

8 July 2021
APDESK webinars



Webinar on application procedure for feed additives and intended renewal applications

Trusted science for safe food



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 Intended Renewals application E-submission (demo) Portal updates and validity of applications Confidentiality Public consultation RA, adoption and publication	Karine Lheureux Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Stefano Cappé Sara De Berardis Simone Gabbi Karine Lheureux Anastasia Livaniou Cinzia Percivaldi Francesca Volpi

Who we are



Presenters of this webinar

- Karine Lheureux
- Anastasia Livaniou
- Simone Gabbi

Q&A contributors:

- Stefano Cappé
- Sara De Berardis
- Simone Gabbi
- Karine Lheureux
- Anastasia Livaniou
- Cinzia Percivaldi
- Francesca Volpi

Webinar moderator:

- Margherita Guidi

Goals



Explain the steps of the applications procedure and renewal of applications for Feed Additives
Address questions encountered by Feed Additives 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>)

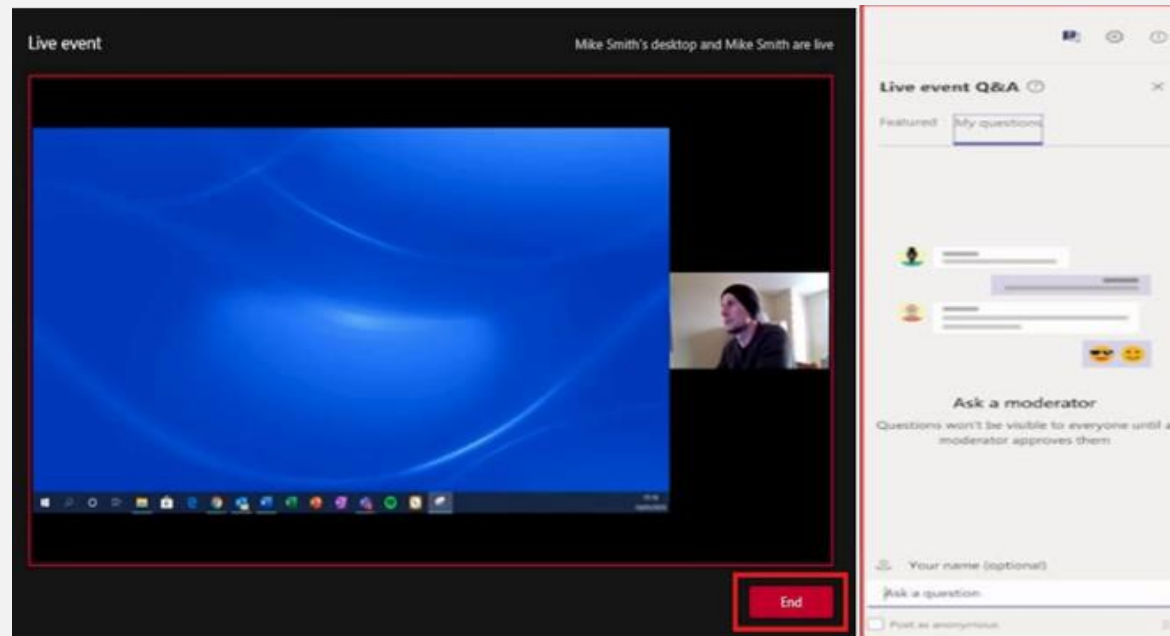


This session is recorded, the materials will be available on the EFSA website including the slides.

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



The screenshot shows a live event interface. On the left, a 'Live event' window displays a blue presentation slide with a small video feed of a speaker in the bottom right corner. A red box highlights the 'End' button in the bottom right corner of the video feed. On the right, a 'Live event Q&A' box is visible, containing a 'Featured' question, a list of questions, and an 'Ask a moderator' section. A red box highlights the 'Ask a question' input field at the bottom of the Q&A box.



Q&A box:
For any
questions
related to
the topic or
unexpected
IT issues

Lifecycle of an application

4 pillars

Transparency

- Better access to scientific studies
- access to documents, studies and information submitted by applicants and supporting application dossiers

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

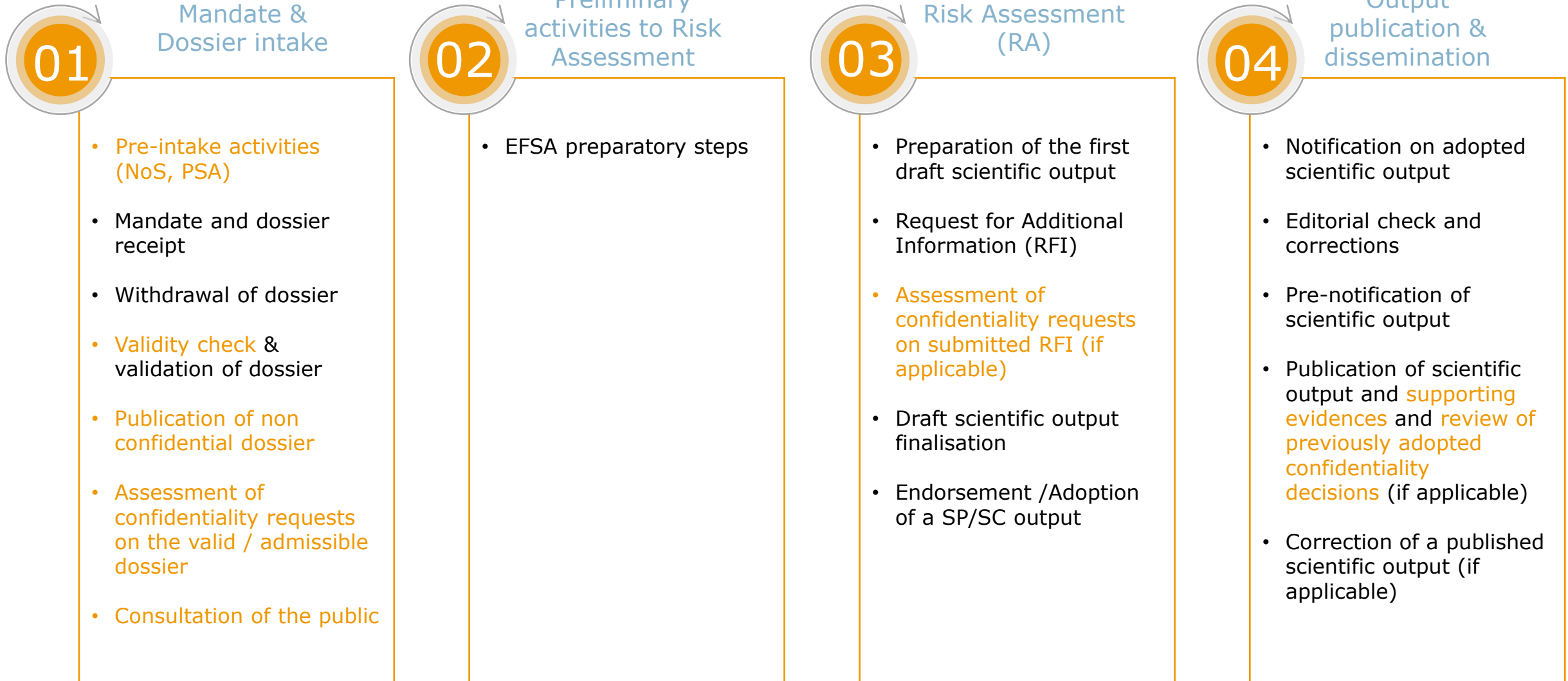
Effective risk communication

- 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"](#)



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

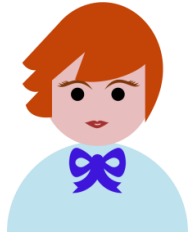
- ✓ Monitoring of risk assessment flow
- ✓ Dissemination portal
- ✓ Proactive disclosure of information

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

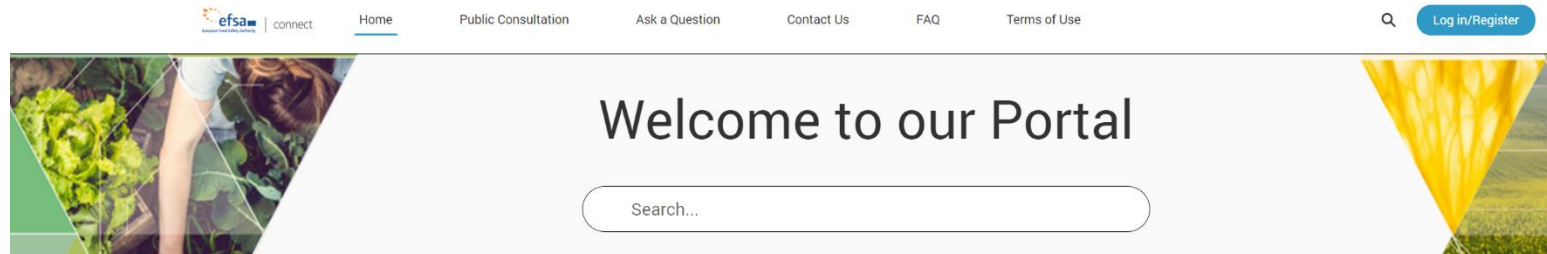
Third parties representing one or more entities shall also register in the Authority system supporting pre-submission activities ...¹ and obtain the authorization by represented entities to act on their behalf

3


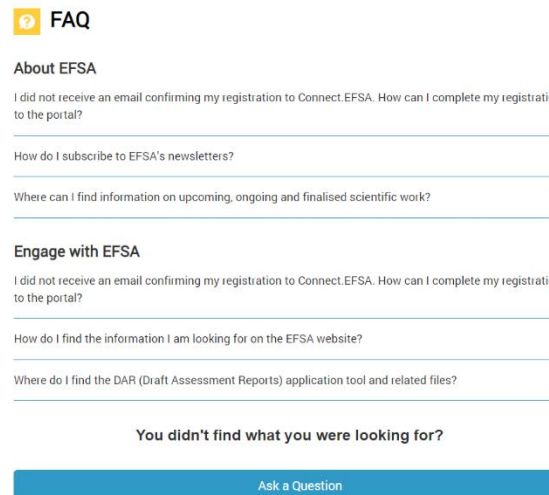
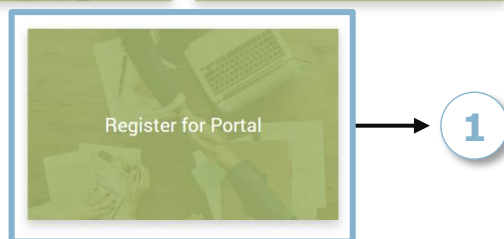
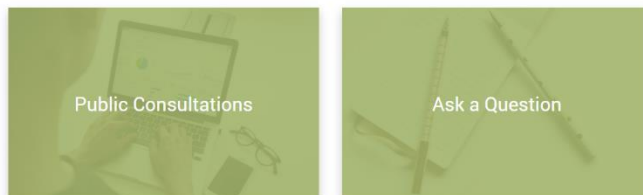
Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.¹

¹) [Practical arrangements on pre-submission phase and public consultations](#)

Connect.EFSA Portal - Account Registration



This portal gives you the possibility to engage with EFSA on a variety of topics. You will be able to check the Frequently Asked Questions, consult and submit comments to EFSA's public consultations, and send requests for access to documents. You can also register for the Portal. Before sending EFSA a question, please read the Frequently Asked Questions.



Sarah

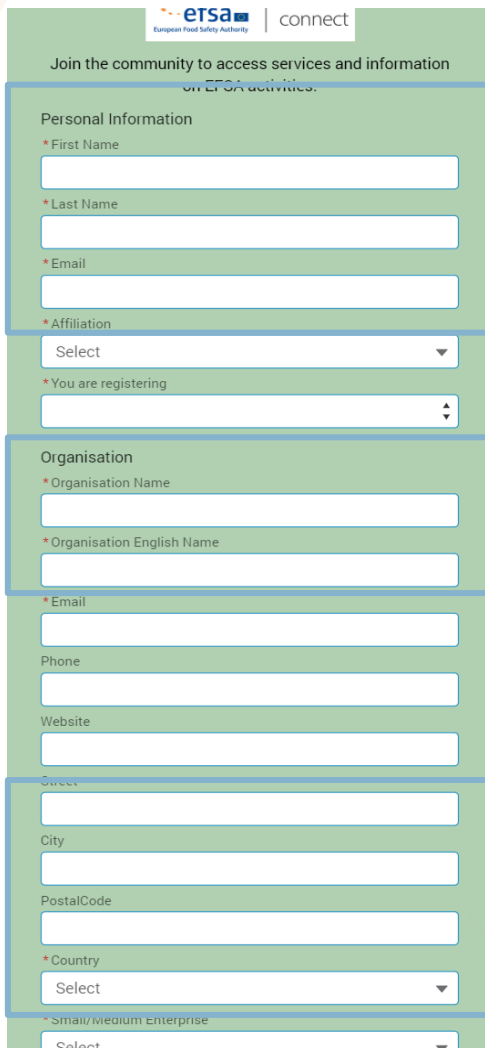
The potential applicant starts the registration in the portal.

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



The screenshot shows the registration form for the EFSA Connect portal. It is divided into three main sections: Personal Information, Organisation, and Billing Address. The Personal Information section includes fields for First Name, Last Name, Email, Affiliation (a dropdown menu), and a checkbox for 'You are registering'. The Organisation section includes fields for Organisation Name, Organisation English Name, Email, Phone, and Website. The Billing Address section includes fields for Street, City, Postal Code, Country (a dropdown menu), and a checkbox for 'Small/medium enterprise'. The form is styled with a green header and footer, and white input fields with blue borders.

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.

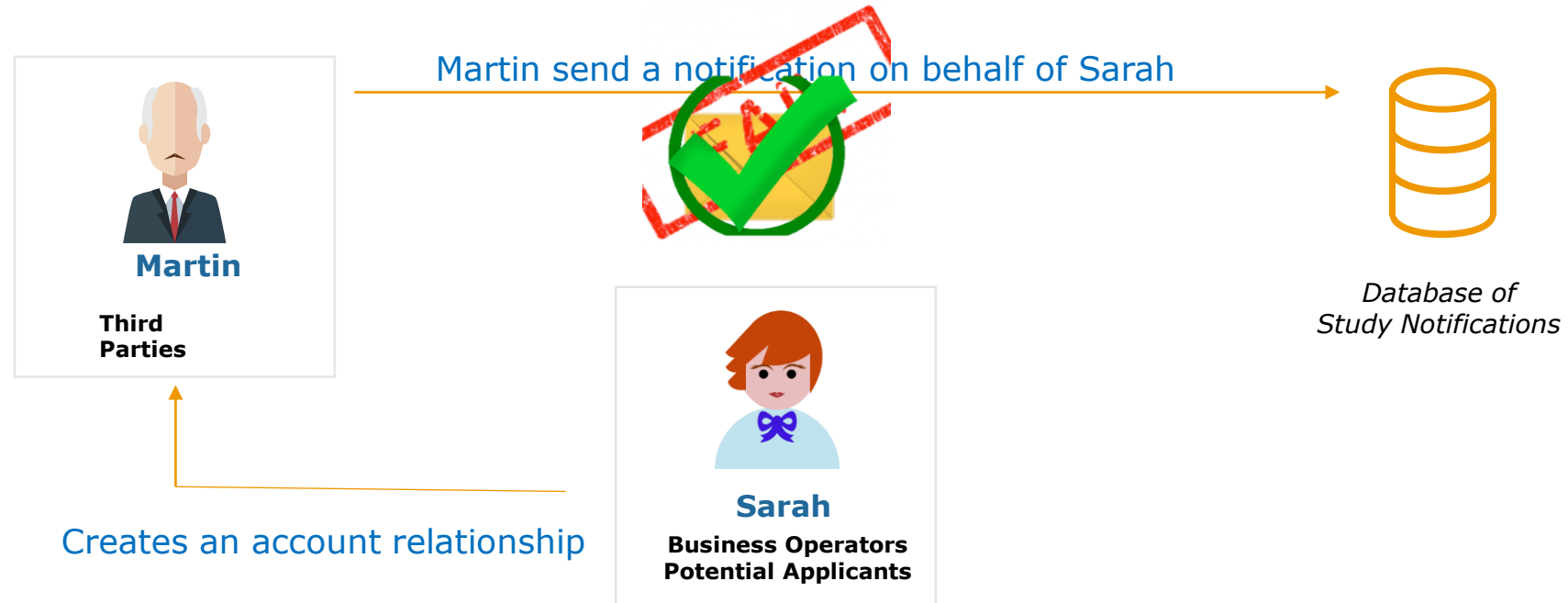


The applicant is ready to use the functionalities of the portal.

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

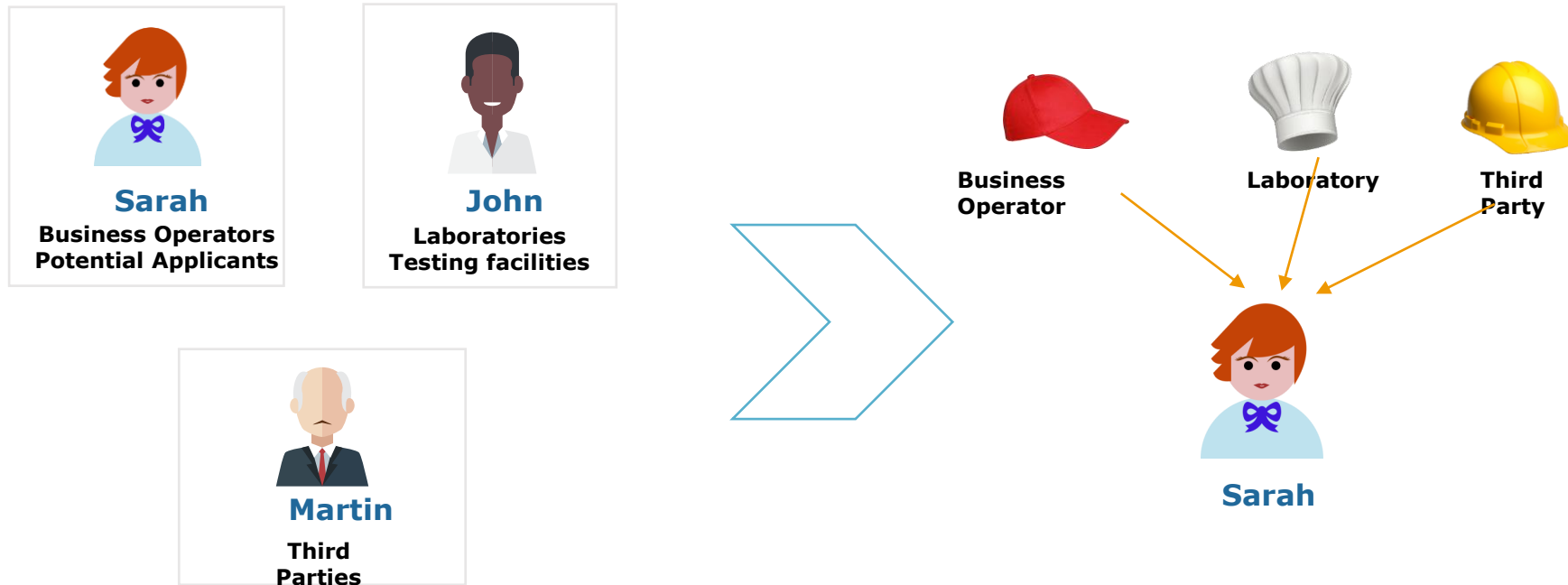
Update from Account Registration



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 26 March ([here](#)).

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!

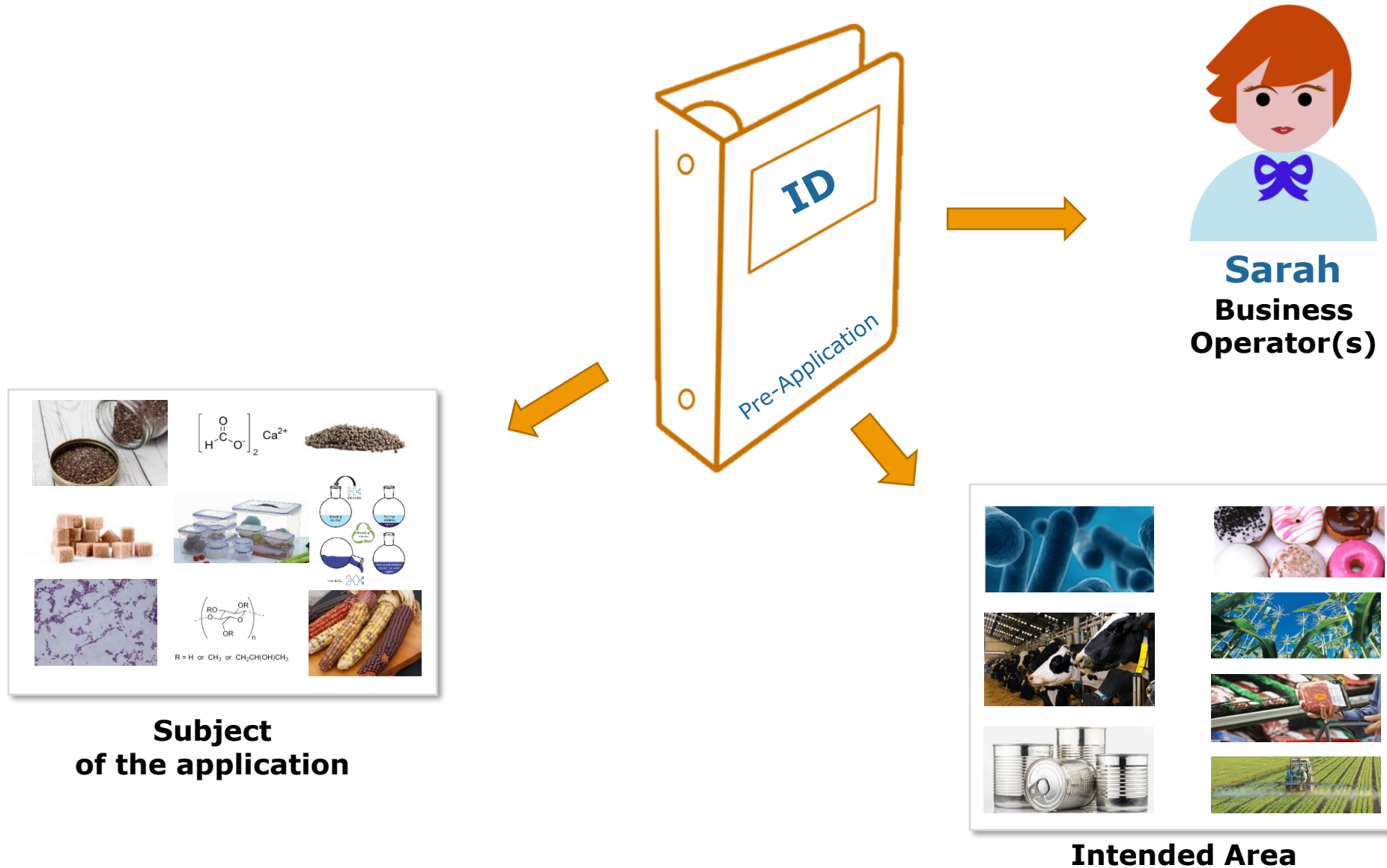
This relationship has to be previously established in the Account Management:

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



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

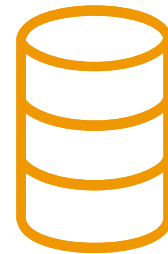
Step 1 Pre-submission phase



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

Intended renewal applications

General Pre-Submission Advice



Sarah

The potential applicant gets the pre-application-ID **for renewal**

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



*Pre-Submission
Advice
tool*



General Pre-Submission Advice

EFSA
provides advice



Step 3 Validation of application



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

Notification of Studies for renewal application

Step 1 Application renewal



Sarah

The potential applicant gets the Pre-Application-ID

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



Database of Study Notifications



Step 2 Public consultation and R-PSA

EFSA
Provides advice



Step 3 Notify studies



Sarah

The potential applicant notifies studies (Article 32b)

Application type – Feed Additives

Feed Additives

* Authorisation Type

Feed Additives

* Application Type

--None--

✓ --None--

Application for authorisation of a new feed additive (Article 4(1) of Regulation (EC) No 1831/2003)

Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Application for the renewal of a feed additive authorisation

Application for urgent authorisation (Article 15 of Regulation (EC) No 1831/2003)



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

For renewal the potential applicant should also prefill some information for the pre-application ID

New Pre-Application ID for Renewal

*Request Name

*Former Application ID ⓘ

*Subject Of The Application ⓘ

*Food Domain

Authorisation Type

Application Type

Note ⓘ



Link to the EFSA question number of the application related to the authorisation to renew

Fill in **relevant information** for intended studies

Once all intended studies are completed, submit the **list of intended studies for renewal**



Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of Intended Studies within the Pre-Application ID for renewal. You can transform an intended study in a draft study notification any time via the button "To Notify" (in the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title

In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study Objective
- Study Test Item
- Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

E-Submission (demo)

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



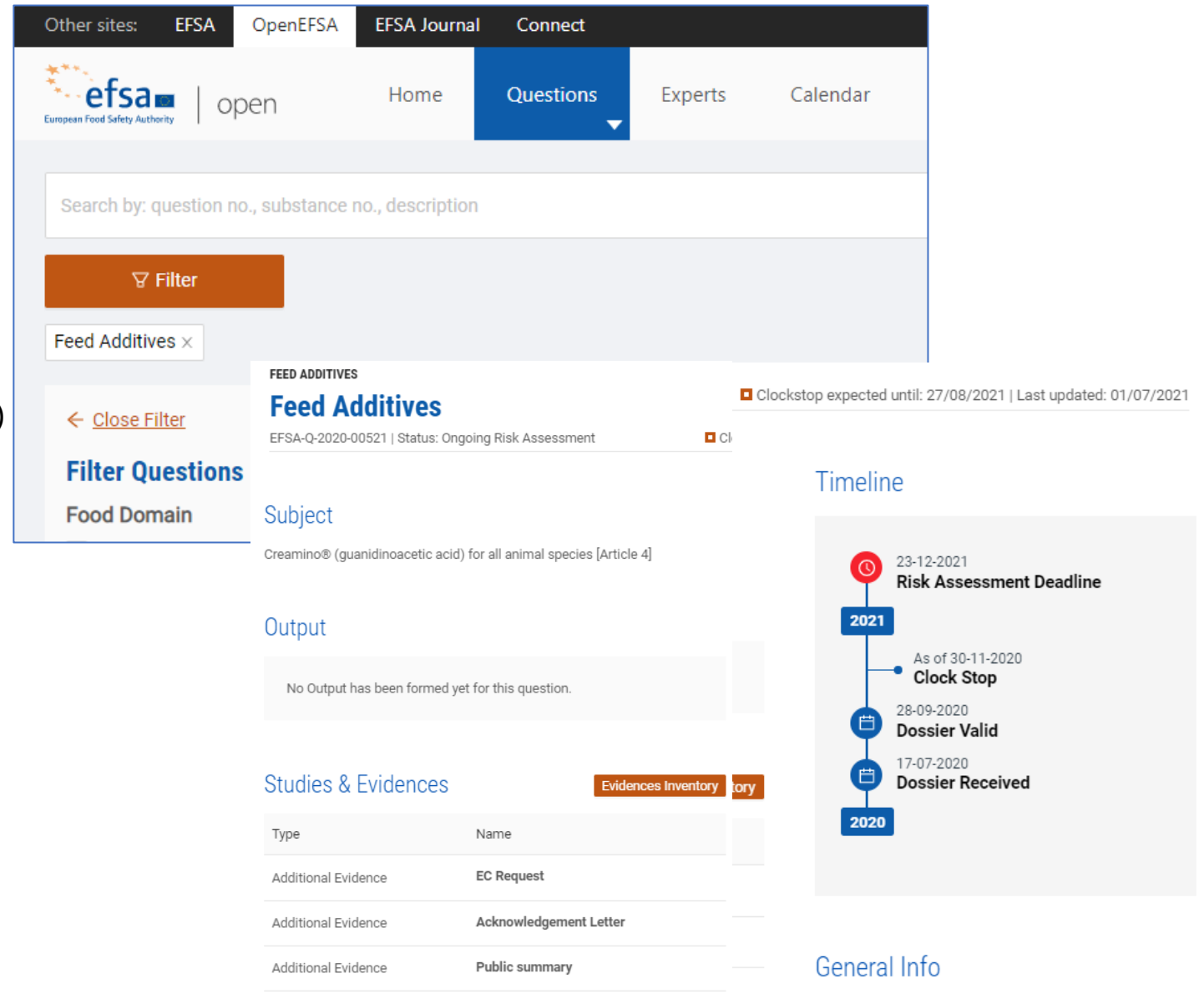
[User Guide](#)

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 completeness check (+NoS check)
- Request for Information (RFI): received and replied to via ESFC (incl. data)
- EFSA declares the application Valid
- EFSA publishes non confidential valid dossier (+ summary Pre-submission advice)
- Assessment of confidentiality requests



The screenshot displays the EFSA OpenEFSA portal interface. At the top, there are navigation tabs for 'Other sites: EFSA', 'OpenEFSA', 'EFSA Journal', and 'Connect'. Below this is a search bar with the text 'Search by: question no., substance no., description' and a 'Filter' button. A filter is currently applied for 'Feed Additives'. The main content area shows a question entry for 'FEED ADDITIVES' with the title 'Feed Additives' and the ID 'EFSA-Q-2020-00521 | Status: Ongoing Risk Assessment'. A 'Clockstop' icon indicates a deadline of 27/08/2021. The 'Subject' is 'Creatino® (guanidinoacetic acid) for all animal species [Article 4]'. The 'Output' section states 'No Output has been formed yet for this question.' The 'Studies & Evidences' section includes an 'Evidences Inventory' button and a table with the following entries:

Type	Name
Additional Evidence	EC Request
Additional Evidence	Acknowledgement Letter
Additional Evidence	Public summary


On the right side, there is a 'Timeline' section showing key dates: 23-12-2021 Risk Assessment Deadline, 2021 (year marker), As of 30-11-2020 Clock Stop, 28-09-2020 Dossier Valid, 17-07-2020 Dossier Received, and 2020 (year marker). Below the timeline is a 'General Info' section.

Confidentiality in the context of feed additives

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

 Submission through E-Submission Food Chain Platform, Portalino

 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

Confidentiality requests only on items on closed positive list

For the feed additives sector:

Article 18(3) of Regulation 1831/2003

- the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) of, and Annex I to Regulation (EC) No 1831/2003;
- specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment;

Article 39(2) of Reg 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;

! The non-confidential version of the application dossier shall not contain personal data of any kind, with the exception of:

- name and address of the applicant
- names of authors of published/publicly available studies supporting the application

Names and addresses of individuals involved in testing on vertebrate animals or in obtaining toxicological information are not disclosed



Identifying clearly the information claimed confidential, with links and references



Indicating the legal basis (or grounds)



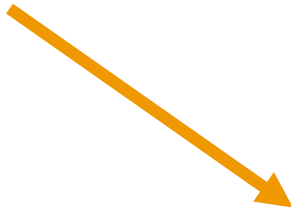
Explaining why the item should be kept confidential:

- Item not publicly available
- Potential harm to a significant degree (5%) if disclosed (negligible harm – rebuttable presumption)
- Novelty - Item finalized up to 5 years prior to the confidentiality request. If older, the applicant must explain why public disclosure would cause harm
- Information acquired legitimately – eligible for legal protection
- Whether environmental information (Art 2 of Aarhus Reg)

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

-	90-day oral toxicity_report_1_confid.pdf	Study Report	Confidential	28/05/2021 21:06	...
+ Metadata					
- Confidentiality treatment ?					
Non confidential file					
	90-day oral toxicity_report_1_non_conf.pdf			28/05/2021 21:07	×
Grounds for confidential file *					
+	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety				×
-	Article 39(e)(2) of Regulation (EC) No 178/2002 - personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies and in toxicological information and personal data of individuals involved or contained in human studies, as well as the name of authors of any unpublished studies				×
Ground ?					
Article 39(e)(2) of Regulation (EC) No 178/2002 - personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies and in toxicological information and personal data of individuals involved or contained in human studies, as well as the name of authors of any unpublished studies					Clear
Justification ?			Excerpt of the text ?		
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.			Consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.		
Related section ?					
page 1, line 15					

Published studies:
Give full citation
(if IPR not owned)



-	Mantova_2015.pdf	Publication	Non-confidential	IPR Protected	28/05/2021 21:10	...
-	Metadata					
Publicly Available ?						
<input type="radio"/> Yes, IRP owned/acquired <input checked="" type="radio"/> Yes, IPR NOT owned <input type="radio"/> No						
IPR Reference						
<p>For publications already available to the public (e.g. studies published in scientific journals which may be accessible upon payment of fees) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements (i.e. reproduction of the study on EFSA's website), the applicant must provide:</p> <p>(a) a copy of the relevant publication. The copy of the relevant publications will be used for assessment purposes only.</p> <p>(b) and in this free text section the relevant bibliographic references/ citations (indicating where these publications are available to the public and their web links for public dissemination on EFSA's website.</p>						
<p><u>Mantova</u>, A. L., Benoit, J. N., Barrowman, J. A., Harper, S. L., <u>Kvietys</u>, P. R., & Granger, D. (2015). Repeated Dose 28-day Oral Toxicity Study in Rodents. American Journal of Toxicology, 247(5), G486-G493.</p>						

Step 4/4: Confidentiality requests * = Mandatory field

Zip files

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco.

Full version *

Non confidential version *

Confidentiality Request

Create the confidentiality requests for the different files in the zip-file describing File name, Ground and conditions, Justification for each ground, Excerpt of the text, Related section.

File name 1 *

Ground *

Justification * 19 / 4000

Excerpt of the text * 333 / 4000

Related section * 8 / 4000

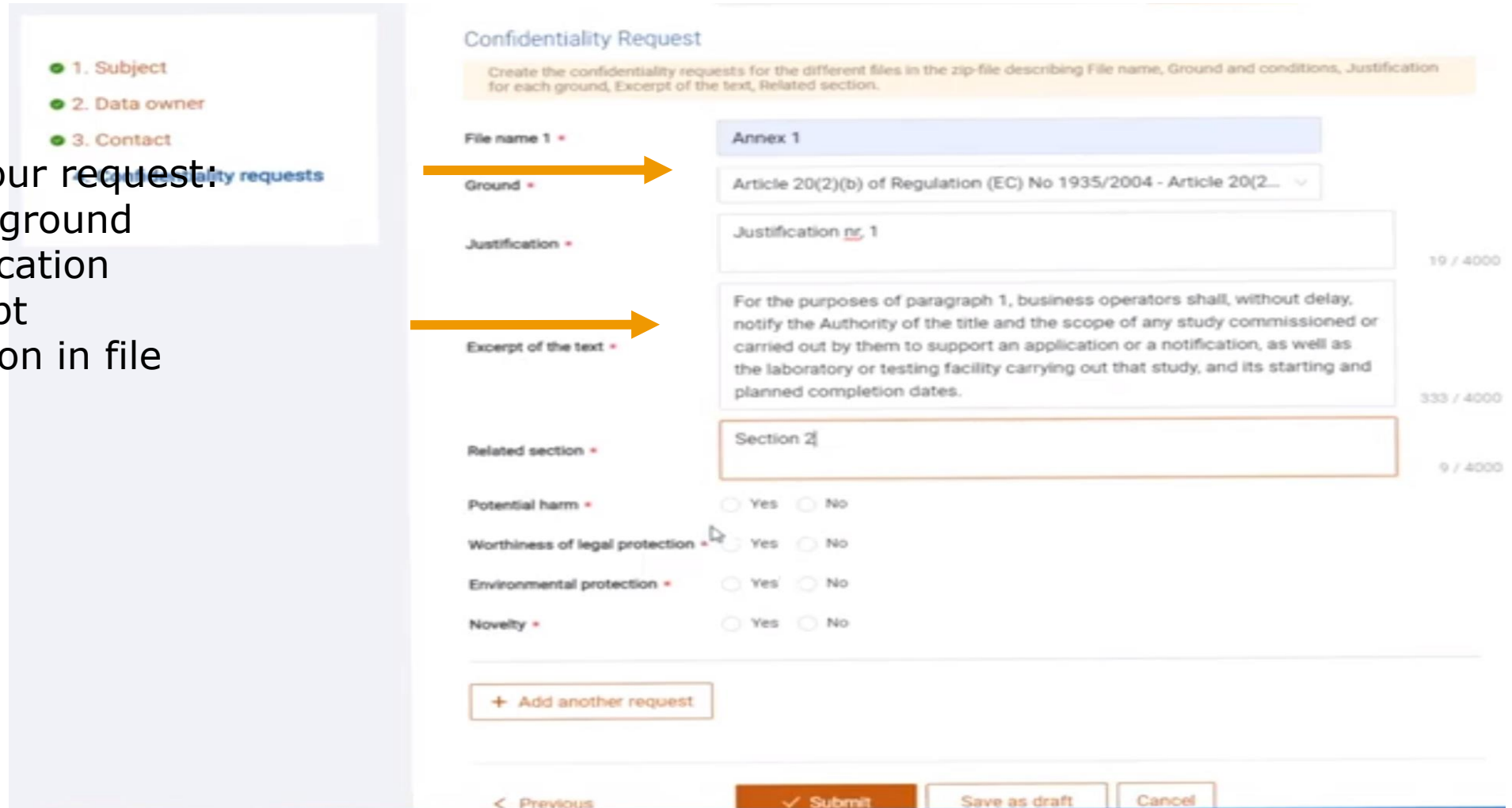
Potential harm * Yes No

Worthiness of legal protection * Yes No

Provide non-confidential file

- Define your request:

- Legal ground
- Justification
- Excerpt
- Location in file



The screenshot shows the 'Confidentiality Request' form in Portalino. The form is titled 'Confidentiality Request' and includes a sub-header: 'Create the confidentiality requests for the different files in the zip-file describing File name, Ground and conditions, Justification for each ground, Excerpt of the text, Related section.'

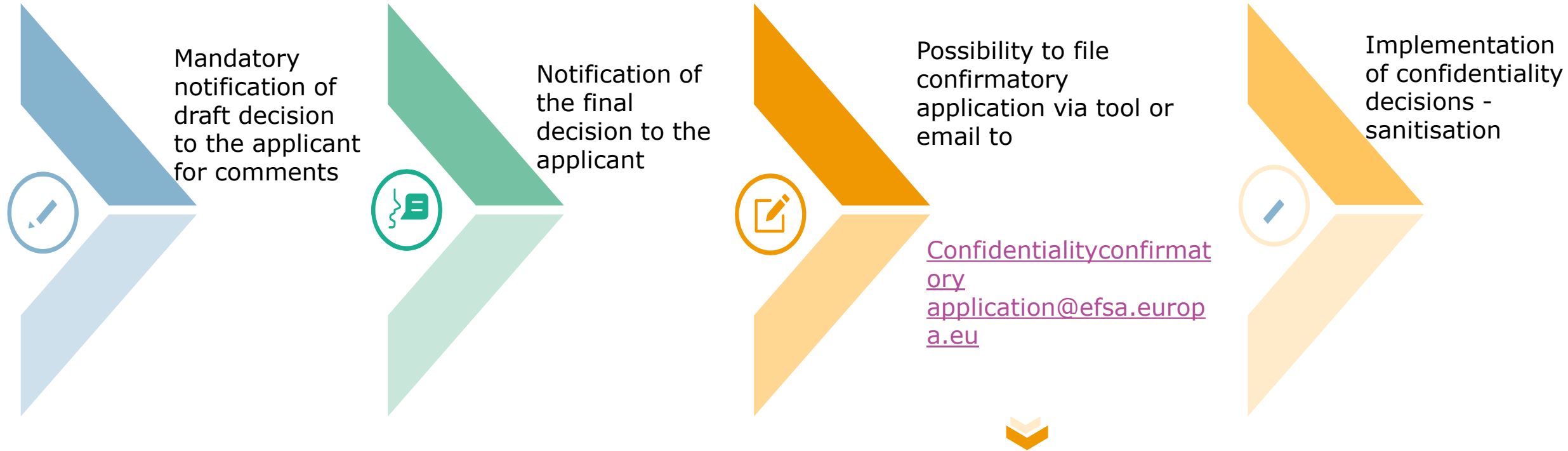
The form is divided into several sections:

- File name 1 ***: A text input field containing 'Annex 1'.
- Ground ***: A dropdown menu showing 'Article 20(2)(b) of Regulation (EC) No 1935/2004 - Article 20(2...'. An orange arrow points to this field.
- Justification ***: A text input field containing 'Justification nr. 1' with a character count of '19 / 4000'.
- Excerpt of the text ***: A text input field containing a paragraph of text: 'For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.' with a character count of '333 / 4000'. An orange arrow points to this field.
- Related section ***: A text input field containing 'Section 2]' with a character count of '9 / 4000'.
- Potential harm ***: Radio buttons for 'Yes' and 'No'.
- Worthiness of legal protection ***: Radio buttons for 'Yes' and 'No'.
- Environmental protection ***: Radio buttons for 'Yes' and 'No'.
- Novelty ***: Radio buttons for 'Yes' and 'No'.

At the bottom of the form, there is a button '+ Add another request' and a navigation bar with buttons: '< Previous', '✓ Submit', 'Save as draft', and 'Cancel'.

Procedural steps EFSA confidentiality assessment

STEPS

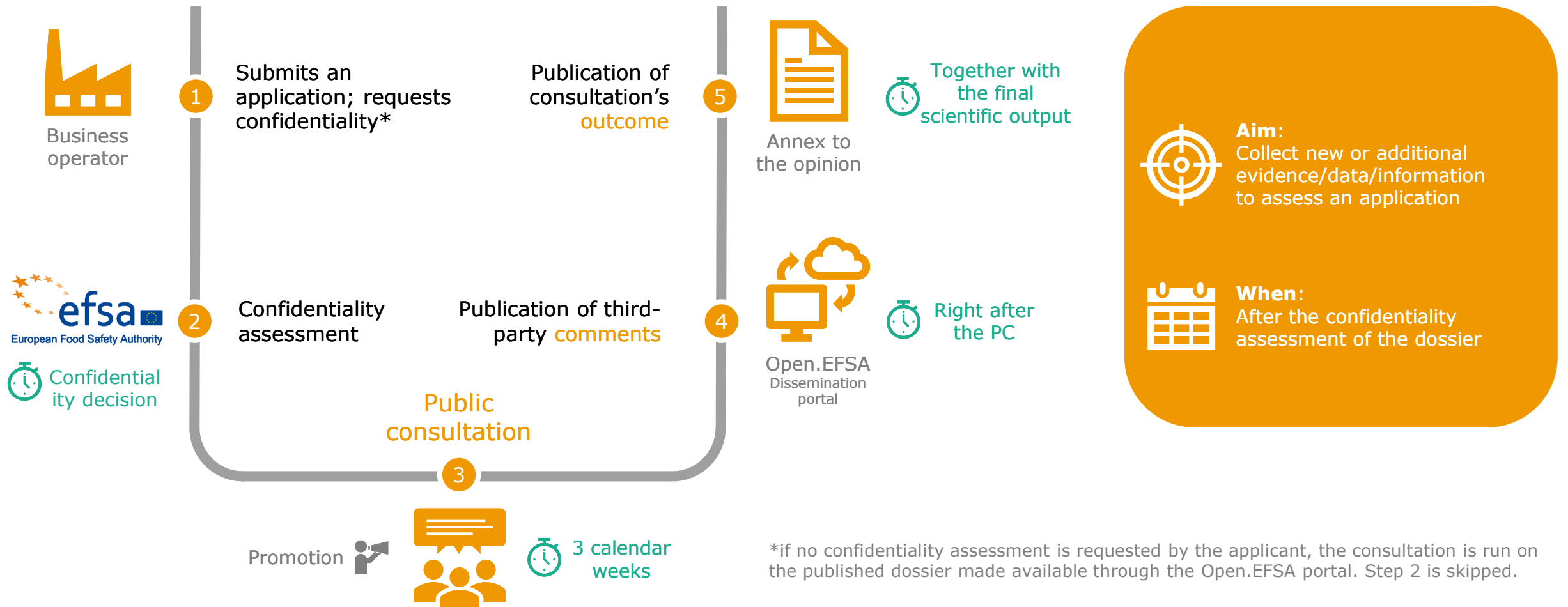


EFSA may review its decision in case output identifies foreseeable effects on human health, animal health or the environment (*Art 39c GFL*)

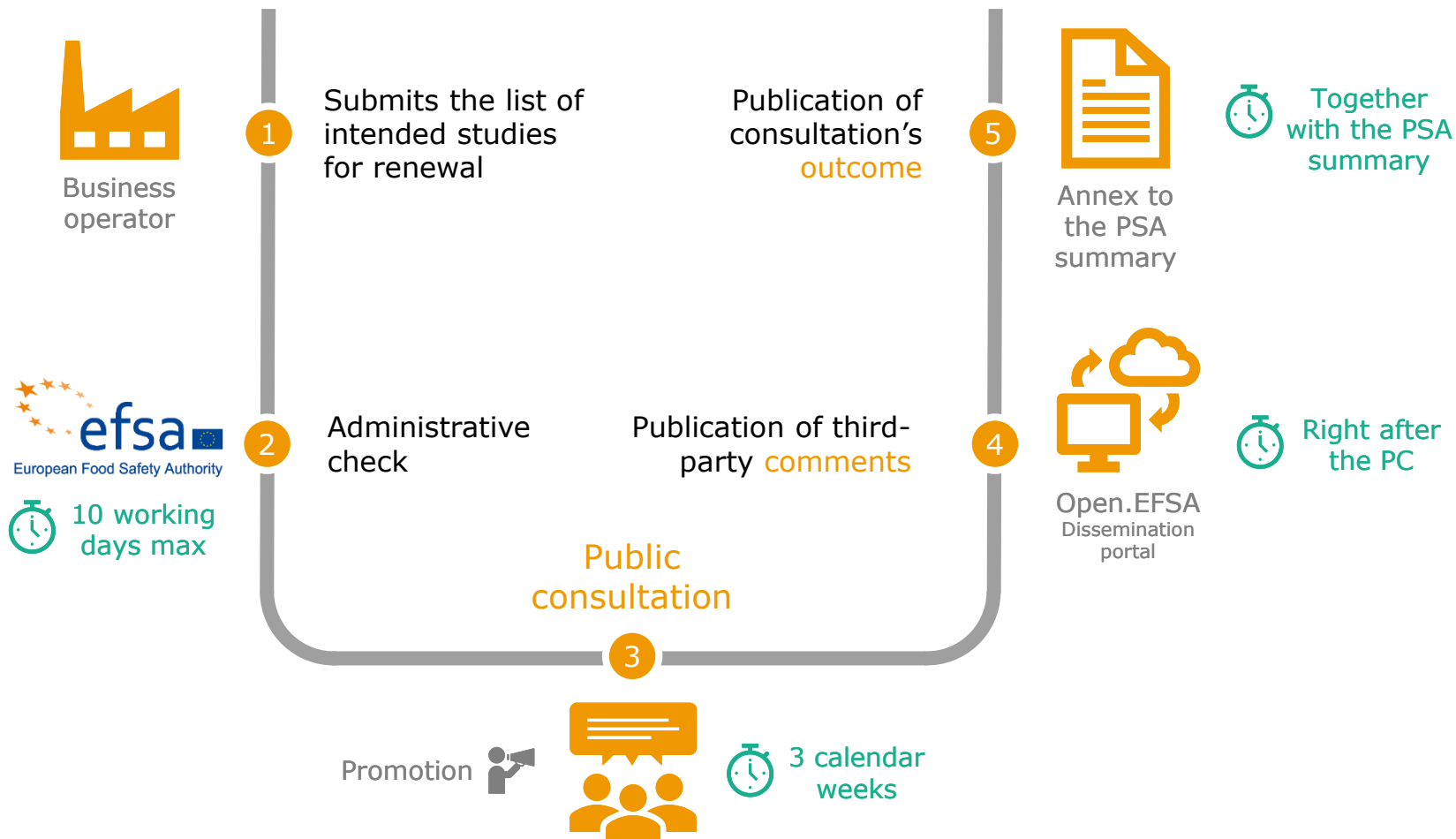
Public Consultation

- 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

PC on the non-confidential version of a validated application



PC on the list of intended studies for application renewal



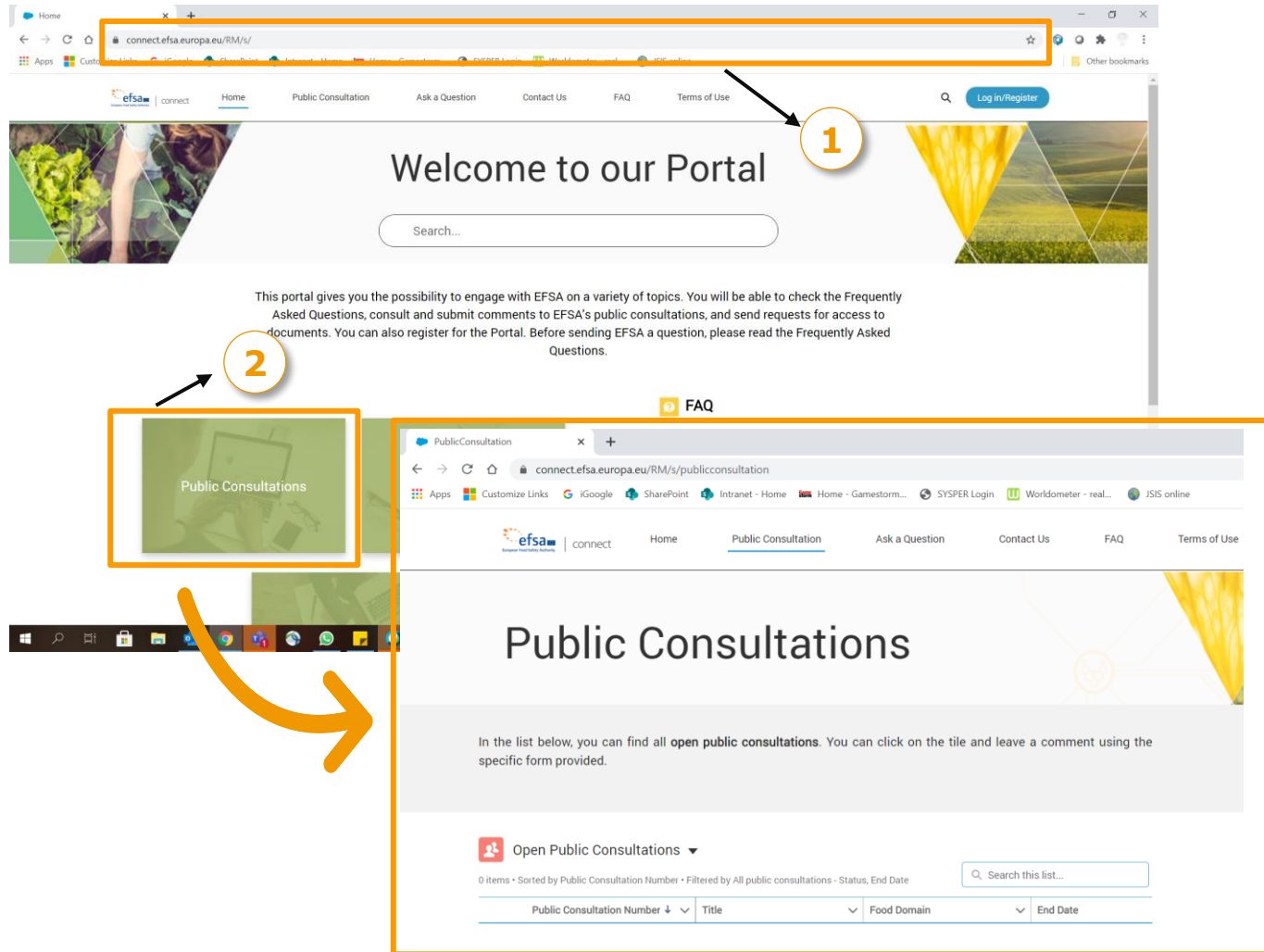
Aim:
Inform the elaboration of the renewal pre-submission advice to a potential applicant



When:
Pre-application phase (ahead of renewal)

Public interface: The Connect.EFSA community portal

Screen



How to access the portal

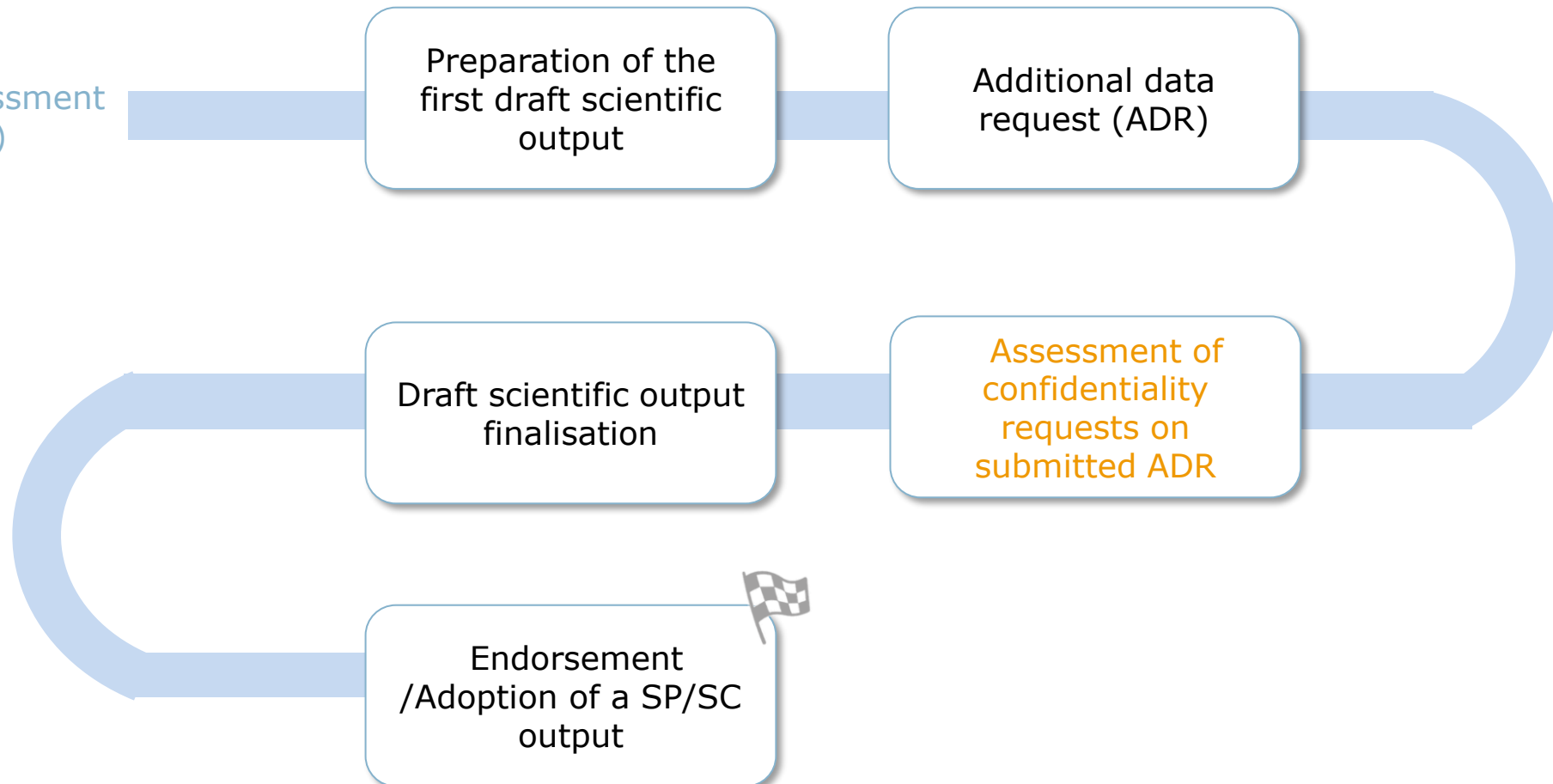
- 1 Click **this link**
<https://connect.efsa.europa.eu/RM/s/publicconsultation>
- 2 Click on '**Public Consultations**'
- 3 Display the **list** of planned/open/closed consultations

The portal will be easily accessible from the EFSA website

Risk Assessment, Adoption and Publication

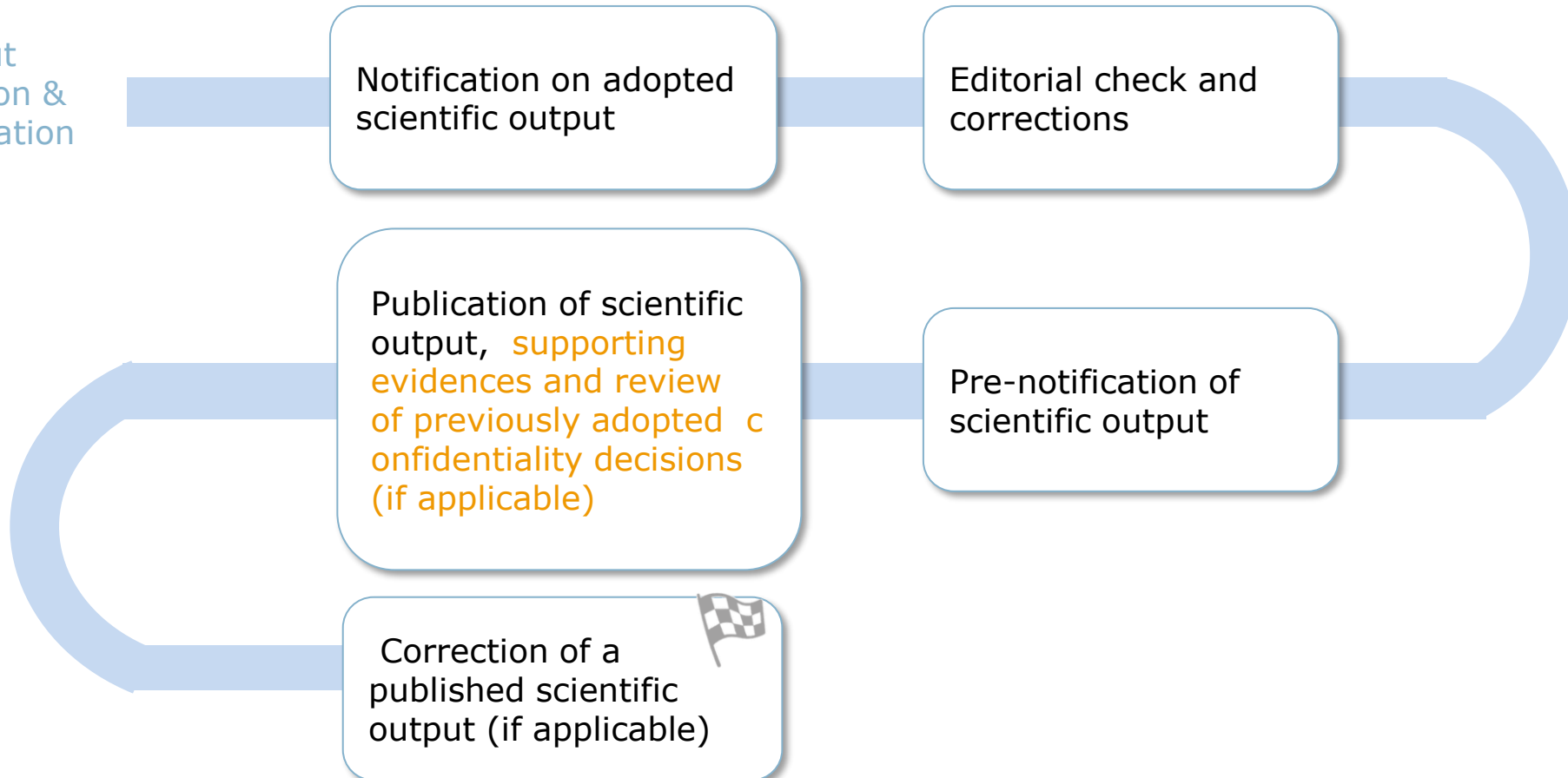
03

Risk Assessment (RA)



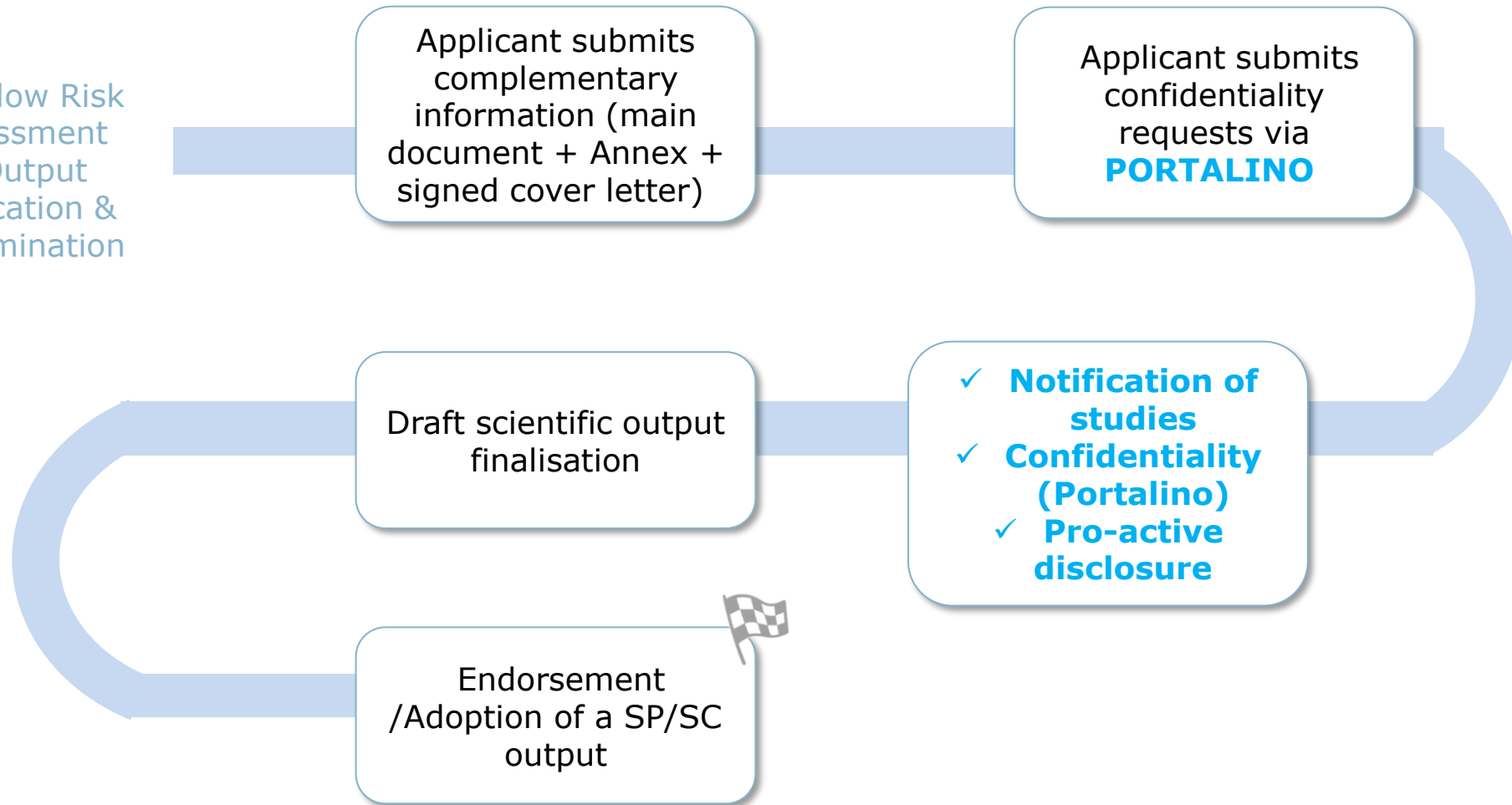
04

Output
Publication &
Dissemination



05

Workflow Risk Assessment + Output Publication & Dissemination



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>





FAQ from feed additives applicants

Feed additive applications: regulations and guidance

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check they are using the latest version before applying.

Regulatory framework

- [Regulation 1831/2003 on additives for use in animal nutrition](#) 
- [Regulation 429/2008 on detailed rules for the implementation of Regulation EC 1831/2003](#) 

Administrative guidance and support initiatives

Applicable to applications submitted until 26 March 2021

[Administrative guidance on the preparation and presentation of applications for authorisation of additives for use in animal nutrition](#)

[Administrative guidance for the processing of applications for regulated products](#)

[EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)

Applicable to applications submitted as of 27 March 2021



[Administrative guidance for the preparation of applications on additives for use in animal nutrition \(update 2021\)](#)

[Administrative guidance for the processing of applications for regulated products \(update 2021\)](#)

[EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products \(update 2021\)](#)

<https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance>

Additional resources

- [EC overview of authorisation process for feed additives](#) 
- [Frequently asked questions to applicants during the assessment of feed additives](#) 

<https://www.efsa.europa.eu/sites/default/files/2021-05/frequently-asked-questions-applicants-assessment-feed%20additives.pdf>

"When checking the register of questions with the feed additives filter, I often do not get search hits when I type a keyword, though I know that an application is pending or published. The former Register of Questions was more practical for searching and selecting the type of application published. Will it be improved?"



- Repeat the search using the **Questions** menu (not from 'Home') and insert the keyword in the search box to see more results.
- For applications received before 21 January 2021, date of migration to the new OpenEFSA portal, refer to the static report available [here](#)

"For feed additive renewal, it seems that data commissioned or carried out before 27 March 2021 is not subject to the study notification obligations. Is it correct?"



- Obligation of study notification under Art 32b of the General Food Law Regulation applies only to studies commissioned or carried out as of the 27 March 2021
- Refer to EFSA Practical arrangement, Chapter IV on the notification of studies Art 19 "Timelines" [here](#)
- More information in the Q&A of the EFSA practical arrangements [here](#)

Question and answer (3)

Applicable to application submitted as of the date of entry into application of the Transparency Regulation, i.e. **27 March 2021**

"EFSA publishes the opinions on feed additives evaluations, are dossiers (sanitized version) published as well?"



Regulation (EU) 2019/1381 (the Transparency Regulation) has introduced a general principle of **proactive disclosure and transparency of information, studies and data** submitted to EFSA for scientific evaluation.

In light of this principle, EFSA must **proactively disseminate all information submitted by applicants** for the purposes of EFSA's scientific evaluation of regulated products, including the information submitted during the assessment process at EFSA's explicit request



Non-confidential version of information provided at EFSA's request for additional information, or as a result of spontaneous submission by the applicant, is published as soon as received

The **non-confidential version of the dossier**, as submitted by the applicant, is **published once** the application has been considered **valid**.

EFSA will proactively disclose on the **OpenEFSA portal** (<https://open.efsa.europa.eu>).

By derogation from the general principle, EFSA, when required to issue an opinion, may grant confidential status to **certain elements of application dossiers**, provided applicants submit a **verifiable justification** and **EFSA accepts the confidentiality request**

If confidentiality requests are rejected by EFSA, an **updated non-confidential version** of the dossier is published upon implementation of EFSA's confidentiality decision.

If confidentiality requests presented on the additional information are rejected, an **updated non-confidential version of the information** is published after implementation of EFSA's confidentiality decision, once EFSA's scientific opinion is adopted

On behalf of a laboratory owner of a new feed additive, we would like to submit an application for its authorisation as a zootechnical additive. The submission of the file will take place in 6 to 10 months.

Who should register in EFSA portal supporting pre-submission activities?

- ***the laboratory owner of the feed additive***
- ***my organization as consultant since we are preparing the dossier and we will submit it on behalf of the owner of the feed additive?***



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 your organisation and add it as **Consultant**: 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 (your company). Please note that the Business Operator must select "on behalf of" as account relationship type, as it is the only way to allow you to operate (view and edit).

Similarly for the notification of studies:

- **Can we do it on behalf of the owner of the feed additive?**
- **How can we have access to the notification database?**



In order to create and manage pre-application ID potential Business Operators (the laboratory owner of the feed additives) must **be registered to ConnectEFSA platform** as applicant. Third parties can act on behalf of business operator, and to do so they need to be registered as well to the Connect.EFSA portal, accessible at (<https://connect.efsa.europa.eu/RM/s/>

Summing up, **you can operate on behalf of the owner of the new feed additive only after the Business Operator delegates you to do so.** This will allow the Business Operator BO to share a pre-existing pre-application ID or notified study(ies) with you, or allow you to create a new pre-application ID and notify studies on behalf of the Business Operator

Wherever a pre-application ID already exists and has been created by the Business Operator it is possible that the Business Operator grant access to it by using the **“share with” function**. Now the Consultant can operate on it. Alternatively, the Consultant can create a pre-application ID on behalf of the Business Operator.

"Should the studies for verification of methods of analysis of the active substance in the feed additive, premix and complete feeding stuffs also be notified?"

These are not directly assessed by EFSA but by EURL and they are not present in the drop down menu where you can select study type when notifying studies".



- 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 (Article 32b of the General Food Law).
- Refer to question 4: "What falls within the definition of "study" of the Q&A of the EFSA Practical Arrangements, Part B for further details [here](#), which will provide you with more examples on what is meant for "study".

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

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

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 arrangements: <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 additives for use in animal nutrition](#)
- Guidance on the [renewal of the authorisation of feed additives](#)
- [Training programme on Transparency regulation](#)
- Feed additive applications: regulations and guidance [web section](#)
- [Catalogue of services](#) (update 2021)
- [Administrative guidance for the processing of applications for regulated products](#) (update 2021)
- 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](#))



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