.
Speakers will go through the application lifecycle and address questions on issues encountered by applicants in recent months following the entry into application of the Transparency Regulation.

Golden rules

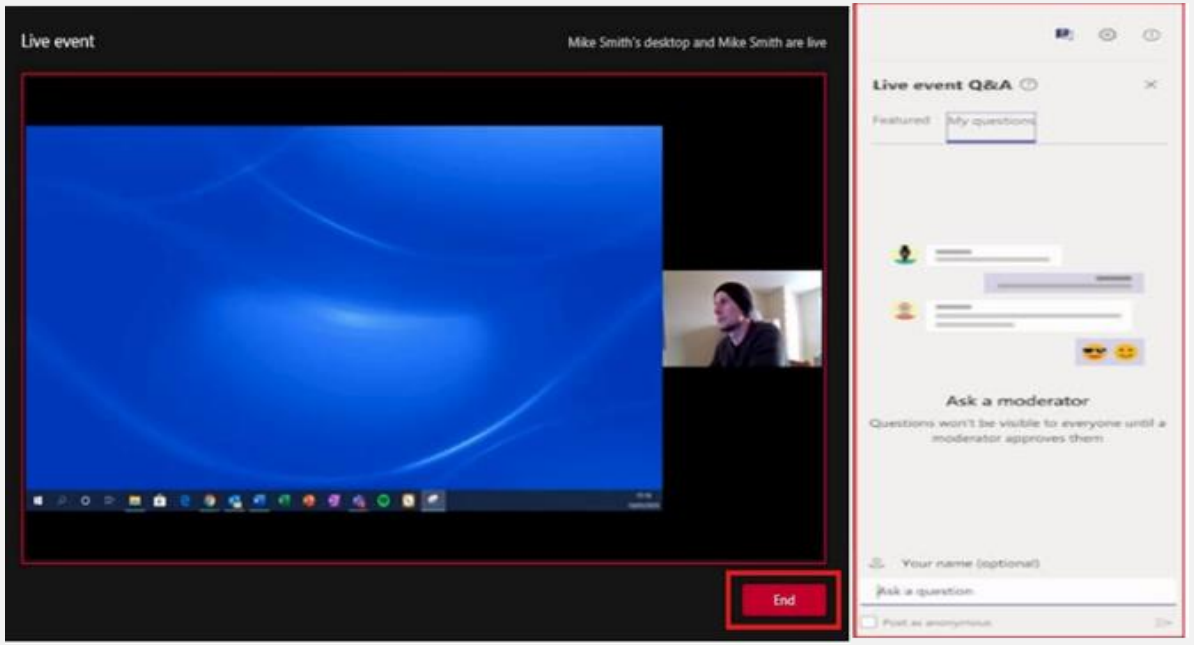
- You can submit questions throughout the webinar via the dedicated Q&A tab on the top right navigation bar
- Some questions will be answered in written and some others will be answered live by our speakers/Q&A contributors
- Questions which will remain answered will not be addressed in the framework of this webinar, but you can resubmit them via the Ask a question Connect.EFSA tool (https://connect.efsa.europa.eu/RM/s/askefsa)

This session is recorded, the materials will be available on the EFSA website including the slides.

Webinar guide for attendees

- This webinar **is being recorded**
- The webinar **is in English** and questions should be submitted in English through the platform.
- You are automatically connected to the audio broadcast. One-way audio (listen only mode).

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, GPSA)
- 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

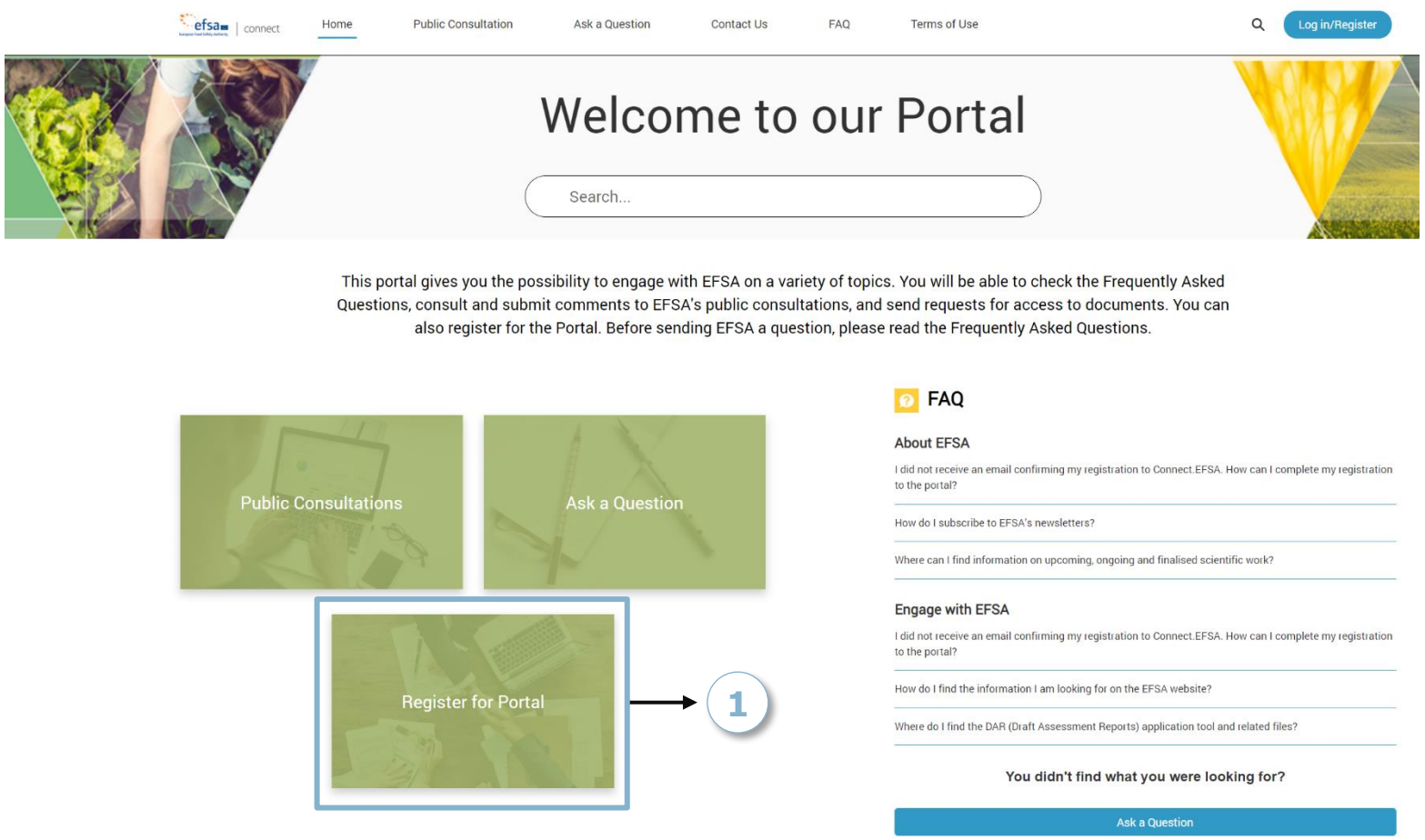
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

PORTALINO

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

Account Creation

Connect.EFSA Portal - Account Registration



Sarah

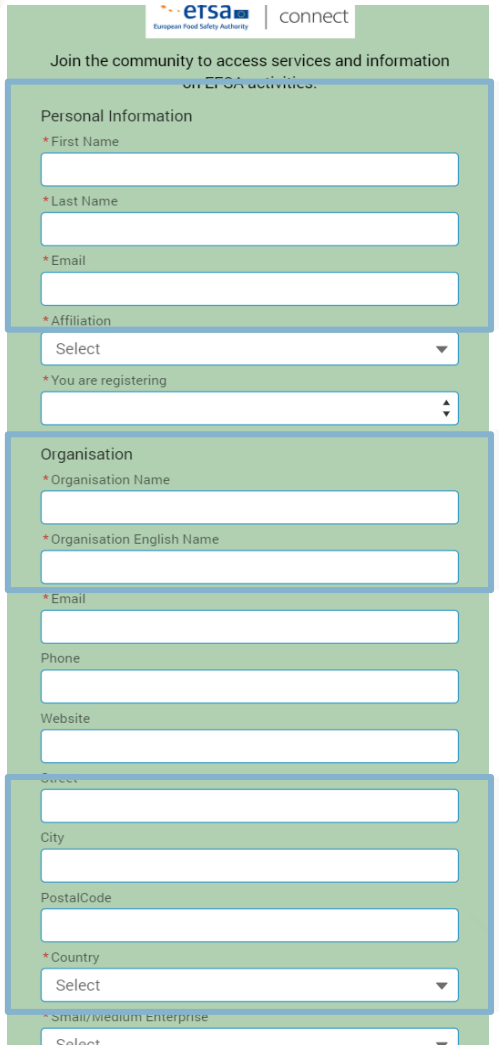
The potential applicant starts the registration in the portal.

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 3** contact persons.

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.

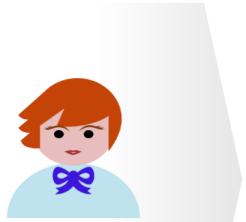
The applicant is ready to use the functionalities of the portal.

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.

Pre-Application ID
Pre-submission advice
Notification of Studies

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

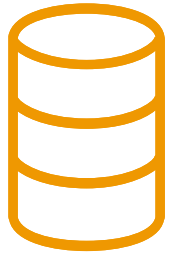
Mandate and Dossier Intake
Notification of Studies for new application

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

Notifying a Study as Business Operator

Sarah

The Business Operator is preparing for notifying

New future application?

YES

Request pre-application ID

NO

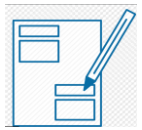
Retrieve pre-application ID

Open pre-application ID "folder" & create new notification

Draft

Fill-in mandatory fields & Notify

Notified



Study performed by internal facility?

YES

END

NO

Alert Email to Lab

John

E-Submission (demo)

E-submission Food Chain Platform (ESFC)

FSCAP v.1 EC web system, operational since Jan 2018 (Novel Foods/Traditional Foods)

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

- **Single point of entry** for Applicant, European Commission, Member States
- **All EFSA Regulated Product** dossiers (excl. pesticides)
- **Submitted to EC > 27 March '21**

6 Food Domains - 37 Application Types (new, modif., renewal)

- **Food Contact Materials**: Substances, Active & Intelligent materials, Recycling processes, cellulose
- **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

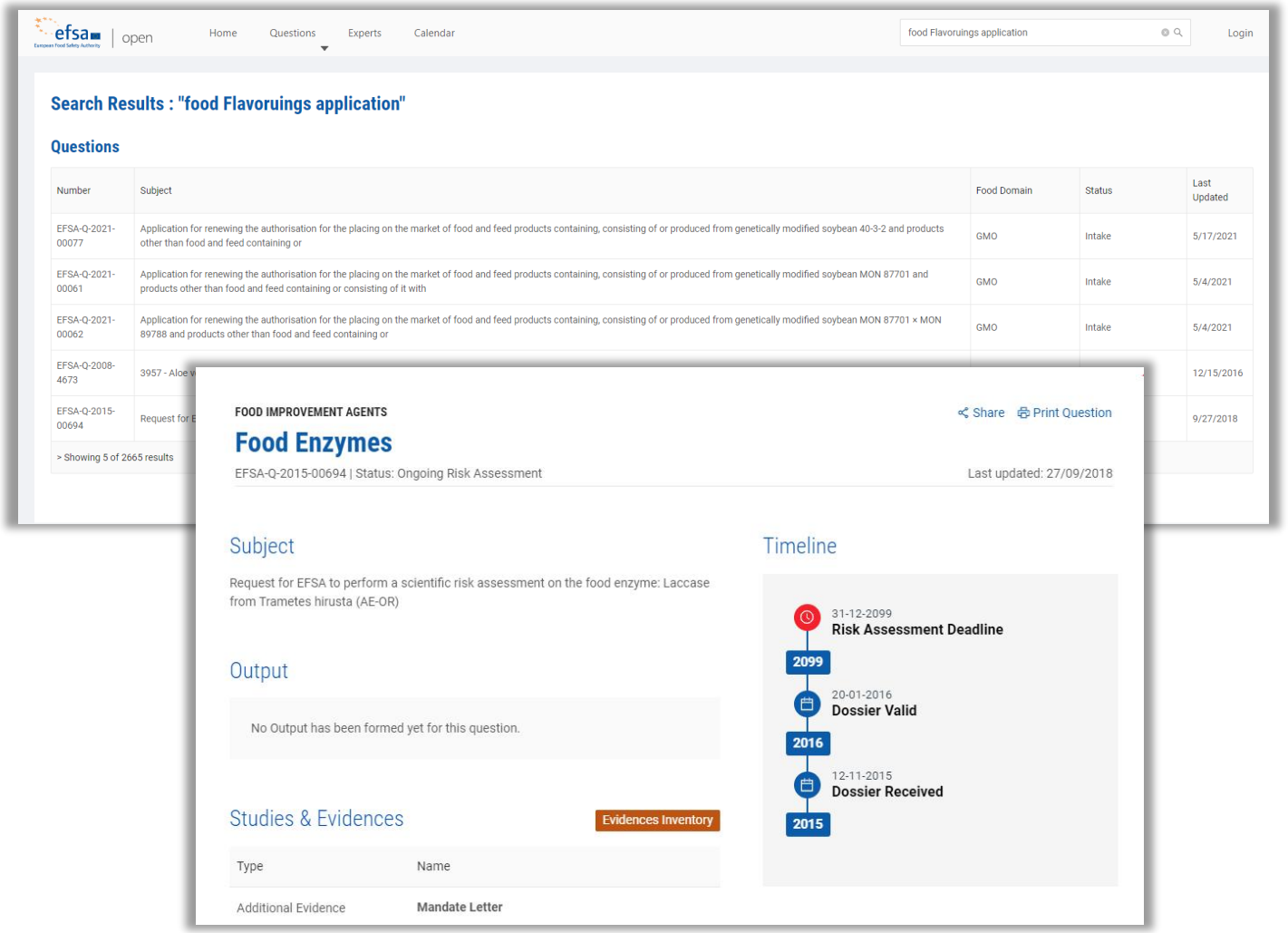
Video Tutorials
Hyperlink

User Guide
Hyperlink

Portal updates and validity of application

Mandate and Dossier Intake

- EC forwards Application to EFSA
- Application registered (Question #) (dossier + mandate)
- Visible in Open.EFSA Portal
- EFSA performs suitability check (+ NoS check)
- Request for Information (RFI): received and replied to via ESFC (incl. data)
- EFSA declares the application Suitable for risk assessment
- EC declares the application Valid
- EFSA publishes non confidential valid dossier (+ summary Pre-submission advice)
- Assessment of confidentiality requests



Confidentiality

Underlying principles

Assessment of confidentiality requests

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

Procedural requirements

- Submission through E-Submission Food Chain Portal
- Including verifiable justifications, a confidential and a non-confidential version of the document
- Providing clarifications ONLY if requested to do so by EFSA
- Submit clarifications within the deadline set by EFSA
- Modifications of submitted requests not allowed
- No fees

Procedural requirements – follows

Confidentiality requests only on items on closed positive list. For this sector:

Information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety

Detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety

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

Quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety

Procedural requirements – follows

Confidentiality requests also on personal data

The non-confidential version of the application dossier shall not contain personal data of any kind, with the exception of the name and address of the applicant, and the names of authors of published or publicly available studies.

Substantive requirements

Identifying clearly the information claimed confidential, possibly 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»

Procedural steps EFSA decision making

STEPS

Mandatory consultation with applicant on the draft decision

Communication of the final decision

Possibility to file confirmatory application via EFSC or if unavailable by writing to

Confidentialityconfirmatory application@efsa.europa.eu

Art 39b GFL

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

Implementation of Confidentiality Decision

EFSA sanitises the information, data sets, documents etc in accordance with the confidentiality decision

EFSA may share the sanitised information prior to its dissemination with the applicant for verification

The publication of the sanitised information will take place on OpenEFSA Portal at the earliest two weeks after notification of the confidentiality decision

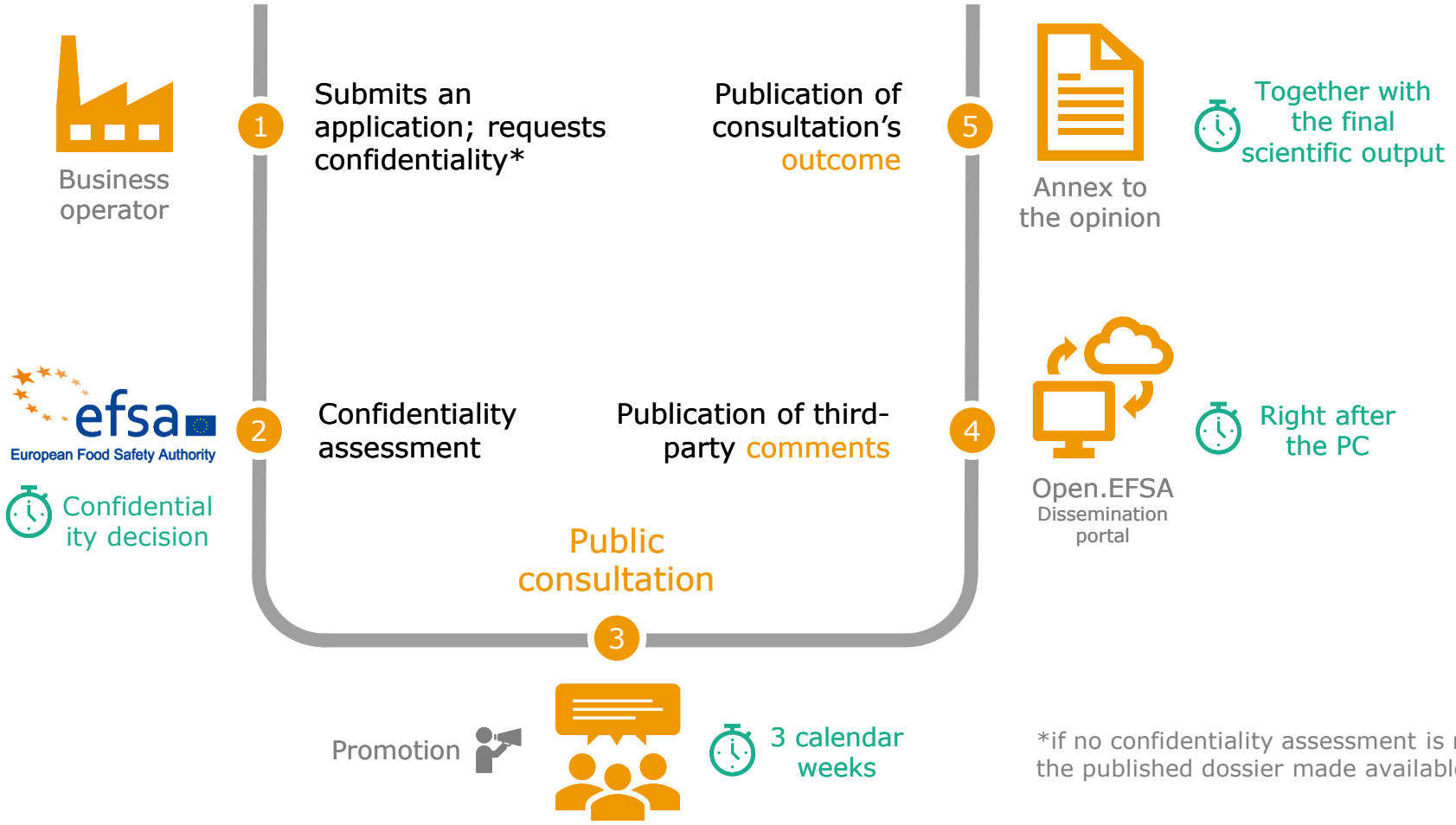
Public Consultation

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



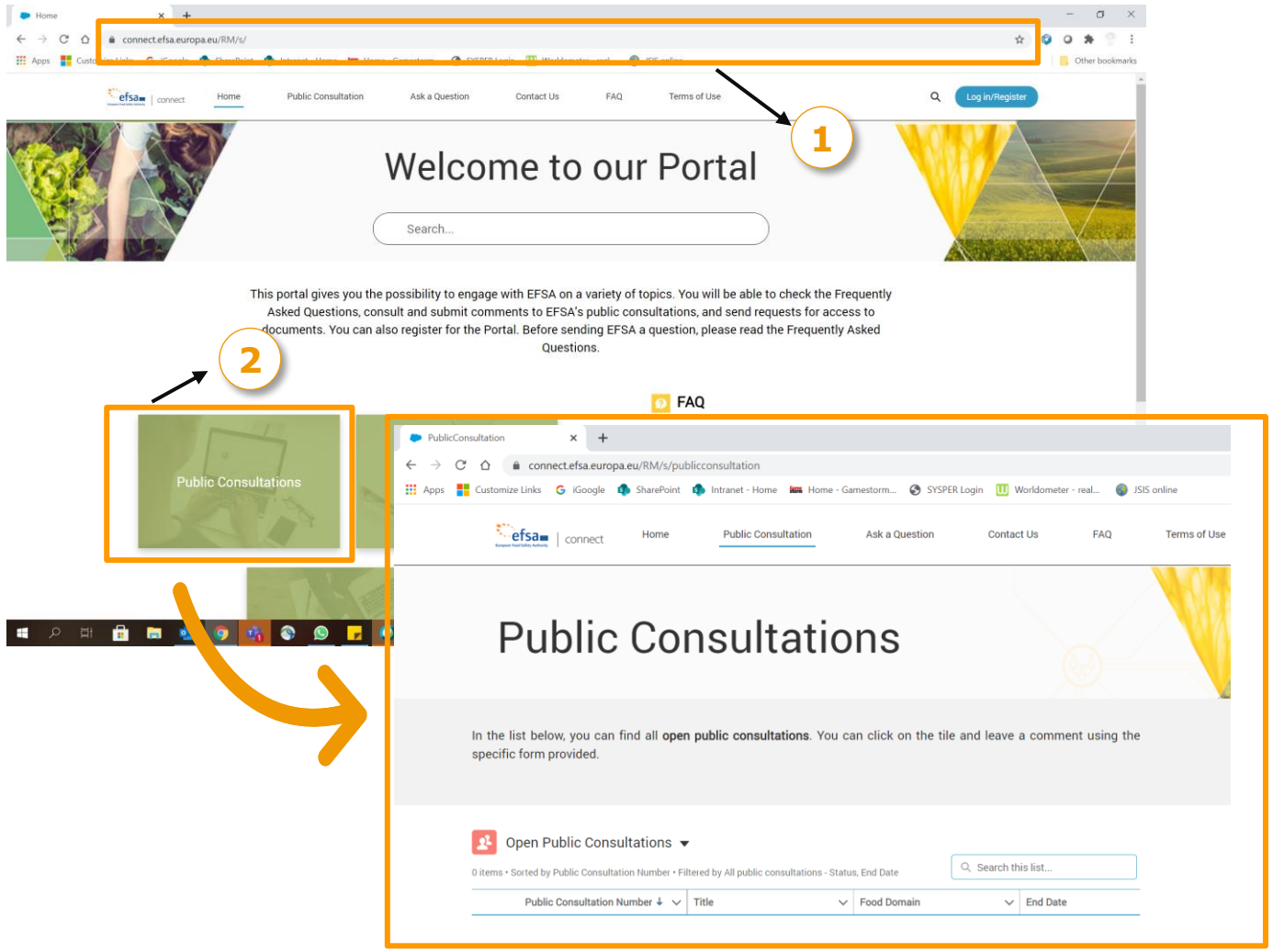
Aim:
Collect new or additional evidence/data/information to assess an application

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



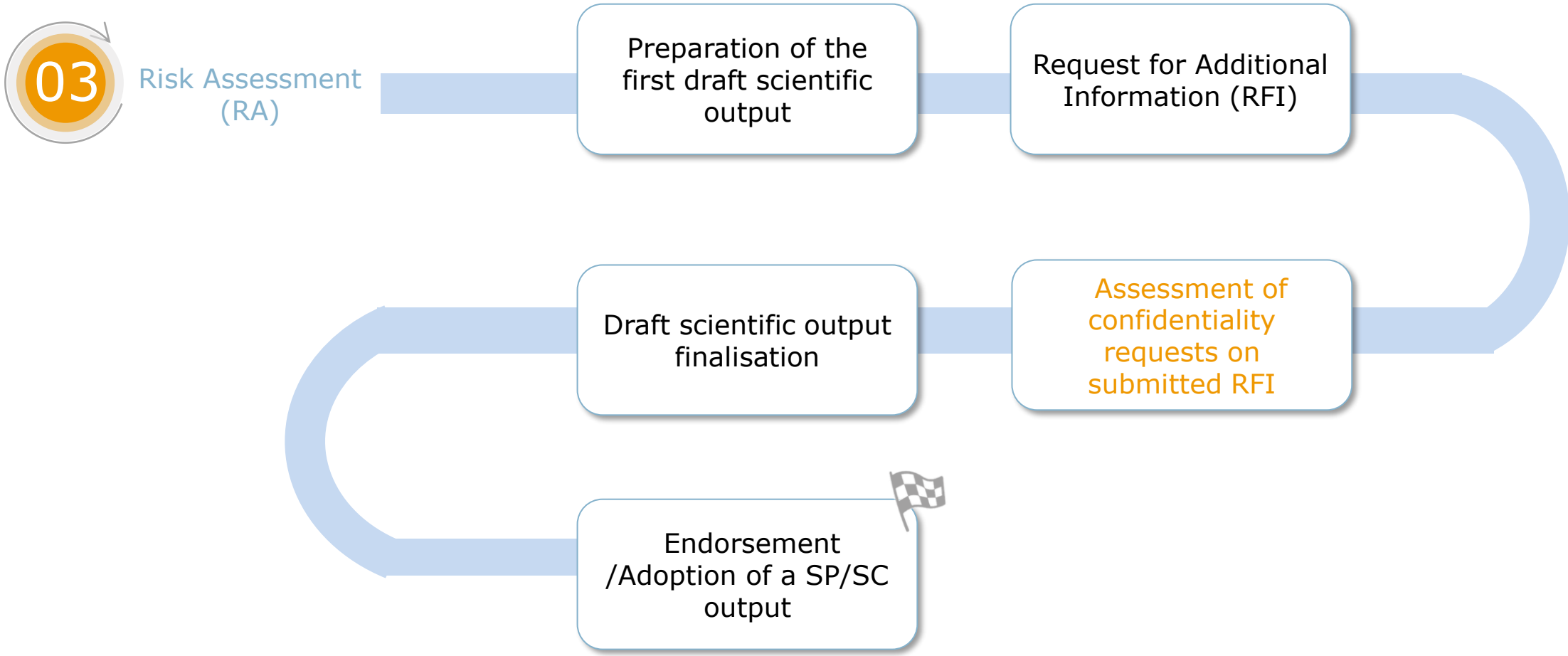
How to access the portal

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

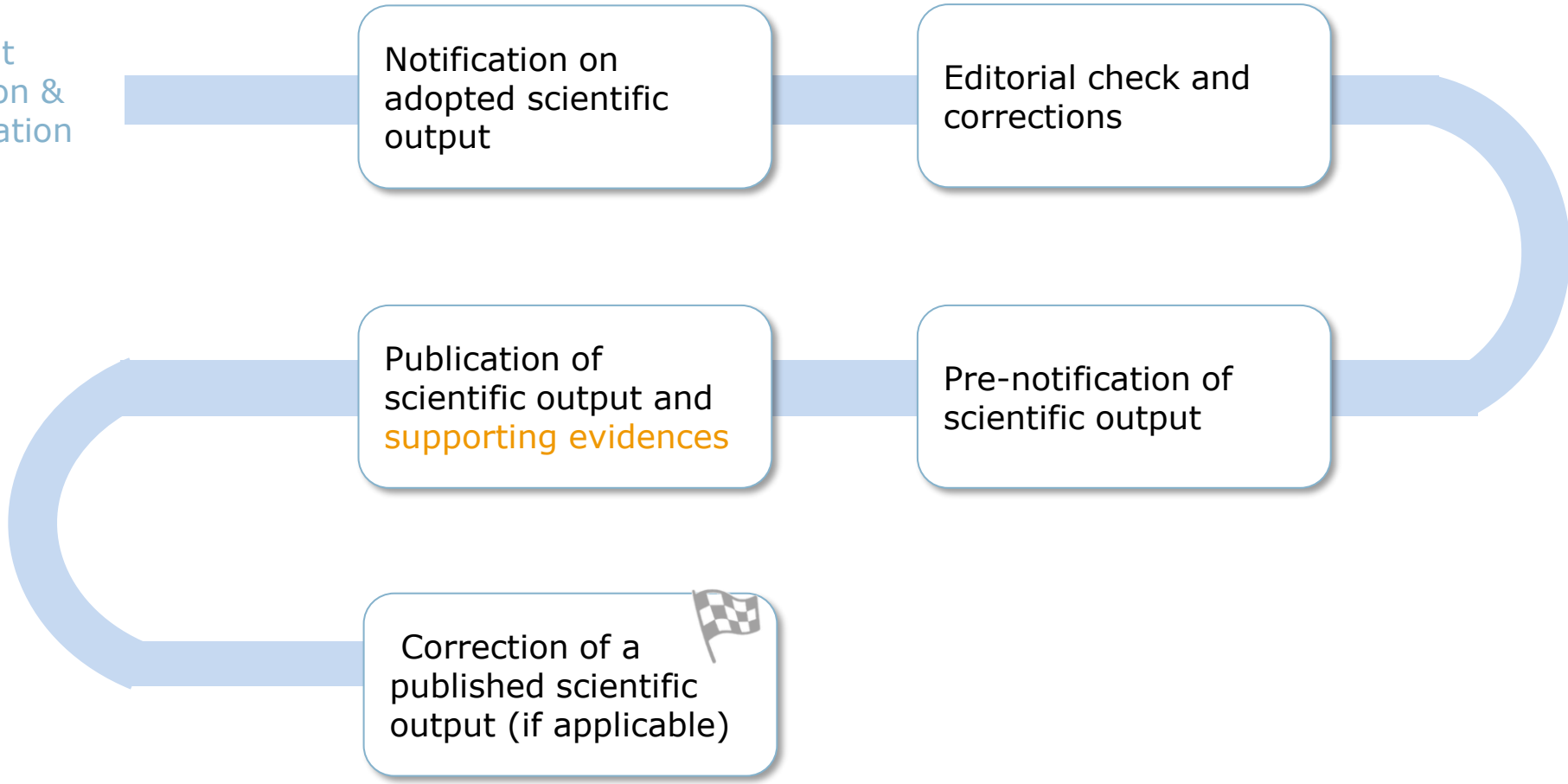
Risk Assessment, Adoption and Publication

Risk Assessment Phase



Output Publication & Dissemination phase

04 Output Publication & Dissemination



More Information

Useful documents

Legal documents:

Hyprlink Transparency Regulation: Regulation (EU) 2019/1381

Hyprlink General Food Law: consolidated text of Regulation (EC) No 178/2002

Hyprlink Practical arrangements on pre-submission phase and public consultations

Hyprlink Practical Arrangements concerning transparency and confidentiality

Hyprlink EFSA Practical Arrangement on Access to Document (March 2020)

Guidance/training materials:

Hyprlink Q&As on PAs: Questions and Answers on the EFSA Practical Arrangements

Hyprlink EFSA digital toolkit page https://www.efsa.europa.eu/en/applications/toolkit

Hyprlink Updated administrative guidance for regulated products: Administrative guidance for the processing of applications for regulated products (update 2021)

Hyprlink Catalogue of services: EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (update 2021)

Hyprlink Training material, including video introductions/tutorials and webinar recordings, are available under the dedicated section "Transparency Regulation Implementation Training Programme" on the EFSA website

Hyprlink Dedicated support to small and medium-sized enterprises https://www.efsa.europa.eu/en/applications/about/services

Tailored webinar series
Proposed planning

Today!

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Transparency Regulation Implementation Training Programme

04/06/2021	Application procedure for food enzymes, food flavourings and food additives	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
July 2021	Application procedure for feed additives	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
September 2021	Application procedure for pesticides active substances and MRL	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
October 2021	Application procedure for novel food	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
November 2021	Application procedure for GMO	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
December 2021	Application procedure for smoke flavourings	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
January 2022	Application procedure for health claims	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar
February 2022	Application procedure for Food Contact Materials	Business operators, small and medium-sized enterprises, laboratory/testing facilities	Webinar

Hyperlink

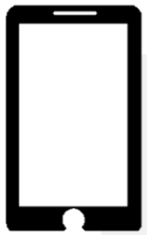
Thank you for attending our webinar

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

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

Stay connected



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