



25 January 2022
EFSA webinar series

Webinar on application procedure for health claims

Trusted science for safe food



Time



Topic



Speaker

Time	Topic	Speaker
11.00-11.05	Welcome and introduction	Goran Kumric
11.05-12.00	Lifecycle of an application Account creation and management Pre-application ID, Pre-Submission Advice and NoS Applications and modification of authorisation E-submission (demo) Portal updates and validity of applications Confidentiality in the context of health claims Public consultation RA, adoption and publication	Bénédicte Vagenende Anastasia Livaniou Simone Gabbi
12.00-12.30	Q&A session and conclusions	Stefano Cappé Anastasia Livaniou Sara De Berardis Simone Gabbi Leng Heng Janusz Ciok Goran Kumric Francesca Volpi



Who we are

Presenters of this webinar

- Bénédicte Vagenende
- Anastasia Livanou
- Simone Gabbi

Q&A contributors:

- Stefano Cappé
- Sara De Berardis
- Leng Heng
- Janusz Ciok
- Francesca Volpi

Webinar moderator:

- Goran Kumric

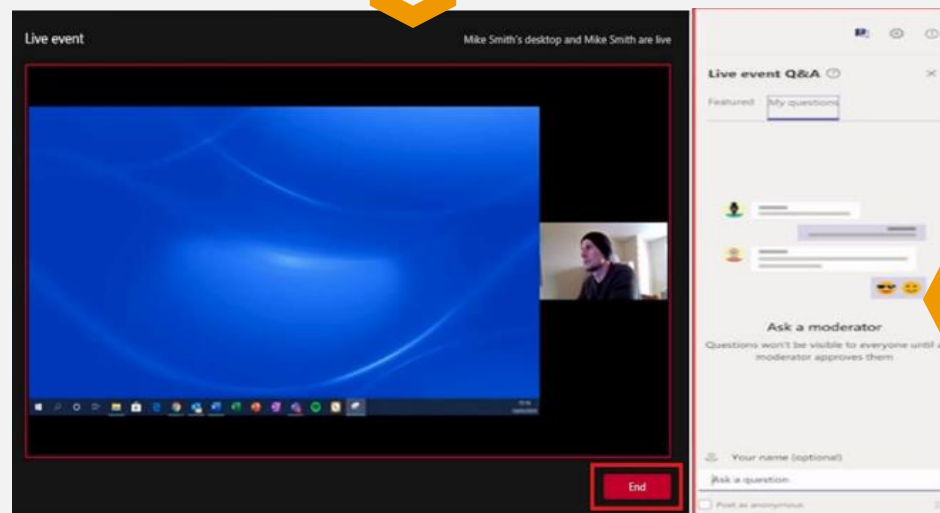


Goals

- What is the goal of this webinar? The aim is to explain the arrangements, steps and the tools of the application procedure for health claims implemented by EFSA following the entry into force of the Transparency Regulation.
- Applicable to health claim applications submitted pursuant to Articles 13.5, 14 and 19 of Regulation (EC) No 1924/2006
- Address questions encountered by applicants in recent months following the entry into application of the Transparency Regulation.
- **Out of scope:** Clarifications about aspects of the authorization process which have not been affected by the Transparency Regulation.

- 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

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

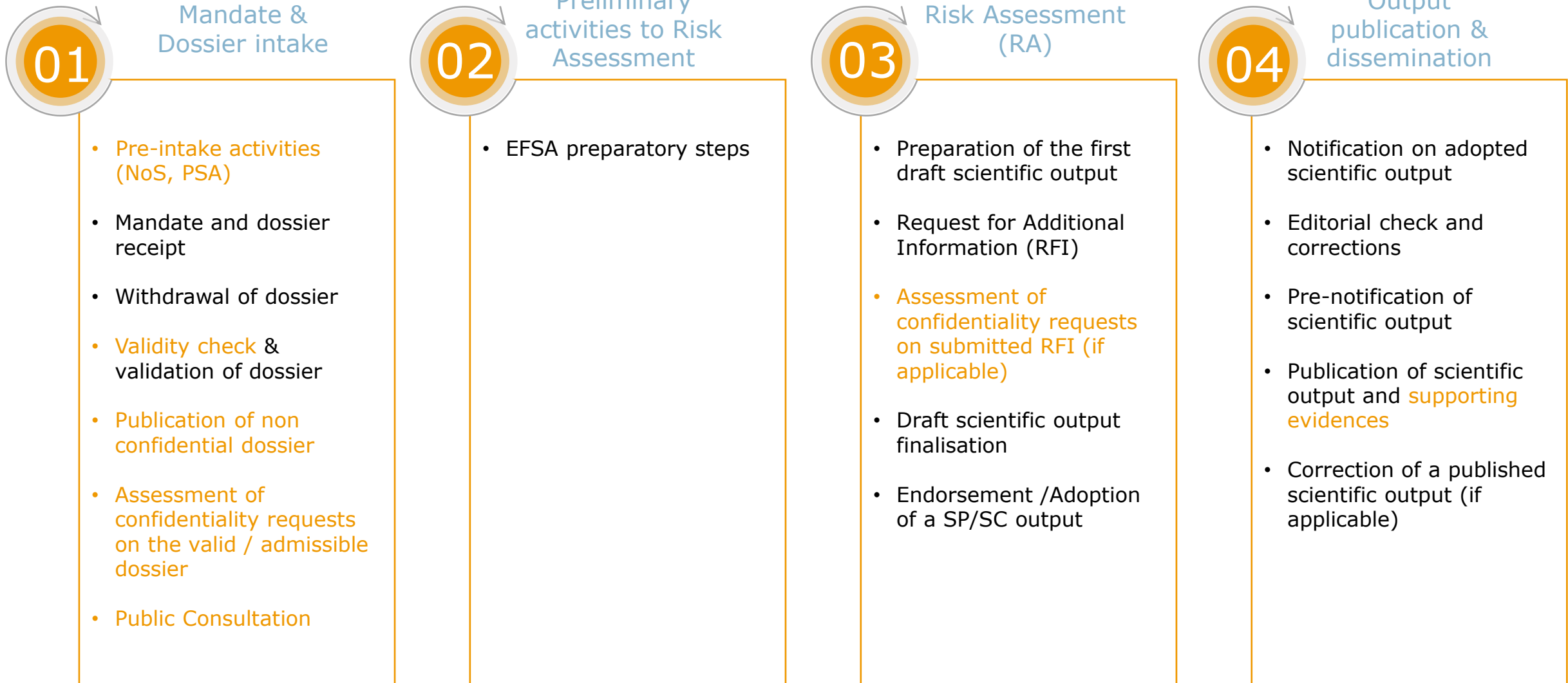
Effective risk communication

- 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"



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

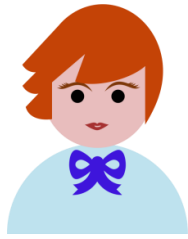
Open EFSA

- ✓ 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



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

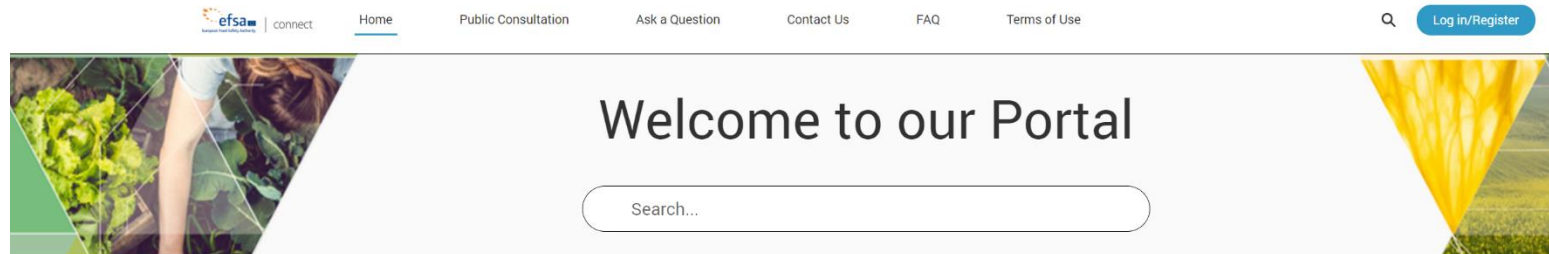
Third parties representing one or more entities shall also register in the Authority system supporting pre-submission activities ...¹ and obtain the authorization by represented entities to act on their behalf

3


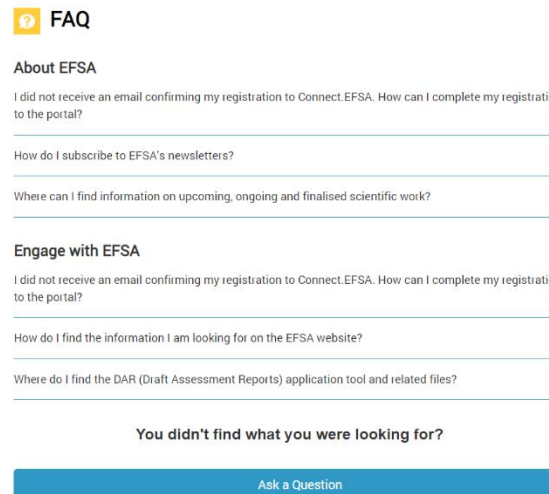
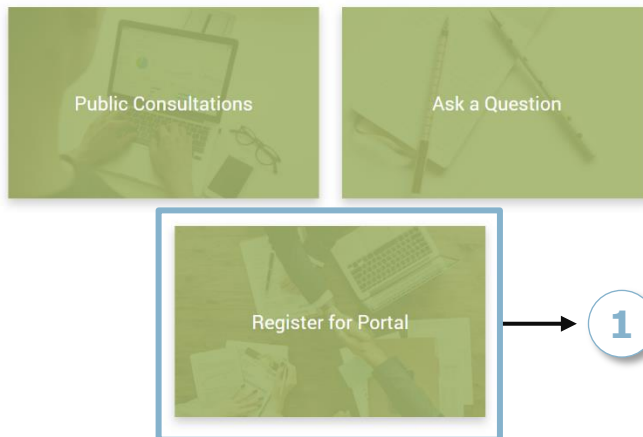
Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.¹

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

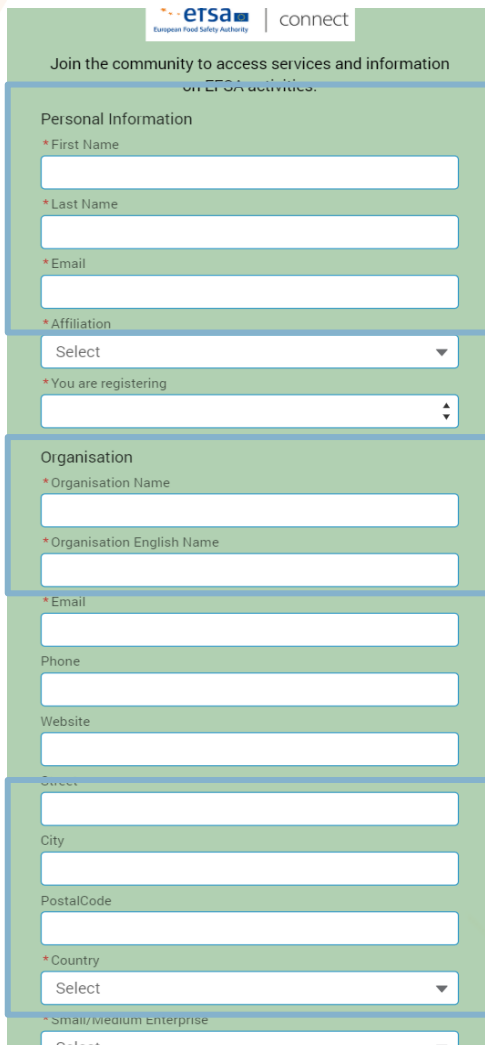
The potential applicant starts the registration in the portal.

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 EFSA logo and 'connect' branding are visible at the top left of the form.

Information related to the **contact person** of the account. The information and the e-mail address must be person specific and linked to the entity registered. No functional and generic mailboxes (e.g @gmail).

Each account can register a **maximum of 6** contact persons (NEW since 30 June).

Information related to the organisation (e.g company). The name inserted will be the **account name**.

A **complete billing address** is essential for a clear identification of the company.

After the registration, the account and the contact(s) are not active yet.



Upon registration, EFSA performs a security check of the account in few days.



Once the account is considered valid, EFSA activate the account and the contact(s) inside.

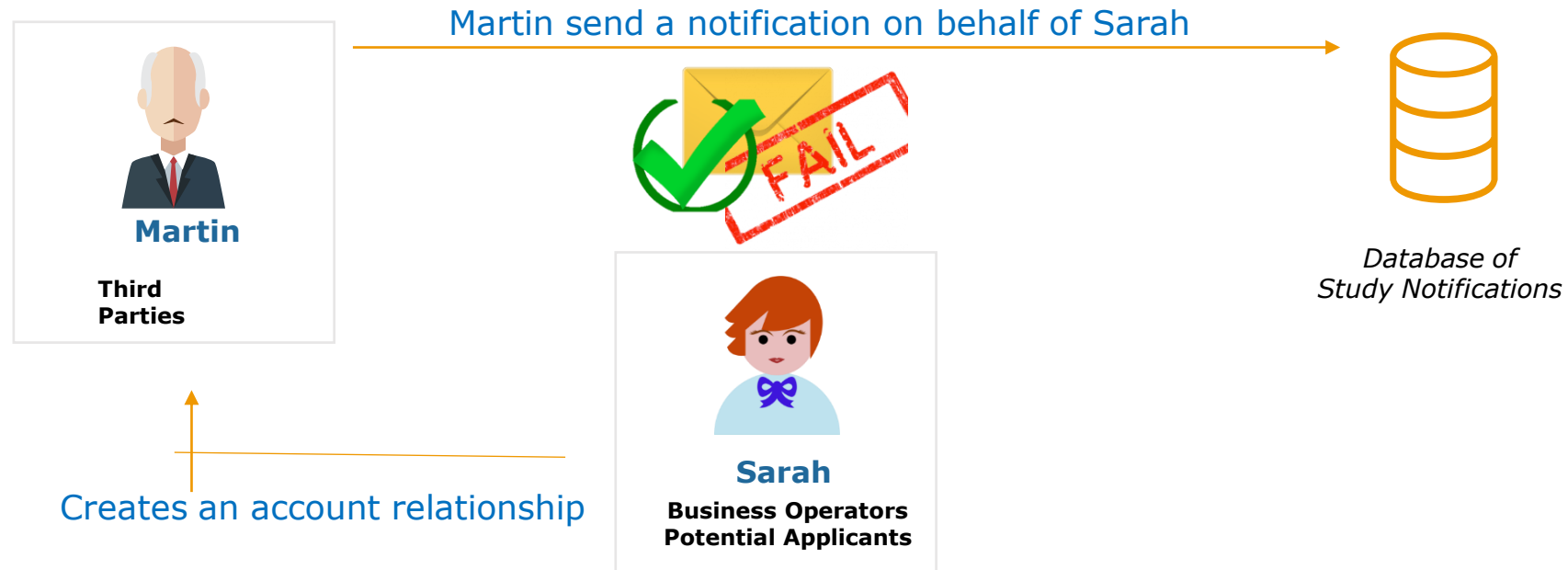


The applicant is ready to use the functionalities of the portal.

As regards **multinational companies** made up of several entities, any of these entities may register provided that the registered entity is recognised as having a **separate legal personality** under the national law of the country in which it has its registered office.

Authorisation of delegation to third parties – NEW since 30th April

Update from Account Registration



This feature is in place since 30/04.

Organisations playing multiple roles NEW since 30th June

Update from Account Registration



The implementation of this feature required some adjustments to the user interface.

This feature is in place from 30th June.

Webinars: Webinar 16 February ([here](#)). Webinar 25 March ([here](#)).

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'.

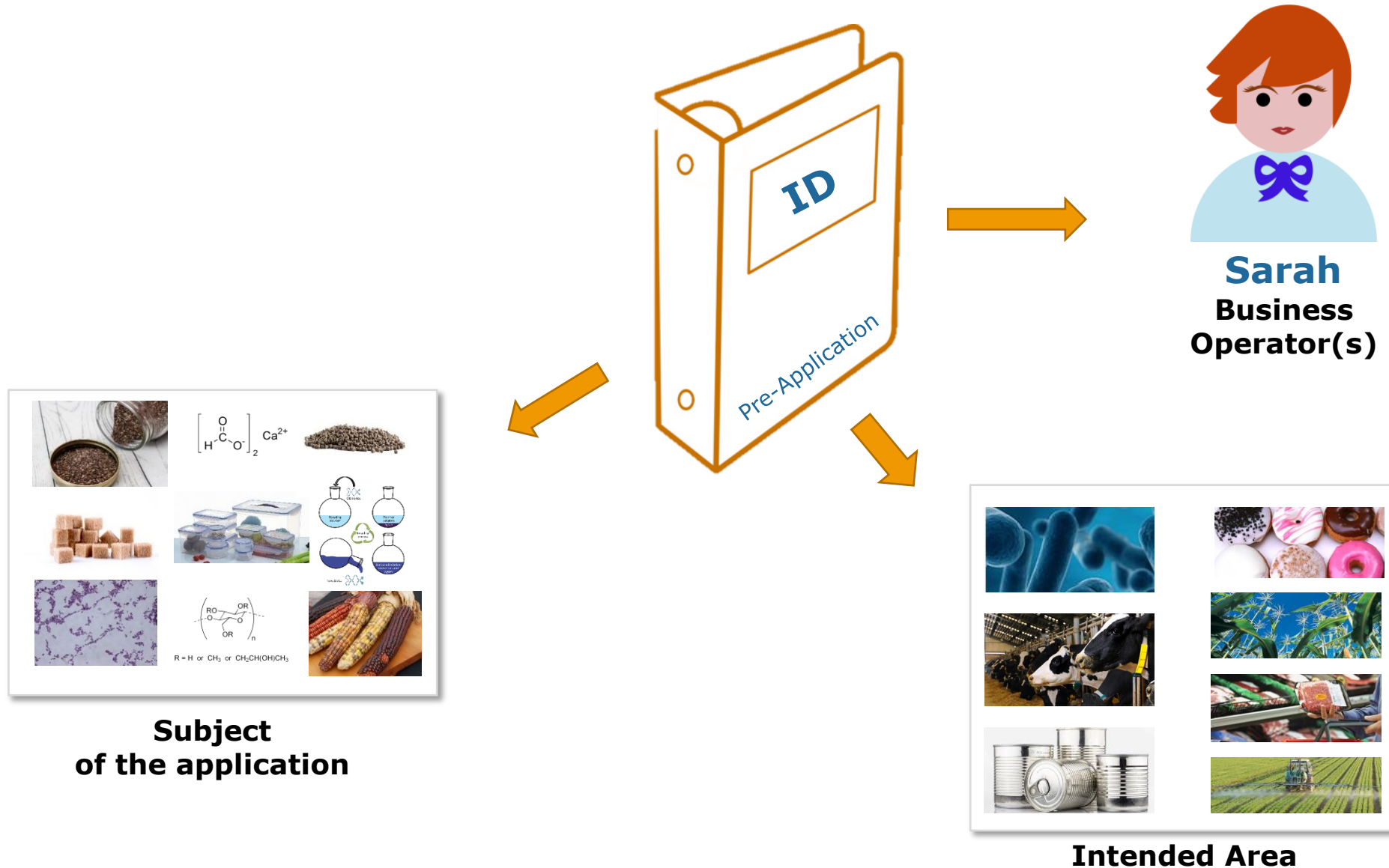


This relationship has to be previously established in the Account Management:

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

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

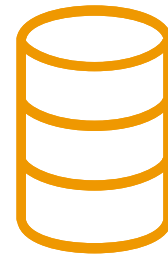
Step 1 Pre-submission phase



Sarah

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

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



Database of Study Notifications

Step 2 Submission of application

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



Step 3 Validation of application



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

E-Submission (demo)

FSCAP v.1 EC web system, operational since Jan 2018

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

- **TR compliance:** NoS, Confidentiality assessment, Dissemination
- **All Regulated Products** dossiers (excl. pesticides)
- **Single point of entry** for Applicant, European Commission, Member States

6 Food Domains - 37 Application Types (new applications, modifications & renewals)

- **Food Contact Materials:** Substances, Active & Intelligent materials, Recycling processes
- **Food Improvement Agents:** Food Additives, Food Enzymes, Food Flavourings, Smoke Flavourings Primary Products
- **GMO:** Food-feed (Regulation), GMO Directive;
- **Nutrition:** Novel/Traditional Foods, **Health Claims**, Infant formulae, Food allergens, Nutrient sources
- **Biological hazards:** Decontamination substances
- **Feed Additives**



[URL for ESFC](#)

Hyperlink



[Video Tutorials](#)

Hyperlink



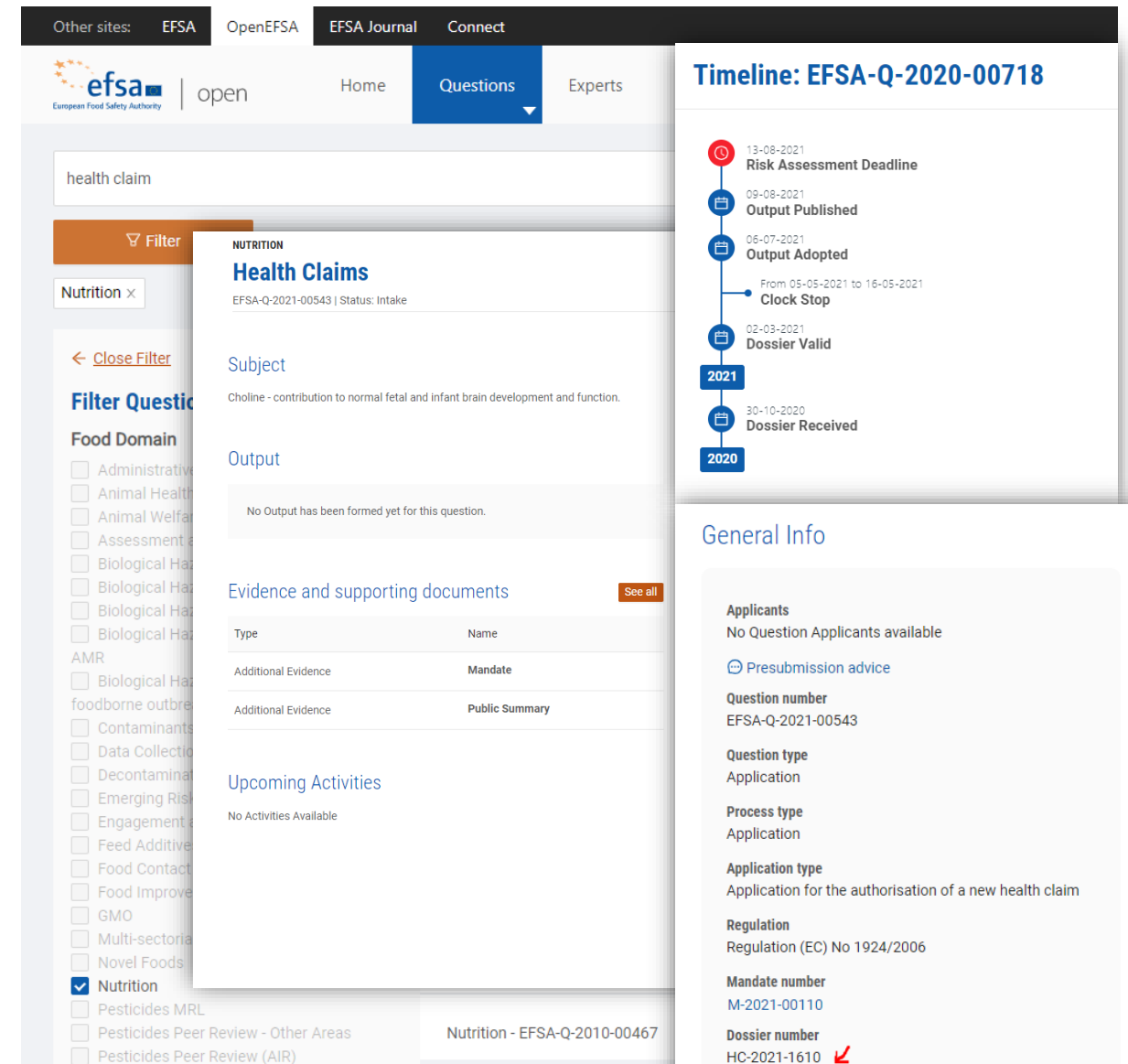
[User Guide](#)

Hyperlink

Portal updates and validity of application

Mandate and Dossier Intake

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



The screenshot displays the EFSA OpenEFSA portal interface. At the top, navigation links include 'Other sites: EFSA', 'OpenEFSA', 'EFSA Journal', and 'Connect'. The main header shows 'efsa | open' and navigation options 'Home', 'Questions', and 'Experts'. A search bar contains 'health claim'. A filter is applied for 'Nutrition'. The main content area shows details for 'Health Claims' (EFSA-Q-2021-00543) with a status of 'Intake'. The subject is 'Choline - contribution to normal fetal and infant brain development and function.' The output section states 'No Output has been formed yet for this question.' Below this is a table for 'Evidence and supporting documents' with columns for 'Type' and 'Name'. The table lists 'Additional Evidence' for 'Mandate' and 'Public Summary'. The 'Upcoming Activities' section shows 'No Activities Available'. On the right, a 'Timeline: EFSA-Q-2020-00718' shows key events: 'Dossier Received' (30-10-2020), 'Dossier Valid' (02-03-2021), 'Clock Stop' (05-05-2021 to 16-05-2021), 'Output Adopted' (06-07-2021), 'Output Published' (09-08-2021), and 'Risk Assessment Deadline' (13-08-2021). The 'General Info' section provides details: 'Applicants: No Question Applicants available', 'Question number: EFSA-Q-2021-00543', 'Question type: Application', 'Process type: Application', 'Application type: Application for the authorisation of a new health claim', 'Regulation: Regulation (EC) No 1924/2006', 'Mandate number: M-2021-00110', and 'Dossier number: HC-2021-1610'.

Confidentiality in the context of health claims

Application submitted
before 27/03/2021



Application submitted
on/after 27/03/2021

**Pre-Transparency Regulation
Regulation 178/2002 applies**

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

**Regulation 178/2002 as amended by
Transparency Regulation applies**

- Practical Arrangements concerning transparency and confidentiality apply
- Confidentiality requests assessed in accordance with Articles 39-39e of the amended Regulation 178/2002



Proactive Disclosure

Art 38(1) of Reg 178/2002 **Proactive disclosure e.g. for:**

- Information data or studies submitted to support an application dossier
- Other information identified by EFSA and used as basis for opinion



Confidentiality

Articles 39-39e of Reg 178/2002 **Confidential status:**

- Only for items included in the closed positive list of the Practical Arrangements concerning transparency and confidentiality Annex
- Only if substantive and procedural requirements are met

Underlying principles



Proactive disclosure of non-confidential version of application dossiers as of validation



Confidentiality as exception to transparency



Burden of proof on applicants



Non-disclosure of information claimed confidential pending decision-making

Procedural requirements



Submission through ESFC for applications or Portalino for follow up to inconclusive opinions and data supporting general mandates



Including verifiable justifications, a confidential and a non-confidential version of the document



Providing clarifications ONLY if requested to do so by EFSA (via ESFC or email)



Submit clarifications within the deadline set by EFSA (via ESFC or email)




Modifications of submitted requests not allowed, unless requested by EFSA



No fees

Confidentiality requests only on items in closed positive list – for health claims:

- 
- the **manufacturing or production process**, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, **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



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)**



Identifying clearly the information claimed confidential, with references



Indicating the legal basis (grounds)



Explaining why the item should be kept confidential:



Information not publicly available



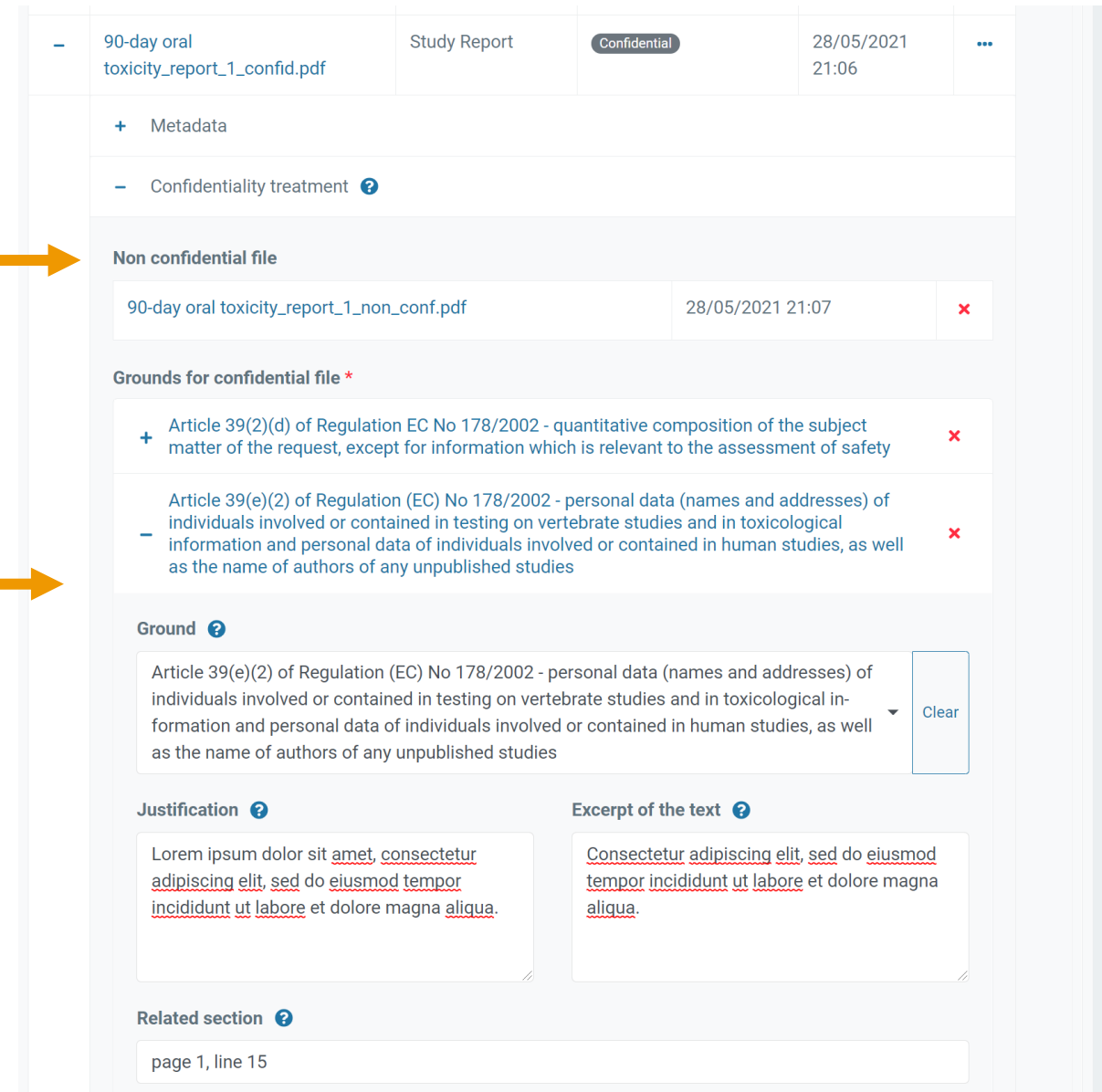
Potential harm to a significant degree

- Information acquired legitimately
- Negligible harm – rebuttable presumption
- Novelty – rebuttable presumption



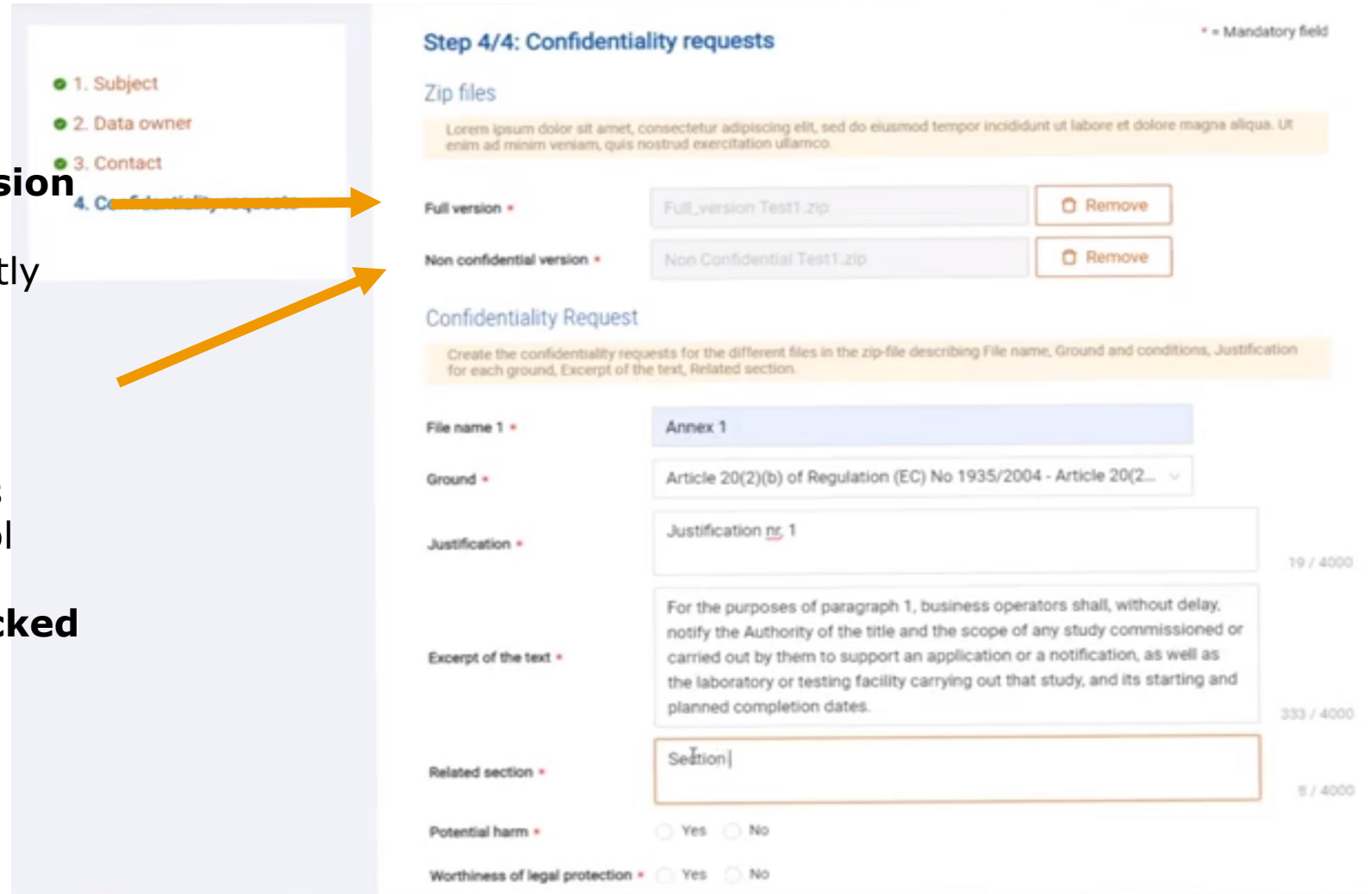
Clarification on whether information claimed confidential falls under “environmental information” (Art 2 of Aarhus Regulation)

- Provide non-confidential file AND confidential version of the file
- Provide non-confidential file
 - Ensure that information claimed confidential is redacted by using a redaction tool which ensures that the **redacted information is irreversibly blocked out.**
- Define and support your request:
 - Legal ground
 - Justification
 - Excerpt
 - Location in file



The screenshot shows a web interface for submitting a confidentiality request. At the top, a table lists the request details: a minus sign, the file name '90-day oral toxicity_report_1_confid.pdf', the document type 'Study Report', a 'Confidential' status badge, the date '28/05/2021 21:06', and a three-dot menu icon. Below this, there are expandable sections: '+ Metadata', '- Confidentiality treatment', and 'Non confidential file'. The 'Non confidential file' section contains a table with one entry: '90-day oral toxicity_report_1_non_conf.pdf' with a timestamp of '28/05/2021 21:07' and a red 'x' icon. Below this is the 'Grounds for confidential file' section, which lists two grounds with plus and minus signs and red 'x' icons: '+ 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' and '- 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'. The 'Ground' section is expanded, showing the selected 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' with a 'Clear' button. Below this are 'Justification' and 'Excerpt of the text' sections, each with a text area containing placeholder text. The 'Justification' text is 'Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.' and the 'Excerpt of the text' text is 'Consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.' At the bottom, there is a 'Related section' section with a text input field containing 'page 1, line 15'.

- Provide non-confidential file AND confidential version of the file
- Ensure that the **confidential version** of the document **includes earmarked parts** matching exactly the blackened parts of the non-confidential version
- Ensure that information claimed confidential is redacted by using a redaction tool which ensures that the **redacted information is irreversibly blocked out.**



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 * Full_version Test1.zip Remove

Non confidential version * Non Confidential Test1.zip Remove

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 * Annex 1

Ground * Article 20(2)(b) of Regulation (EC) No 1935/2004 - Article 20(2... ▾

Justification * Justification nr. 1 19 / 4000

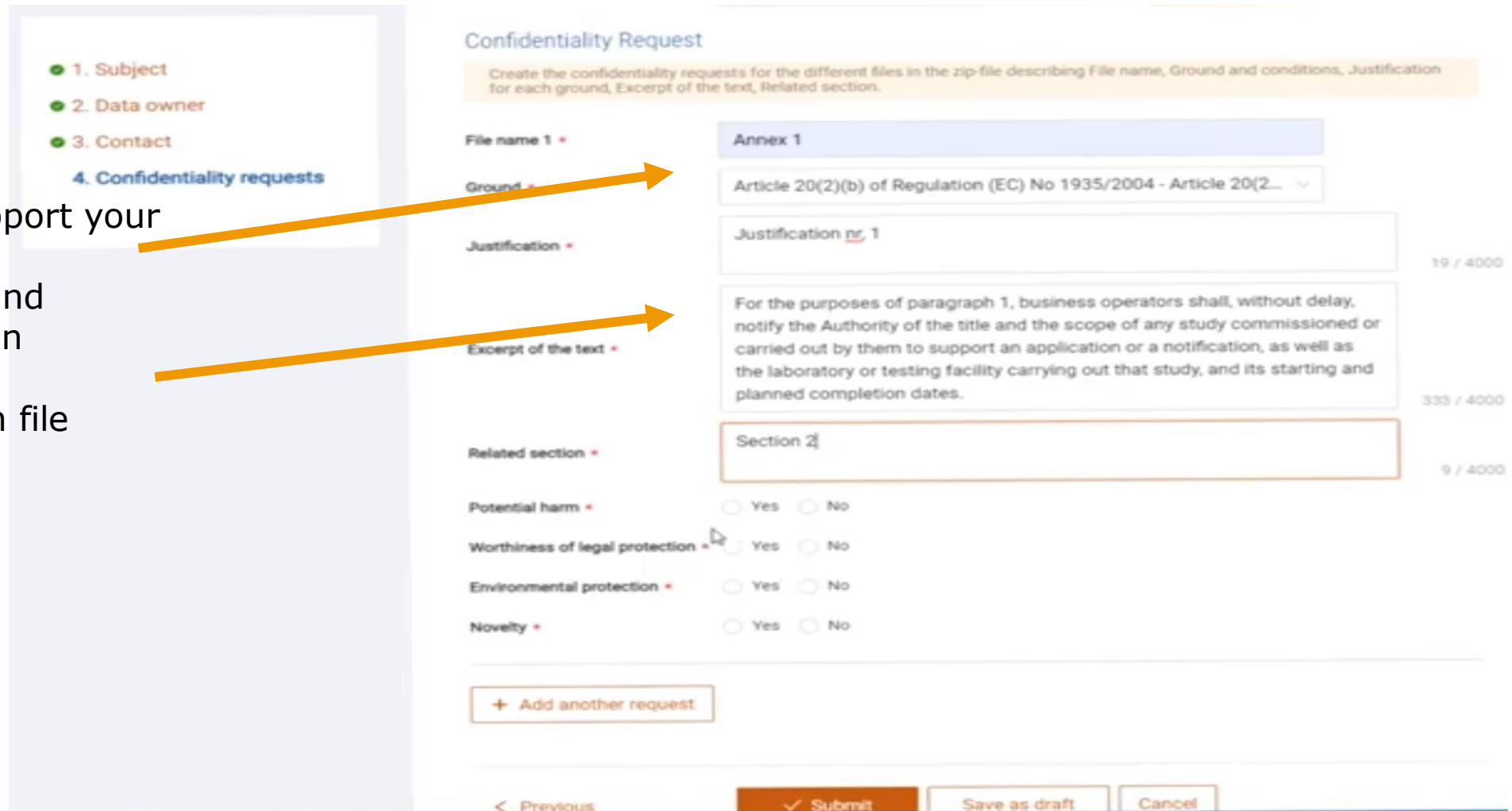
Excerpt of the text * For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates. 333 / 4000

Related section * Section| 8 / 4000

Potential harm * Yes No

Worthiness of legal protection * Yes No

- Define and support your request:
 - Legal ground
 - Justification
 - Excerpt
 - Location in file

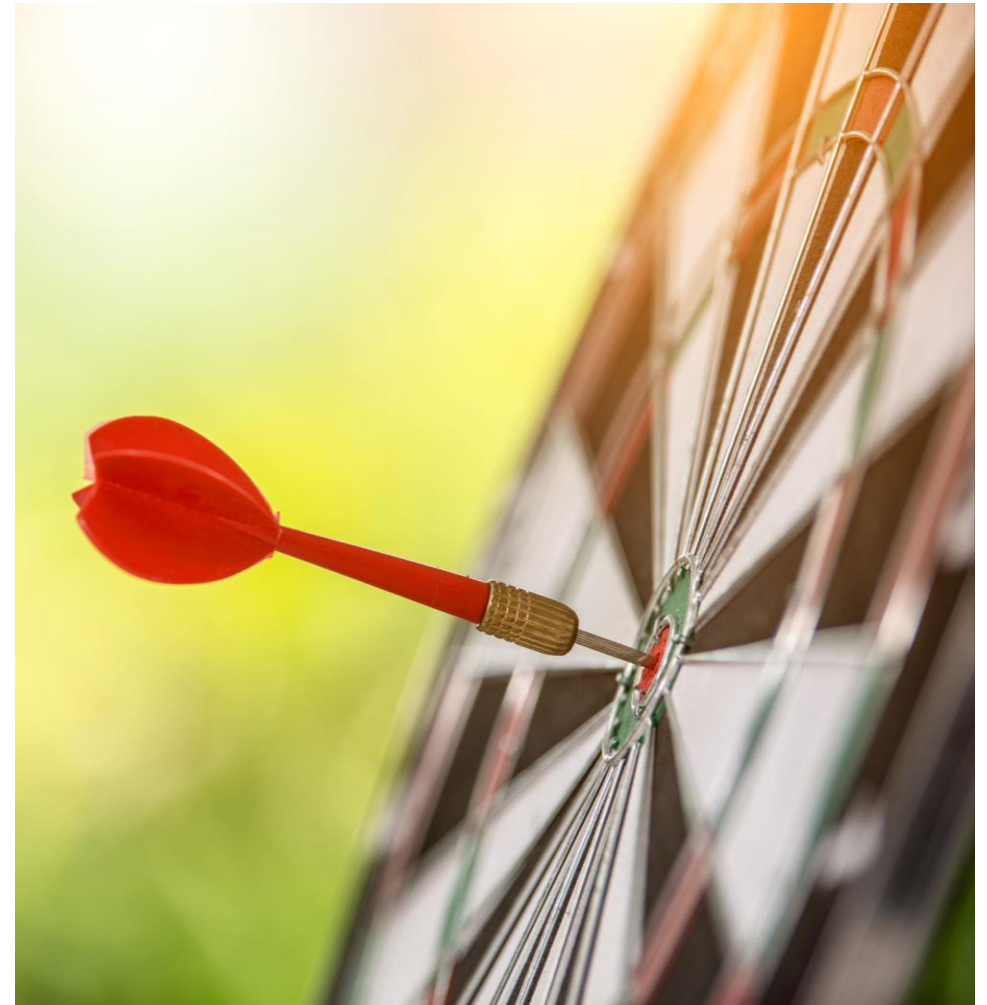


The screenshot shows the 'Confidentiality Request' form in Portalino. The form is titled 'Confidentiality Request' and includes a sub-header: 'Create the confidentiality requests for the different files in the zip-file describing File name, Ground and conditions, Justification for each ground, Excerpt 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 from the 'Ground' label in the sidebar to this dropdown.
- Justification ***: A text input field containing 'Justification nr. 1'. A character count '19 / 4000' is visible to the right.
- 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.' A character count '333 / 4000' is visible to the right. An orange arrow points from the 'Excerpt of the text' label in the sidebar to this field.
- Related section ***: A text input field containing 'Section 2'. A character count '9 / 4000' is visible to the right.
- 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'.

- ✓ Confidential version of the document to highlight **info claimed confidential as boxed or earmarked**, matching exactly with the blackened parts of the non-confidential version
- **In the public version, use a redaction tool which ensures that the redacted information is irreversibly blocked out.**
- ✓ Only **one confidentiality request per document per legal ground** is submitted
- ✓ justification complying with Articles 9 and 10 of EFSA's Practical Arrangements concerning transparency and confidentiality
- ✓ No duplications
- ✓ **No confidentiality requests on publicly available information**




Procedural steps EFSA confidentiality assessment


STEPS




Mandatory notification of draft decision to the applicant for comments via ESFC or email confidentialityrequestassessment@efsa.europa.eu



Notification of the final decision to the applicant via ESFC or email confidentialityrequestassessment@efsa.europa.eu



Possibility to file confirmatory application via tool or email to Confidentialityconfirmatoryapplication@efsa.europa.eu



Implementation of confidentiality decisions – sanitization – by EFSA

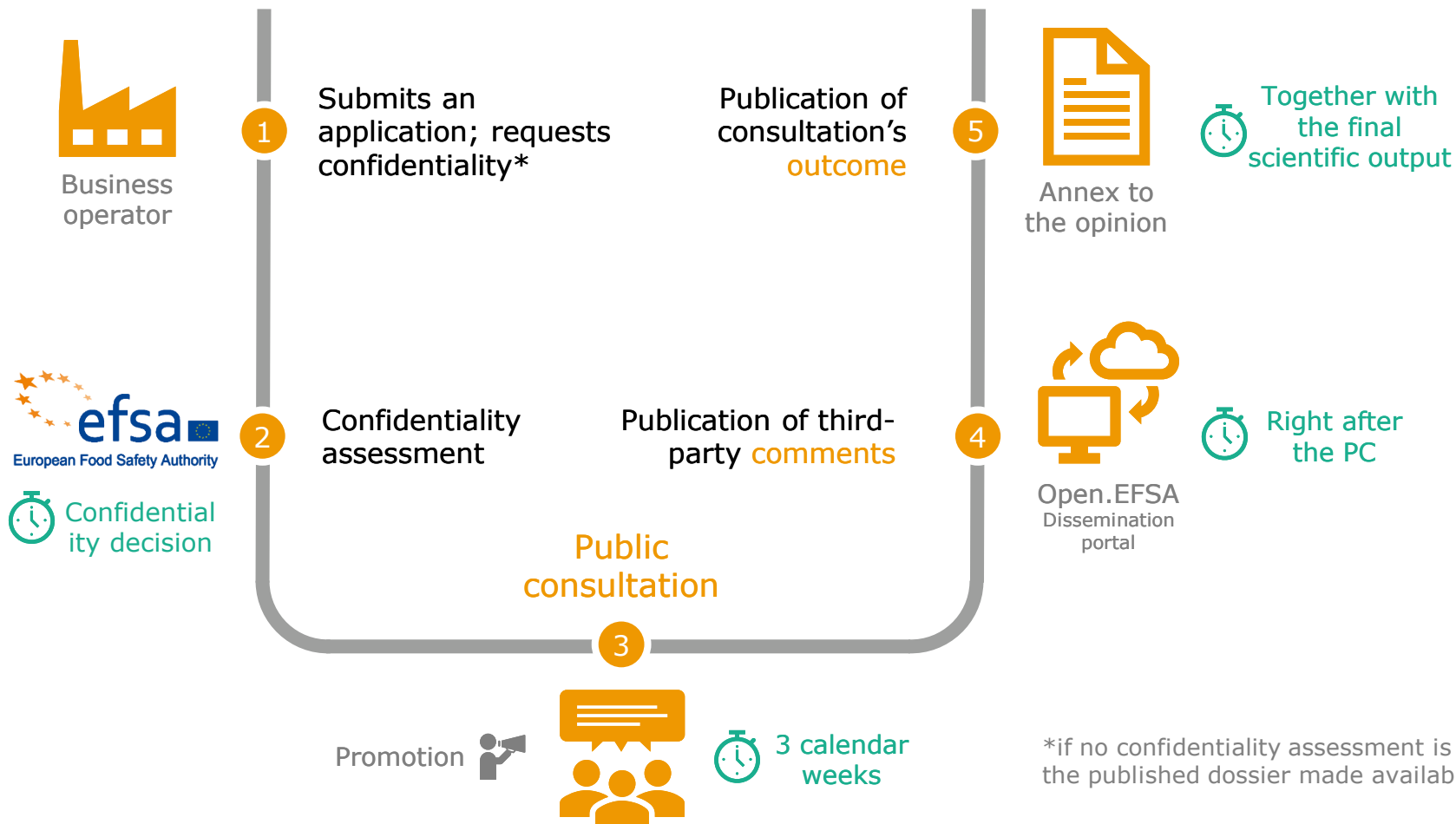


EFSA may review its decision in case output identifies foreseeable effects on human health, animal health or the environment (*Art 39c GFL*)

Public Consultation

- 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



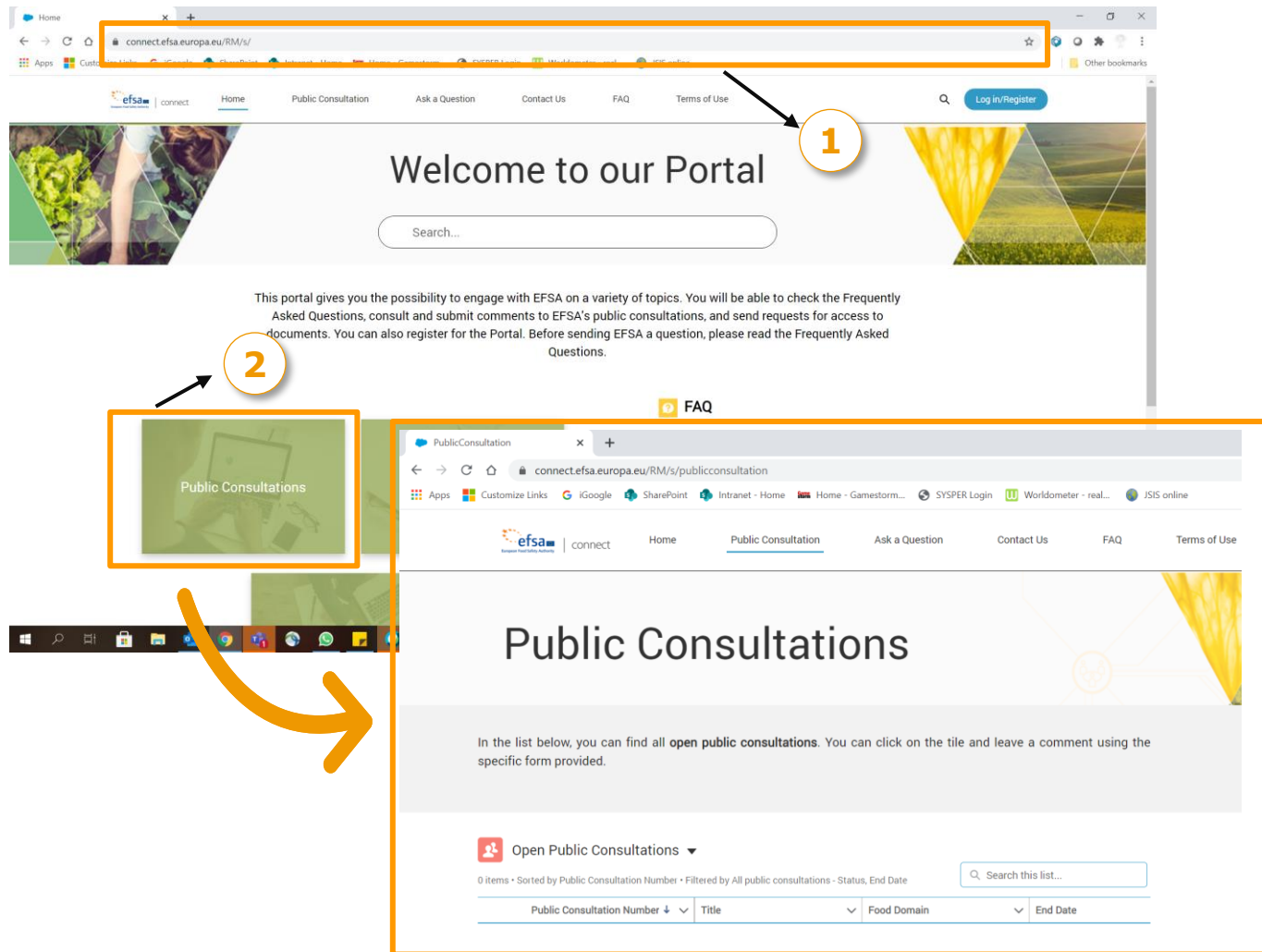
Aim: Collect new or additional evidence/data/information to assess an application

When: After the confidentiality assessment of the dossier

*if no confidentiality assessment is requested by the applicant, the consultation is run on the published dossier made available through the Open.EFSA portal. Step 2 is skipped.

Public interface: The Connect.EFSA community portal

Screen



How to access the portal

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

The portal is easily accessible from the EFSA website

Open EFSA - Publishing of comments

Open EFSA

Calendar

Closed consultations

Calendar Filters

Calendar of Public Consultations

Public Consultation Details

General info

Title	Draft Scientific Opinion on testing and the generation of comparative data evaluation studies
Responsible	Procedure Peer Review - Other topics
Consultative Type	FC on the draft scientific submission to be adopted
Created on	30/06/2017
Status	Closed

EFSA Files

File name	Size	Download
Draft PRS opinion consultation in the preparation for FC.pdf	140Kb	Download

Comments

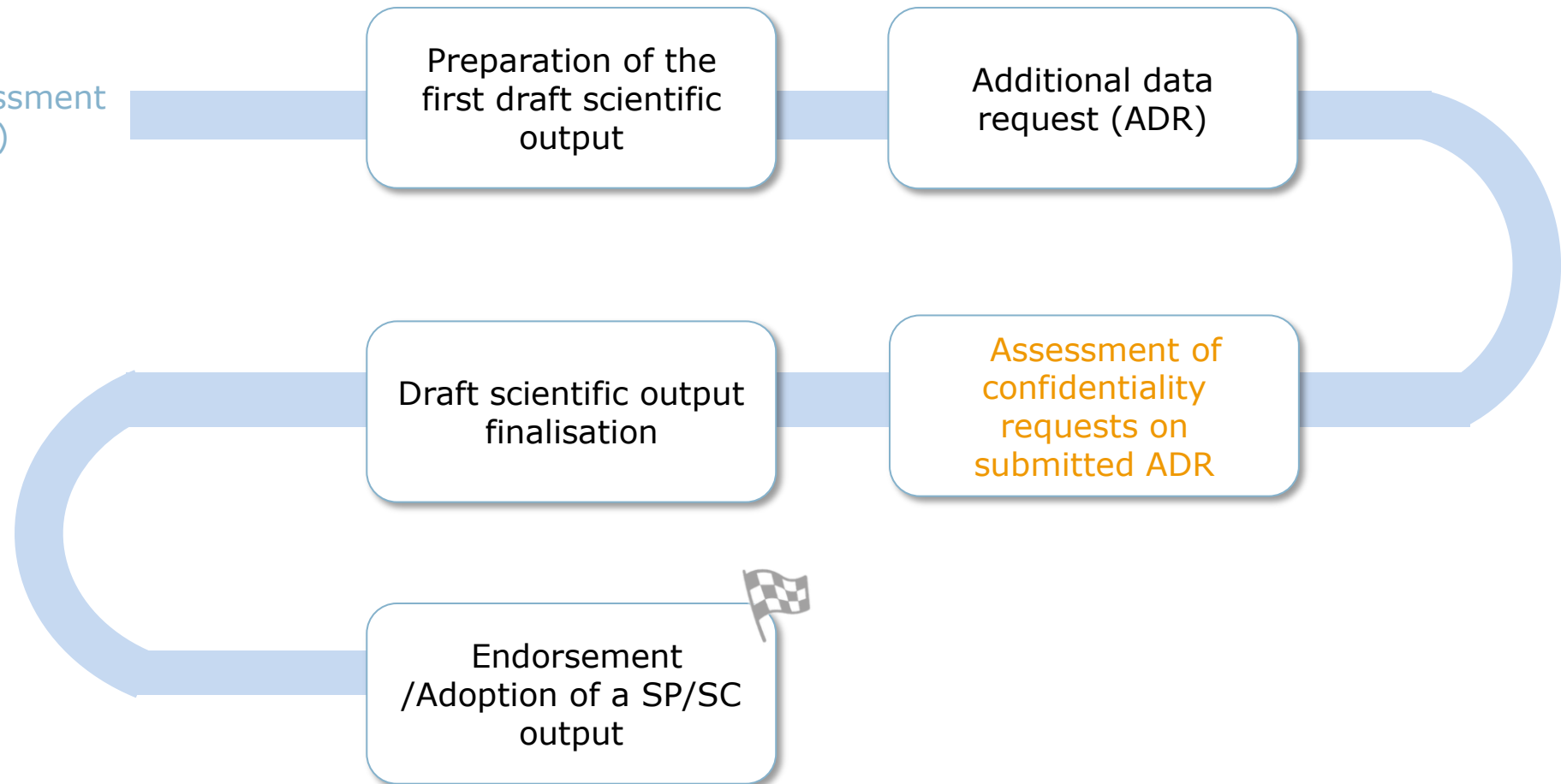
- Comment 1** Test open access documents (20/08/18)
Lines 1294-1307: Please perform proofreading on this section. It is complicated to read. Lines 1303-1307: Could it be considered to increase the maximal concentration of the test item if it is less than or equal to the maximum concentration of the test item as long as a high degree of toxicity is not observed? Lines 1316-1317: Is 100 µg the default maximum concentration? It is not mentioned in section 2.2.3.1. Consider if the flow of information is logical. Lines 1322-1323: The information about st... Expand
- Comment 2** Results of analysis (20/08/18) (20/08/18)
Line 1324: It is a bit difficult to know how to use this table. An explanation would improve readability.
- Reference** (20/08/18)
Line 1327: The reference table is quite relevant but only for use mentioned in the text. Please consider...

Public consultation details including all comments

Risk Assessment, Adoption and Publication

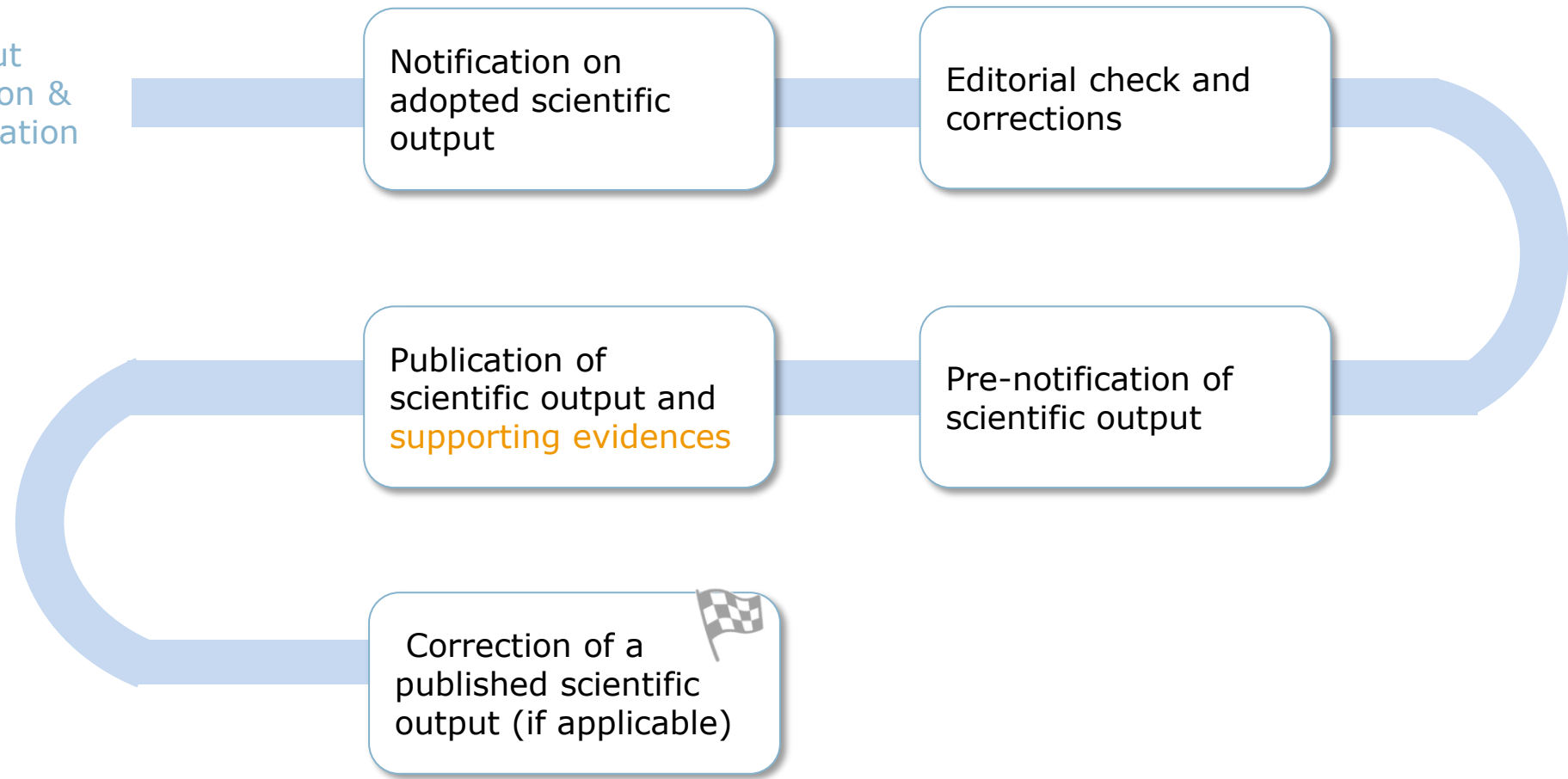


Risk Assessment (RA)



04

Output
Publication &
Dissemination



FAQs from Heath Claims applicants

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



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

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

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



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

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



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

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



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

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



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

Available at:

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



Legal documents:

- TR: [Regulation \(EU\) 2019/1381](#)
- General Food Law: [consolidated text of Regulation \(EC\) No 178/2002](#)
- [Consolidated version Regulation \(EC\) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation \(EC\) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives](#)
- Practical arrangements: <https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements>
- PAs on transparency and confidentiality: [Practical Arrangements concerning transparency and confidentiality](#)
- Q&A on Practical arrangements: <https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>

Guidance/training material:

- [Health Claims: guidance web section](#)
 - [General scientific guidance for stakeholders on health claim applications \(Revision 1\)](#)
 - [Scientific and technical guidance for the preparation and presentation of a health claim application\(revision 3\)](#)
- [Catalogue of services \(update 2021\)](#)
- [Administrative guidance for the processing of applications for regulated products \(update 2021\)](#)
- [Training programme on Transparency regulation](#)
- Toolkit page: <https://www.efsa.europa.eu/en/applications/toolkit>
- [User Guide - Notification of Studies \(NEW since 01 July\)](#)
- [User Guide - Pre-application ID \(NEW since 01 July\)](#)



Questions & answers session

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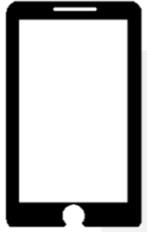
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Thank you for attending our webinar

In case we did not manage to answer all your questions, please feel free to re-submit them via **EFSA Ask a question** webform (EFSA.Connect at: <https://connect.efsa.europa.eu/RM/s/askefsa>)

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

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