23 September 2021
APDESK webinars

Webinar on application procedure for novel food

Trusted science for safe food

efsa
European Food Safety Authority

Tentative 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 novel food Public consultation RA, adoption and publication FAQ from novel food 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 Livaniou
- Simone Gabbi

Q&A contributors:
- Stefano Cappé
- Simone Gabbi
- Goran Kumric
- Karine Lheureux
- Anastasia Livaniou
- Remigio Marano
- Francesca Volpi

Webinar moderator:
- Margherita Guidi

Goals

Explain the steps of the applications procedure of applications for Novel Food
Address questions encountered by Novel Food applicants in recent months following the entry into application of the Transparency Regulation

Golden rules

You are connected through a one-way audio (listen only mode).

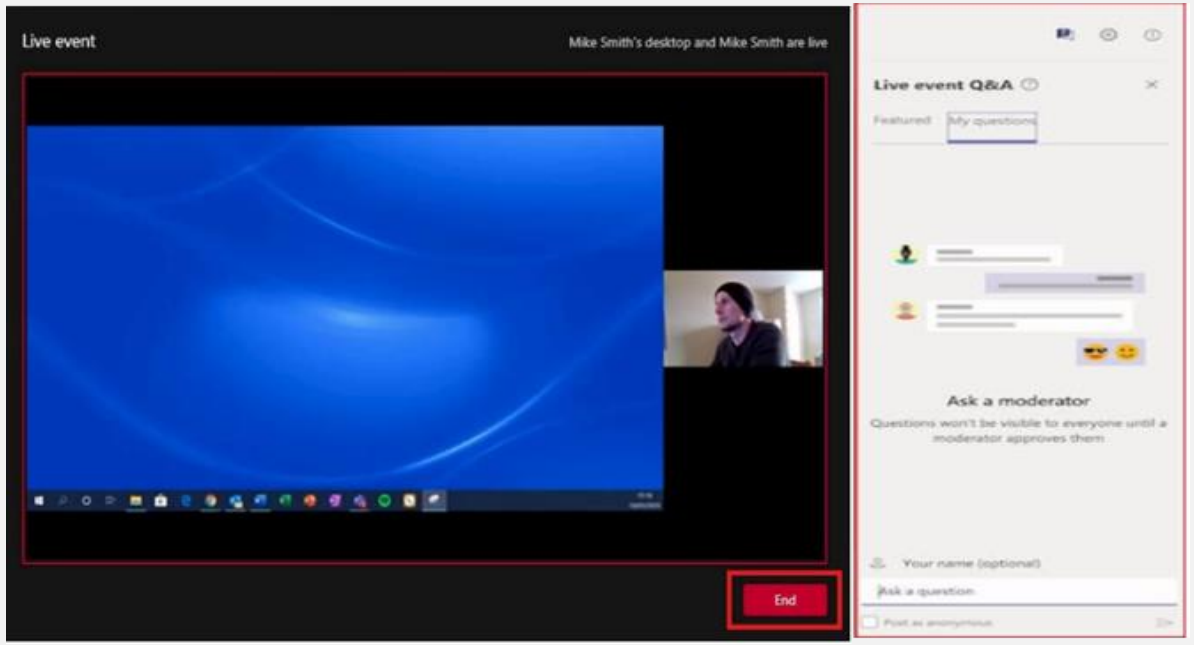
- You can submit questions throughout the webinar via the dedicated Q&A tab on the top right navigation bar
- Some questions will be answered in written and some others will be answered live by our speakers/Q&A contributors
- Questions which will remain answered will not be addressed in the framework 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, 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

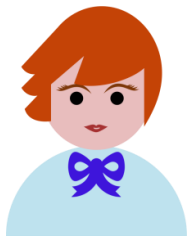
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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)

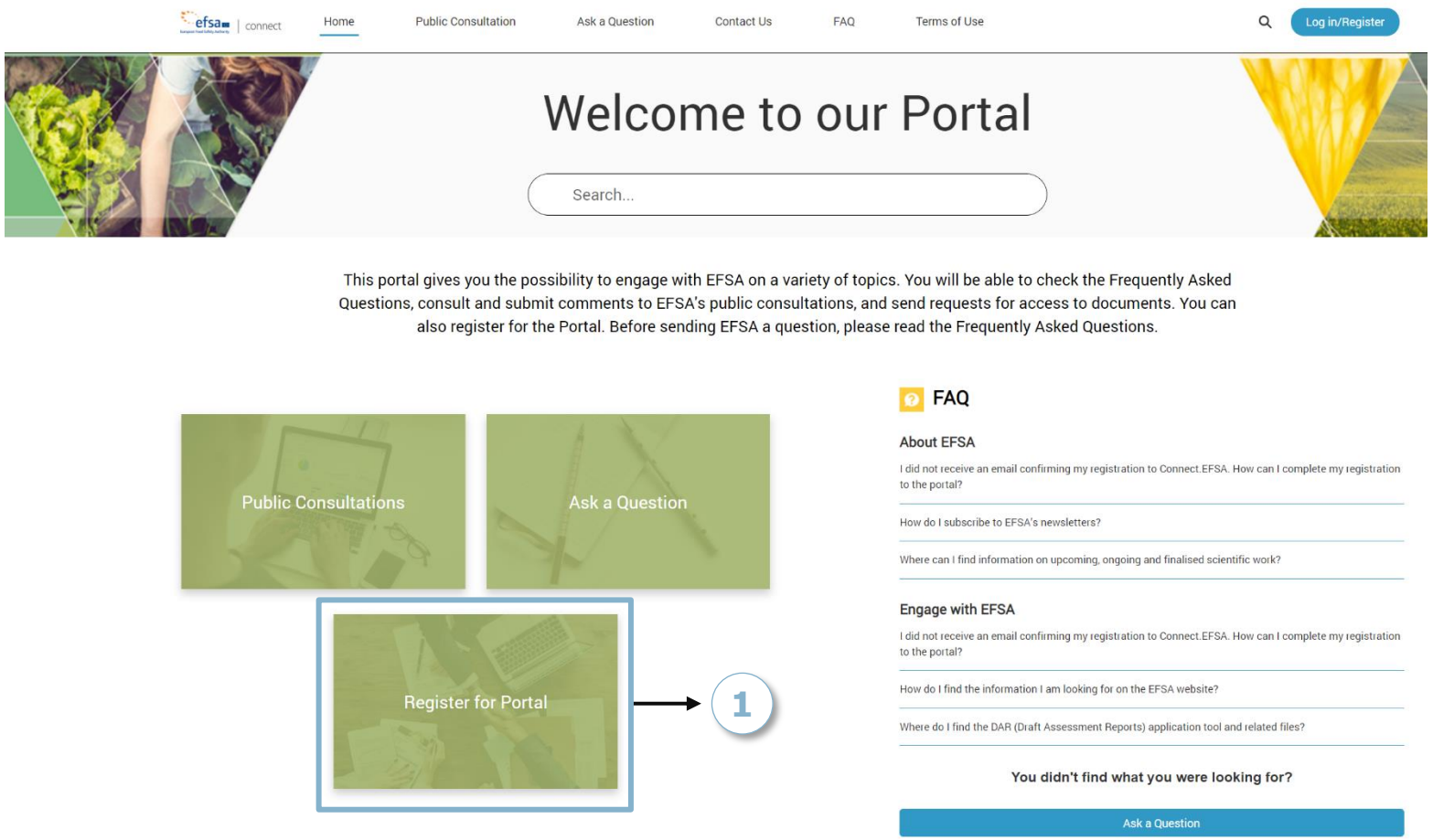
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

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

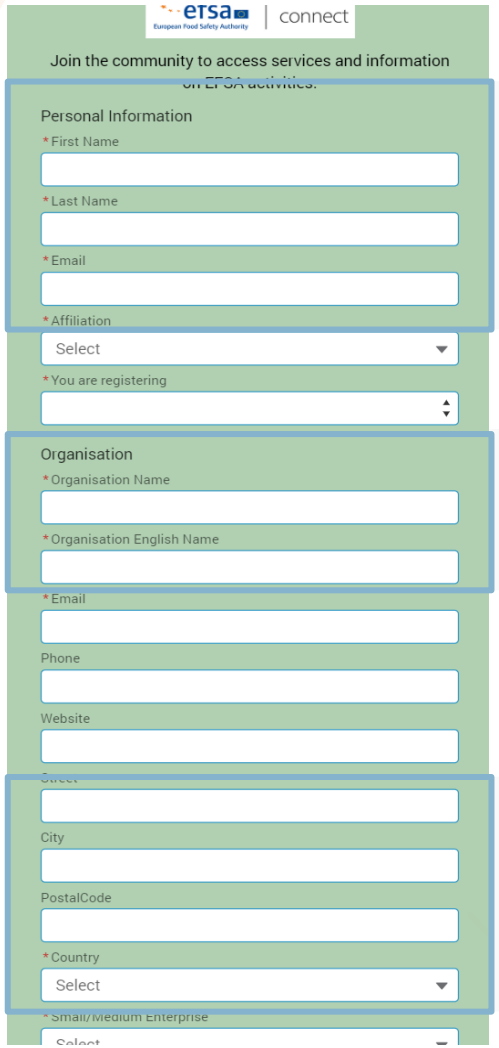
The potential applicant starts the registration in the portal.

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'.

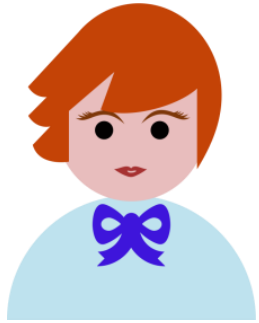
This relationship has to be previously established in the Account Management:

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



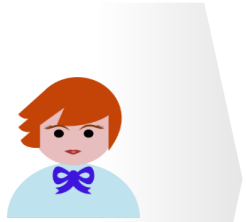
Sarah
Business Operator(s)

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

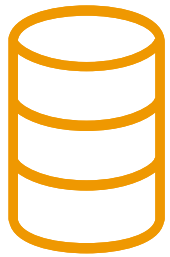
Mandate and Dossier Intake
Notification of Studies for new application

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 (Novel Foods/Traditional Foods)

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, 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

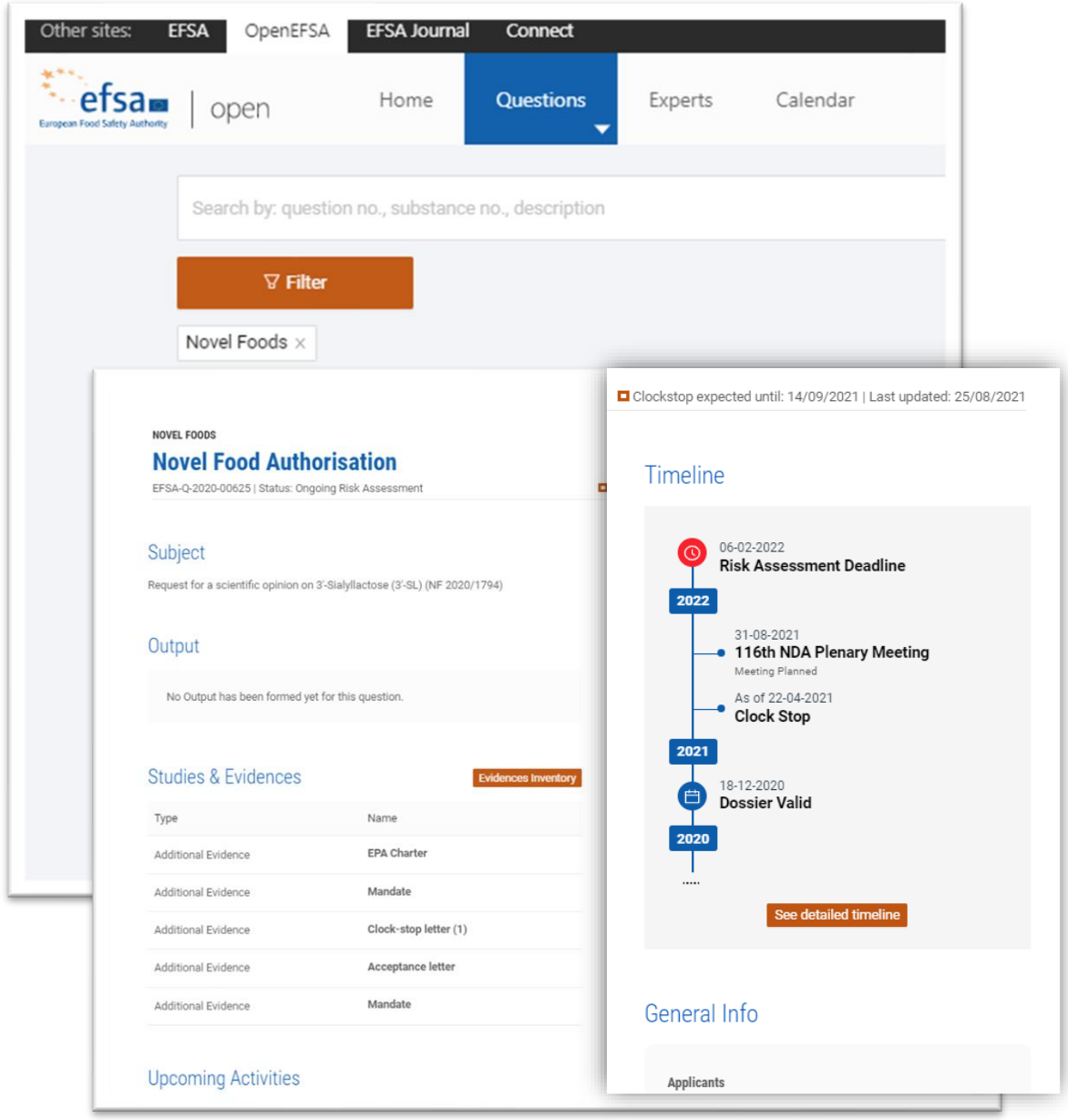
Video Tutorials
Hyperlink

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 in the context of Novel Food

Authorisation of Novel Food

Application/Notification submitted before 27/03/2021

Application/Notification submitted on/after 27/03/2021

Pre-TR GFL applies

- Old SOPs and Old PAs apply
- Confidentiality requests assessed in accordance with Article 39 of the GFL and sectoral legislation

GFL as amended by TR apply

- New SOPs and WINs apply
- PAs on transparency and confidentiality apply
- Confidentiality requests assessed in accordance with Article 39 of the amended GFL and sectoral legislation

TR Criteria

Proactive Disclosure

Art 38 of TR + Reg 2015/2283
Proactive disclosure e.g. for:

- Information submitted to support an application dossier (when EFSA`s opinion is requested)
- Information submitted to support a notification dossier (when EFSA is consulted and it submits safety objections)
- Information submitted to support an application for authorisation of a traditional food from a third country (following a rejected notification)

Confidentiality

Art 39 of TR + Art 23 of Reg 2015/2283
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
- Submit clarifications within the deadline set by EFSA
- 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:

Articles 23(1) and 23(4) of Regulation (EU) 2015/2283 (making reference to Article 39(2) 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 23(4)(a) of Regulation (EU) 2015/2283	where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety;
Article 23(4)(b) of Regulation (EU) 2015/2283	where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety;
Article 39(e)(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 39(e)(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved 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 of any kind, with the exception of:

1. Name and address of the applicant
2. Names of authors of published/publicly available studies supporting the application
3. 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

! ! !

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

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)

Procedural steps EFSA confidentiality assessment

STEPS

Mandatory notification of draft decision to the applicant for comments

Notification of the final decision to the applicant

Possibility to file confirmatory application via tool or email to

Confidentialityconfirmatoryapplication@efsa.europa.eu

Implementation of confidentiality decisions - sanitisation

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

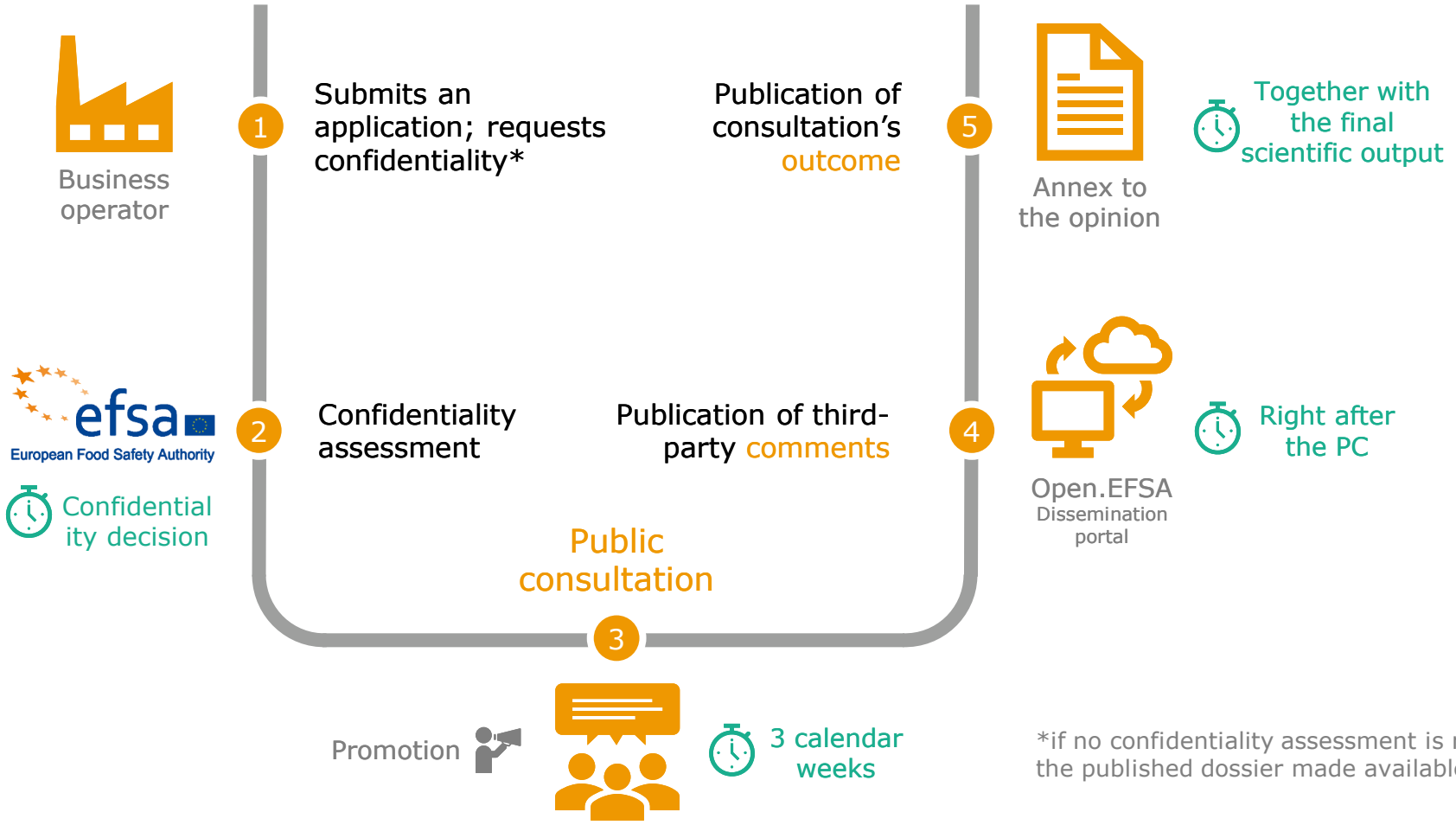
Public Consultation

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



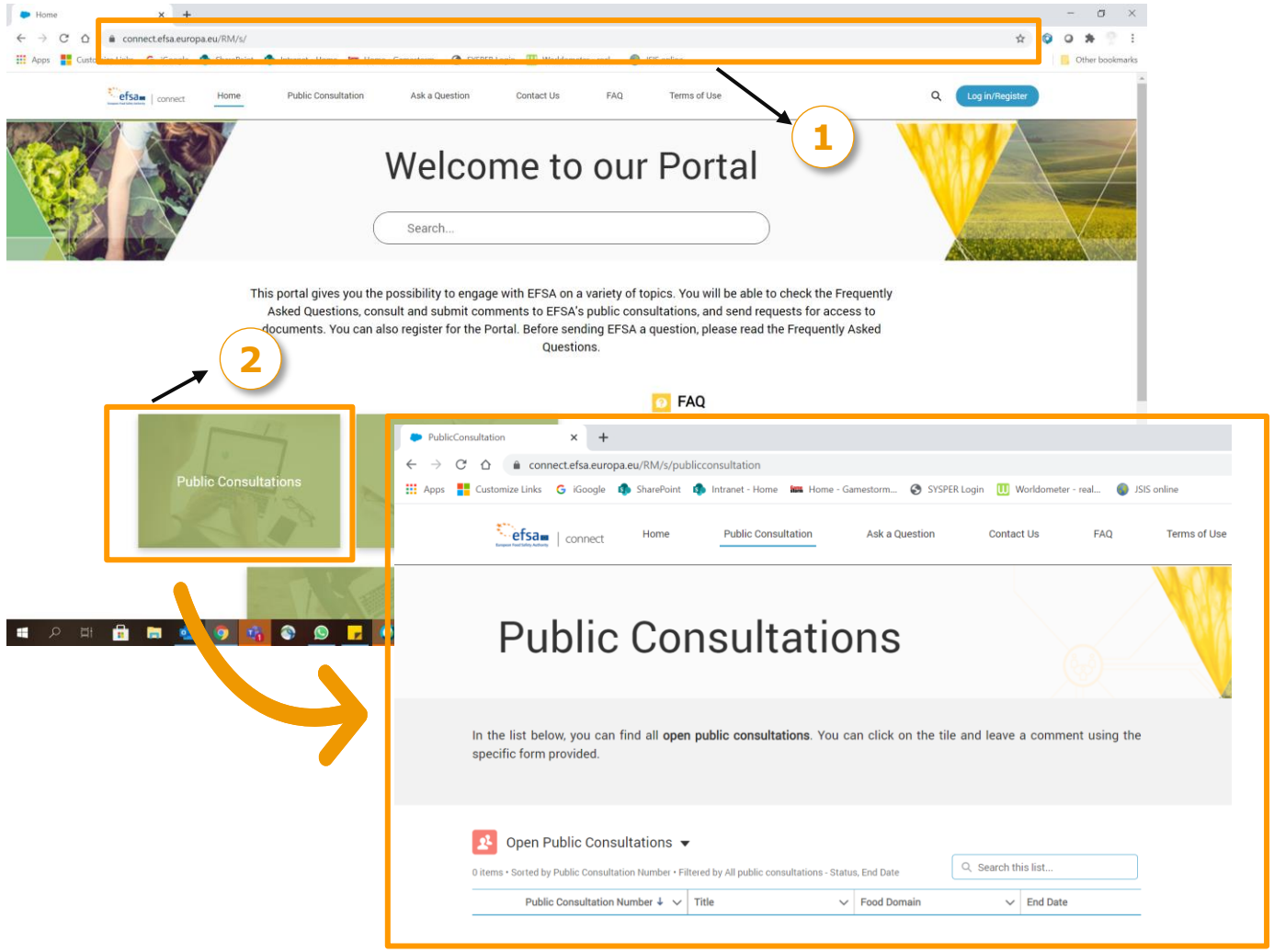
Aim:
Collect new or additional evidence/data/information to assess an application

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



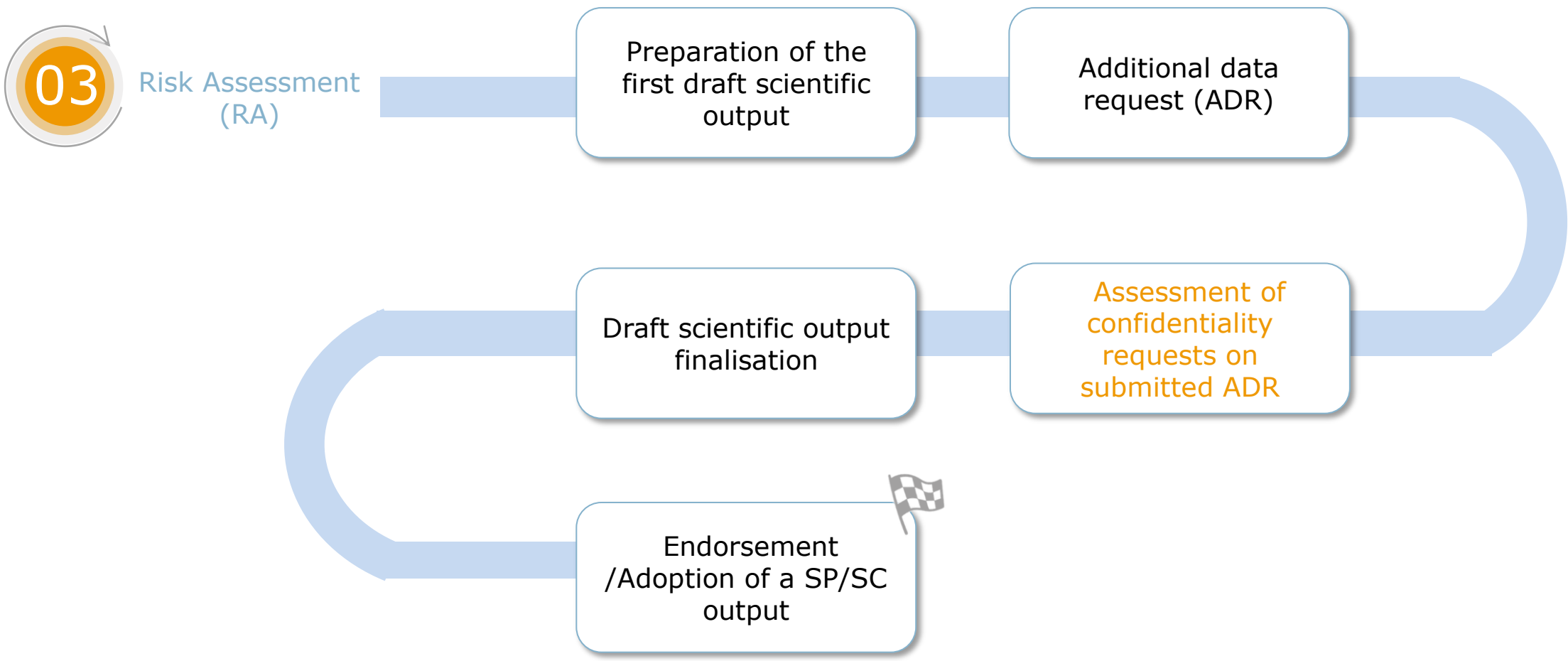
How to access the portal

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

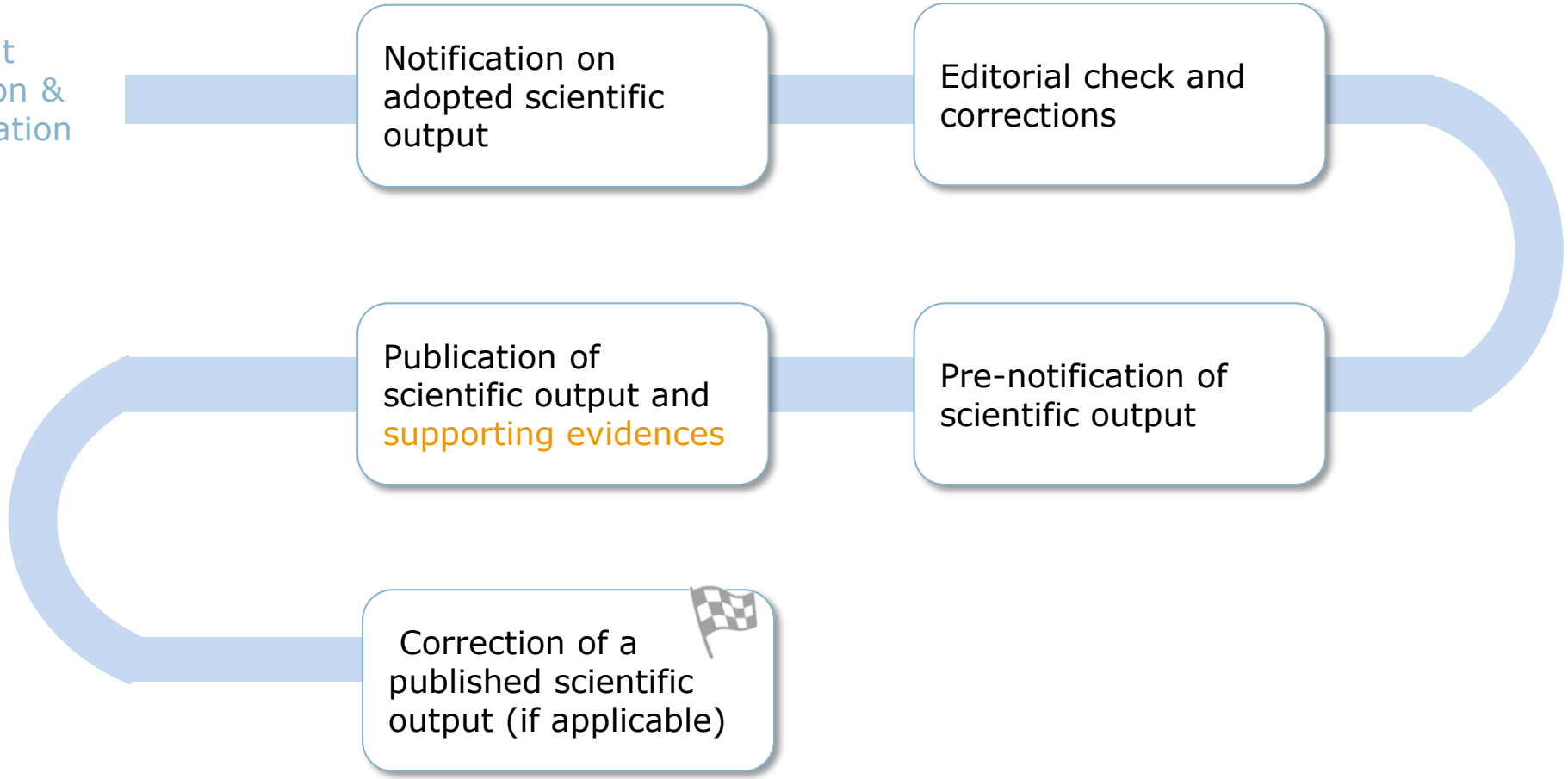
Risk Assessment, Adoption and Publication

Risk Assessment Phase



Output Publication & Dissemination phase

04 Output Publication & Dissemination



FAQ from Novel Food applicants

Question and answer (1)

"Which third countries will be covered by the obligation to pre-notify studies?"

- Refer to Article 18(1) of EFSA's Practical Arrangements on pre-submission phase and public consultations here
- **Obligation to notify studies**: The obligation to submit information on studies commissioned or carried out by business operators to support a future application applies to laboratories and other external testing facilities located in the Union – and those located in third countries (the three EEA EFTA States i.e. Iceland, Liechtenstein and Norway).
- **Obligation to co-notify the studies**: when a study is commissioned to a laboratory or external testing the laboratory or external testing facility is also required to notify the study to EFSA in line with Article 32b(3) of the GFL

Impact of the withdrawal of the United Kingdom from the EU

Agreements make the GFL applicable also to and in the United Kingdom in respect of Northern Ireland. Laboratories or external testing facilities located in Northern Ireland are subject to the co-notification obligations of Article 32b(3) of the GFL whereas laboratories and external testing facilities located in Great Britain are not subject to those obligations

Question and answer (2)

"Are we allowed to have a pre-application ID on behalf of our client? Do we register ourselves, shall our client register also? Can we be connected somehow?"

- Both **client and consultant should be registered** to the Portal on https://connect.efsa.europa.eu/RM
- Business Operators / Consultant users will be able to request and obtain a pre-application identification (ID)and **link to it all the study** notifications related to a specific regulated product in a given regulated product area
- To grant access to the pre-submission activities to a **third-party operator**, they need to select the relevant pre-application ID that they intend to share and use the "**share with**" function
- Once shared, the third party-operator will be able to access to all the new created studies.

Question and answer (3)

"Are nutritional studies of composition included in the notification of studies requirement? Stability studies? Does all studies mean all the analyses included in the application for the authorization of a Novel Food?"

- **Definition of a study:** "an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities"

- **Examples:** stability, efficacy, and safety studies

- **Exclusion of the following studies**:

✓ Desk oriented work such as literature research, bioinformatics studies and other studies not involving laboratories and testing facilities;

✓ Studies which are commissioned or carried out for development reasons as part of the innovation process and which are not relevant for submission to appropriate regulatory authorities.

Refer to question 4: "What falls within the definition of "study" of the Q&A of the EFSA Practical Arrangements, Part B". (Link)

Question and answer (4)

"Is there a manual on how to notify a study for the authorization request of a Novel food?

As a consultant on behalf of a company that wants to request an authorization for a novel food, to notify the start of a stability study, shall the company also be registered in the EFSA tool, or what shall be placed in the "business operator" box?"

When a Business Operator would like to allow a third-party operator (Consultant) to work on its behalf, the two organisations have to **establish an account relationship**.

To do so the Business Operator should select in its "My Details" page the button "Manage Relationship". The following guided procedure will allow the Business Operator to find his organisation and add it as **Consultan**t: after clicking on "Manage Relationship", a pop-up where to select "create a new account relationship" will appear.
Then, the Business Operator will have to select the country of the third party organisation and then the name of the third party organisation. T
The Business Operator must select "on behalf of" as account relationship type, as it is the only way to operate (view and edit).

Question and answer (5)

"We are preparing the dossier for a Novel Food application. As part of the studies that will be presented, we sent some analysis during last days of March 2021, and beginning of April 2021.

Is there any chance to notify them now, or we need to send them again?"

- Obligation to notify studies commissioned or carried to support a future application applies to **studies** that are **commissioned or carried out as of 27 March 2021**.
- Potential applicants and laboratories or external testing facilities to which studies are commissioned must submit study notifications to EFSA **"without delay"**.
- For any study notification submitted after the starting date of the study, when submitting the application, the applicant must **provide justifications for the delay**.
- The field 'Justification for delay' in the study record on Connect.EFSA portal will be editable when submitting the notification.

Question and answer (6)

"When uploading an application via the webgate, how can I ensure the confidential nature of my submission?"

- **Default option** when uploading a file on ESFC portal is **'non-confidential'**
- **To submit confidentiality requests, when uploading the full confidential file you need to:**

✓ Click on the three-dot menu to the right
✓ Select "Request confidentiality treatment"
✓ Submit the non-confidential version
✓ Build your confidentiality requests by selecting the legal grounds and giving the necessary justification

Useful information

Legal documents:

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- Consolidated text of Regulation (EC) No 1831/2003 on additives for use in animal nutrition
- 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 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 novel food
- Novel food applications: regulations and guidance web section
- 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/new-ask-efsa-request)

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

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