13 September 2022

Update on implementation of the Transparency Regulation in the context of Directive 2001/18/EC Part C

Trusted science for safe food

efsa
European Food Safety Authority

Welcome and Introduction

Who we are

Presenters of this webinar:

- Pietro Piffanelli
- Gunda Kriz

Q&A contributors:

- Simone Gabbi
- Gunda Kriz
- Pietro Piffanelli
- Francesca Volpi
- Claudia Parisi
- Alexios Zormpas
- Alexandru-Dan Anastasiu
- Alexandre Huchelmann
- Estera Cretu
- Dominic Turnbull
- Claudia Baciu

Webinar moderator:

- Simone Gabbi

Goals

- **To explain the implementation for GMO Part C** put in place by EFSA following the entry into force of the Transparency Regulation.
- **To provide an overview of** the pillars of the **Transparency Regulation and** the **new tools** available to business operators
- **To outline the risk assessment process to implement Directive 2001/18/EC**
- **To outline the confidentiality assessment under EFSA's responsibility relevant for Directive 2001/18/EC**
- **To address questions from Business Operators**

Out of scope

- **Clarifications about aspects of the authorization process** which have not been affected by the Transparency Regulation.
- **Renewal applications**
- **Confidentiality assessment by notified Member State**

Agenda

Time	Topic
11:00 – 11:05	Welcome and introduction
11:05 – 12:00	➢ Risk Assessment, Adoption and Publication ➢ Confidentiality Assessment of requests submitted with regard to GM Food and Feed notifications Art. 39C
12:00 – 12:30	Q&A session and Conclusions

Also of interest

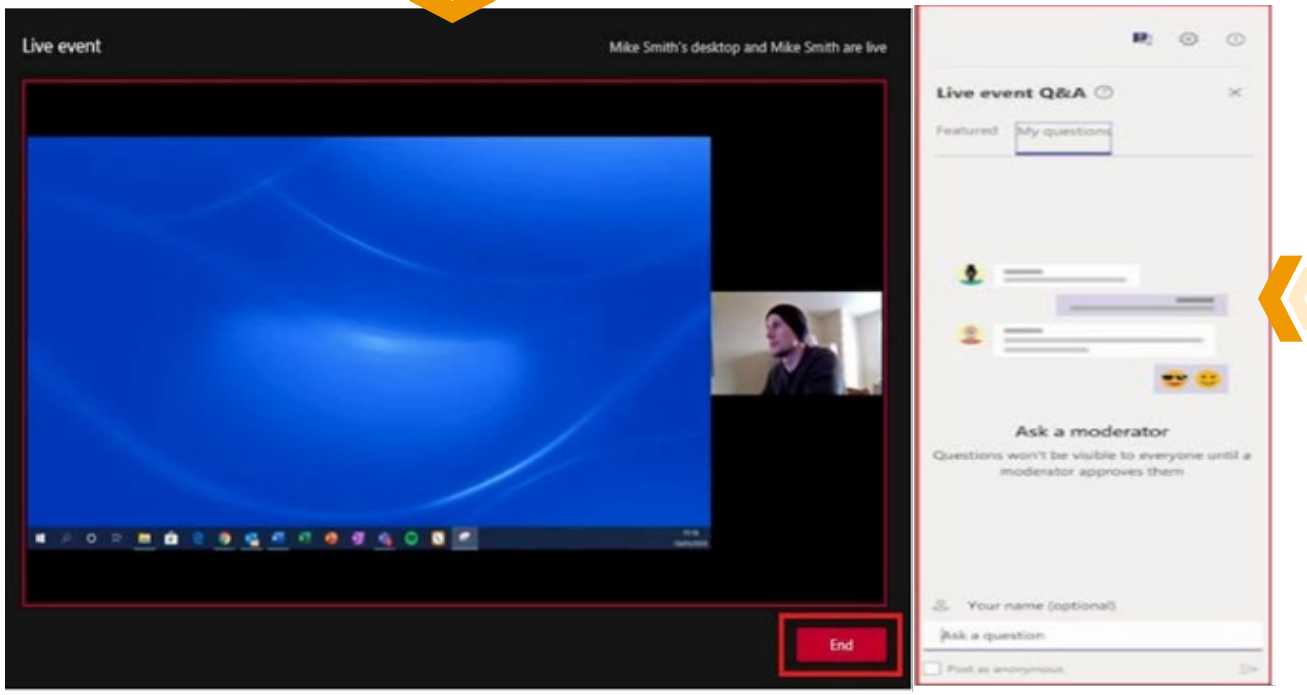
- Link to previous webinars - information not covered in today's webinar:
  - Webinar on application procedure for GMO
  - Webinar: Implementing the Transparency Regulation. Requirements, tools and services
  - Webinar: Confidentiality for applicants/business operators

Webinar guide for attendees

Some informations

- 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

Transparency Regulation applicable as of 27th March 2021

European Food Safety Authority

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

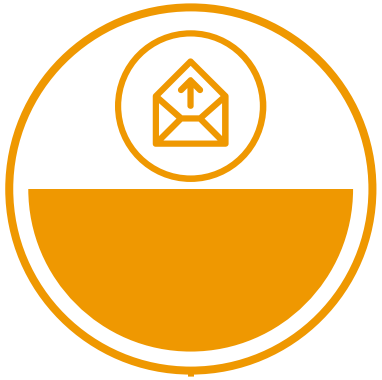
Applicable For - New dossiers/applications submitted on or after 27th March 2021

Click here to access the Factsheet: "A Modern and Sustainable Food Law in the EU"

TOOLS available to Business Operators

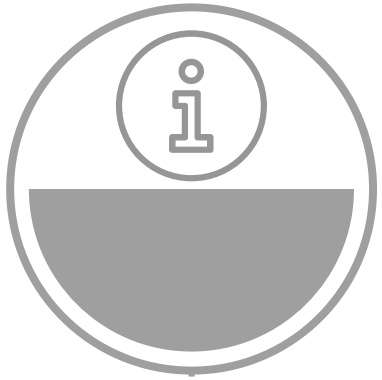
Connect EFSA

- ✓ Notification of Studies (NoS)
- ✓ Pre-submission Advice (PSA)
- ✓ AskEFSA
- ✓ Public Access to Document
- ✓ Targeted MS consultation
- ✓ Public consultation



E-Submission Food Chain

- ✓ Dossier eSubmission
- ✓ Request for Information (RFI)
- ✓ Additional Data Request (ADR)
- ✓ Follow-up lifecycle

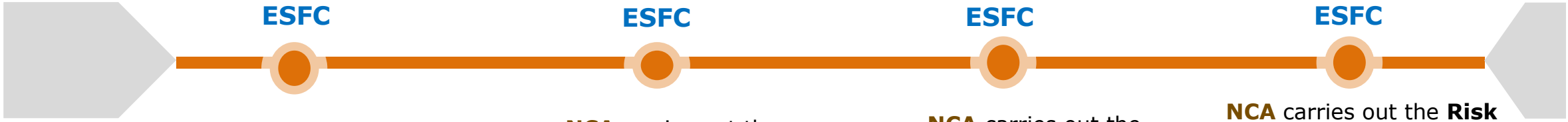


Open EFSA

- ✓ Monitoring of Risk Assessment workflow
- ✓ Dissemination portal
- ✓ Proactive disclosure of non-confidential information

Risk assessment of GMO Part C notifications

GMO Part C Dossier Intake: Business Operator to National Competent Authority [NCA]



Business Operator submits to **National Competent Authority (NCA)** the **GMO Part C Notification consisting of the Dossier** and any **Confidentiality Requests** of specific sections of the dossier [e.g. studies, data]
EC is informed

NCA carries out the **Completeness and NoS Checks** of the submitted GMO Part C dossier and sends **Request for Information (RFI)** to **Business Operator**

NCA carries out the **Confidentiality Assessment** of the Confidentiality Requests relating to the submitted GMO Part C dossier and to the Missing Information (MI) received by **Business Operator** following the RFI.

NCA may request **Business Operator** to provide clarifications on the submitted set of Confidentiality Requests

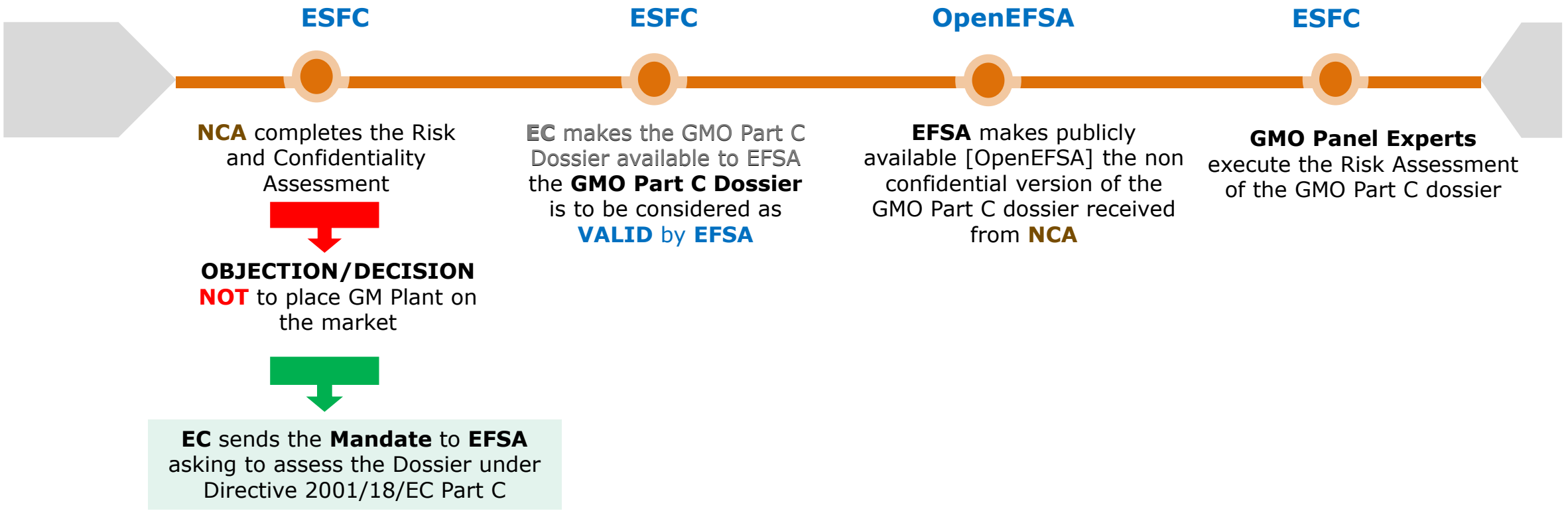
NCA carries out the **Risk Assessment** of the notified GMO Part C Dossier

NO OBJECTION
NCA proceeds with authorisation

EFSA is NOT called upon by NCA

Commission Notice on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms

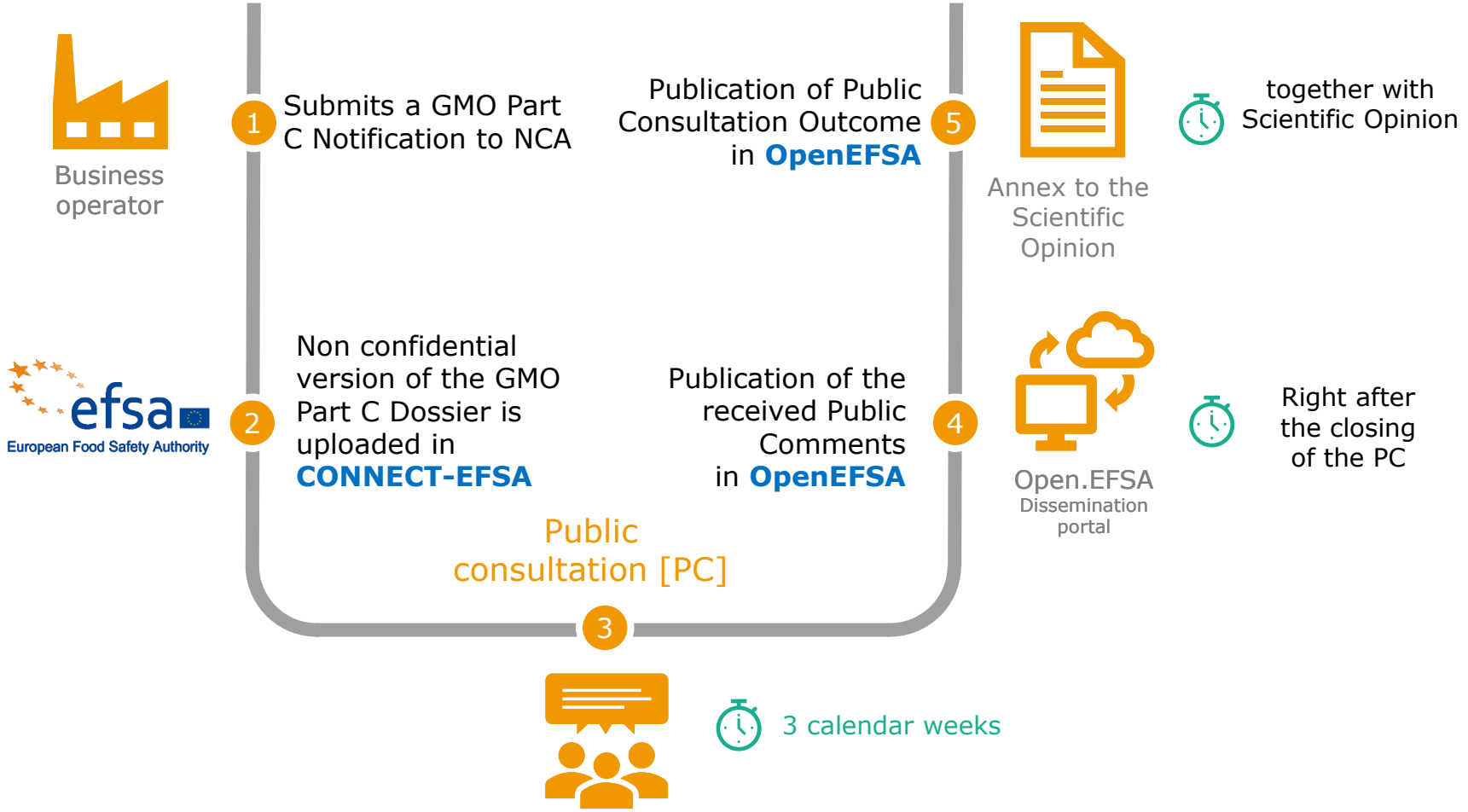
GMO Part C Dossier Intake: EC to EFSA



Commission Notice on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms

Risk Assessment, Public Consultation, Adoption and Publication

Public Consultation [PC] of the GMO Part C Dossier



Aim:
Collect new or additional evidence/data/information to assess the GMO Part C dossier

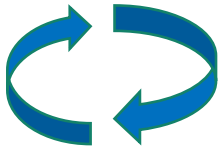
When:
After the confidentiality assessment of the dossier by the MS

GFL Regulation (Regulation (EC) No 178/2002), Article 32c(2)

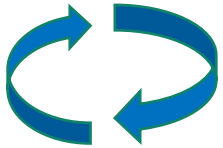
GMO Part C Dossier: Risk Assessment by the GMO Panel 1

GMO Part C VALID dossier

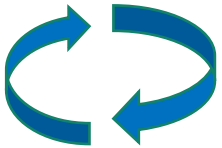
EFSA Scientific Officers and Contractors
pre-Risk Assessment [e.g., GLP/scientific compliance of the submitted Tox. studies]



GMO Panel Experts
Risk Assessment of the submitted studies, data, information
MC-WG meeting/s
CompERA WG meeting/s
FF-WG meeting/s



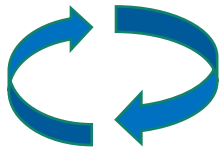
GMO Panel Experts
identify "gaps" [if any] in the submitted studies data, information
[WG Meetings]



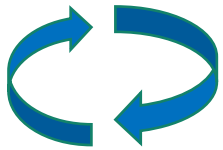
Administrative guidance for the processing of applications for regulated products [update 2021]

GMO Part C Dossier: Risk Assessment by the GMO Panel 2

EFSA [NIF Unit]
Scientific Officers
Additional Data Request delivery to the Business Operator

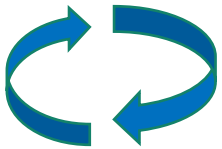


Additional Information from the Business Operator to EFSA [NIF Unit]



NCA assesses Confidentiality Requests submitted by the Business Operator

GMO Panel Experts
Risk Assessment of the Additional Information [WG Meetings]



GMO Part C Notifications Risk Assessment Workflow @EFSA

1 Mandate & Dossier intake

- Mandate and dossier **receipt from EC**
- **Publication** of the public version of the GMO Part C dossier
- **Public Consultation**

2 Risk Assessment

- **Risk Assessment** by the GMO Panel Experts
- **Additional Data Request** (ADR), if needed
- **Adoption** of the Scientific Opinion by the GMO Panel

3 Output publication & dissemination

- **Notification** of the adopted Scientific Opinion to **Business Operator**, NCA, EC, JRC[EURL]
- **Publication** of the Scientific Opinion

IDENTIFIED foreseeable **effect on human health, animal health or the environment** which concerns items that were granted **Confidential Status by NCA**

Art. 39c REVIEW PROCESS of concerned CONFIDENTIALITY REQUESTS

EFSA Confidentiality assessment of GMO Part C notifications

Confidentiality assessment – summary

Measures have been put in place to ensure the efficient collaboration and consistent approach between the NCA, EC and EFSA:

- NCA applies EFSA's PAs concerning Transparency and Confidentiality in confidentiality decision making
- IT solution to provide enhanced workflow between NCA/EC and EFSA - notification arrives at EFSA with the confidentiality assessment already having been performed by NCA
- Article 39c review is handled internally in EFSA's confidentiality assessment workflow

Transparency Regulation (TR) principles 1

Proactive Disclosure

Art. 28(4) of Directive 2001/18/EC
Proactive disclosure e.g. for:

The notification, relevant supporting information and any supplementary information supplied by the notifier with the exception of information for which confidential treatment has been granted

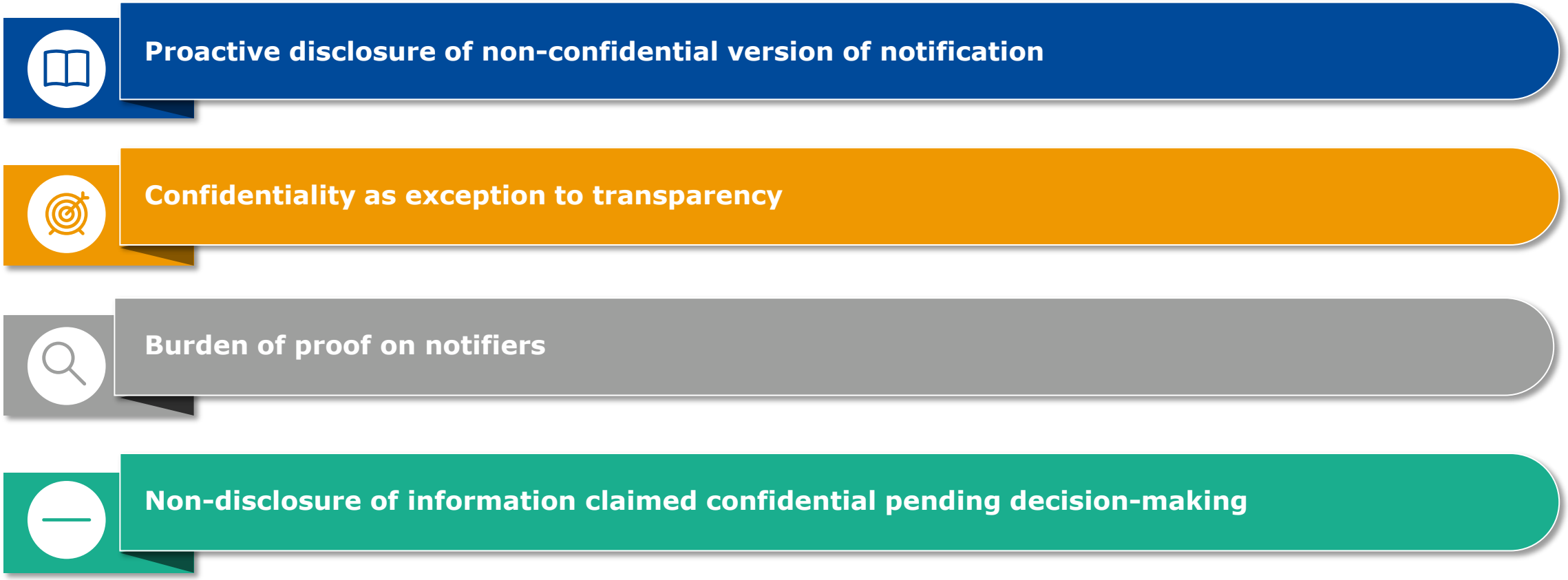
Confidentiality

Art. 25 of Directive 2001/18/EC
Confidential status:

Only for items included in the closed positive list of the Annex to the Practical Arrangements concerning transparency and confidentiality

Only if substantive and procedural requirements are met

Transparency Regulation (TR) principles 2



Procedural requirements

- **Submission through ESFC for notifications or Portalino for follow up to inconclusive opinions**
- 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)
- **Submitting clarifications within the deadline** set by EFSA (via ESFC or email)
- **Modifications of submitted requests not allowed**, unless requested by EFSA

- **No fees**

Procedural requirements – closed positive list for Directive 2011/18/EC – Article 25(3)

Confidentiality requests only on items in closed positive list

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

DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event

Breeding patterns and strategies

Processing of Personal Data

Legal Ground: GFL Art 39e(1)

Always disclosed:

- **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(2 & 3)

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

Substantive requirements

Identify

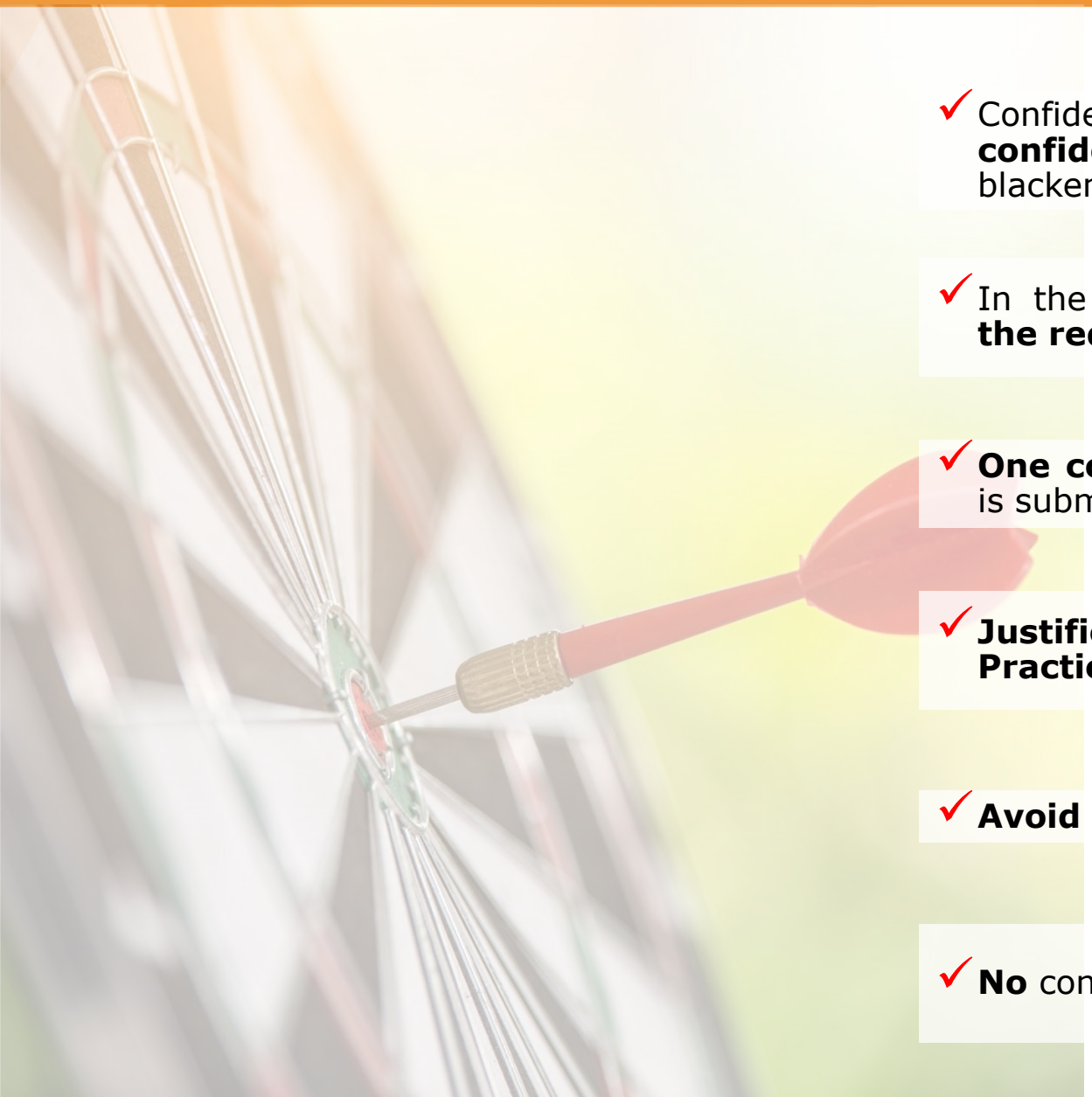
- **Identifying clearly the information** claimed confidential, with references
- **Indicating the legal basis** (grounds) – closed positive list

Explain

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)

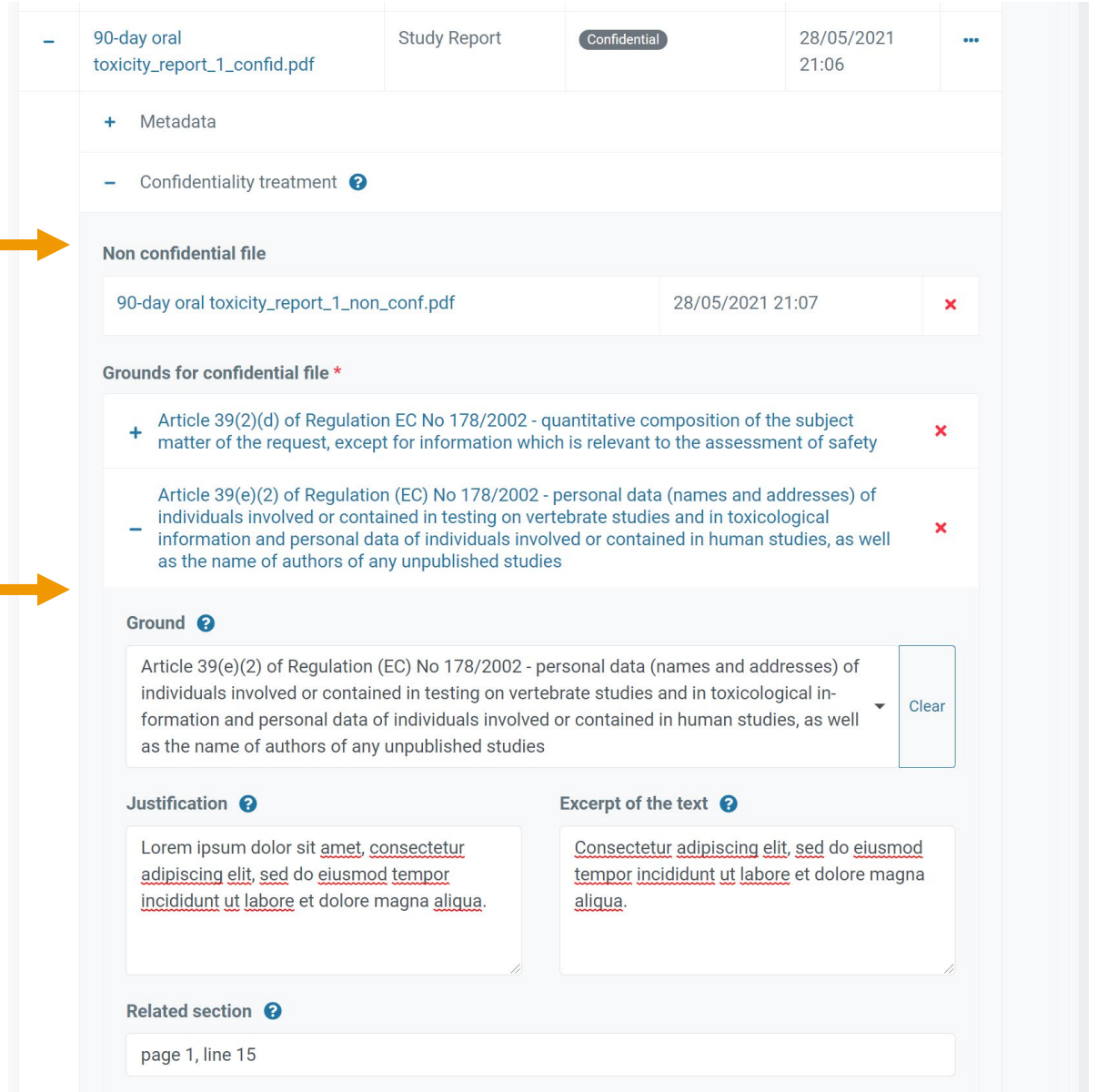
Practical Tips



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

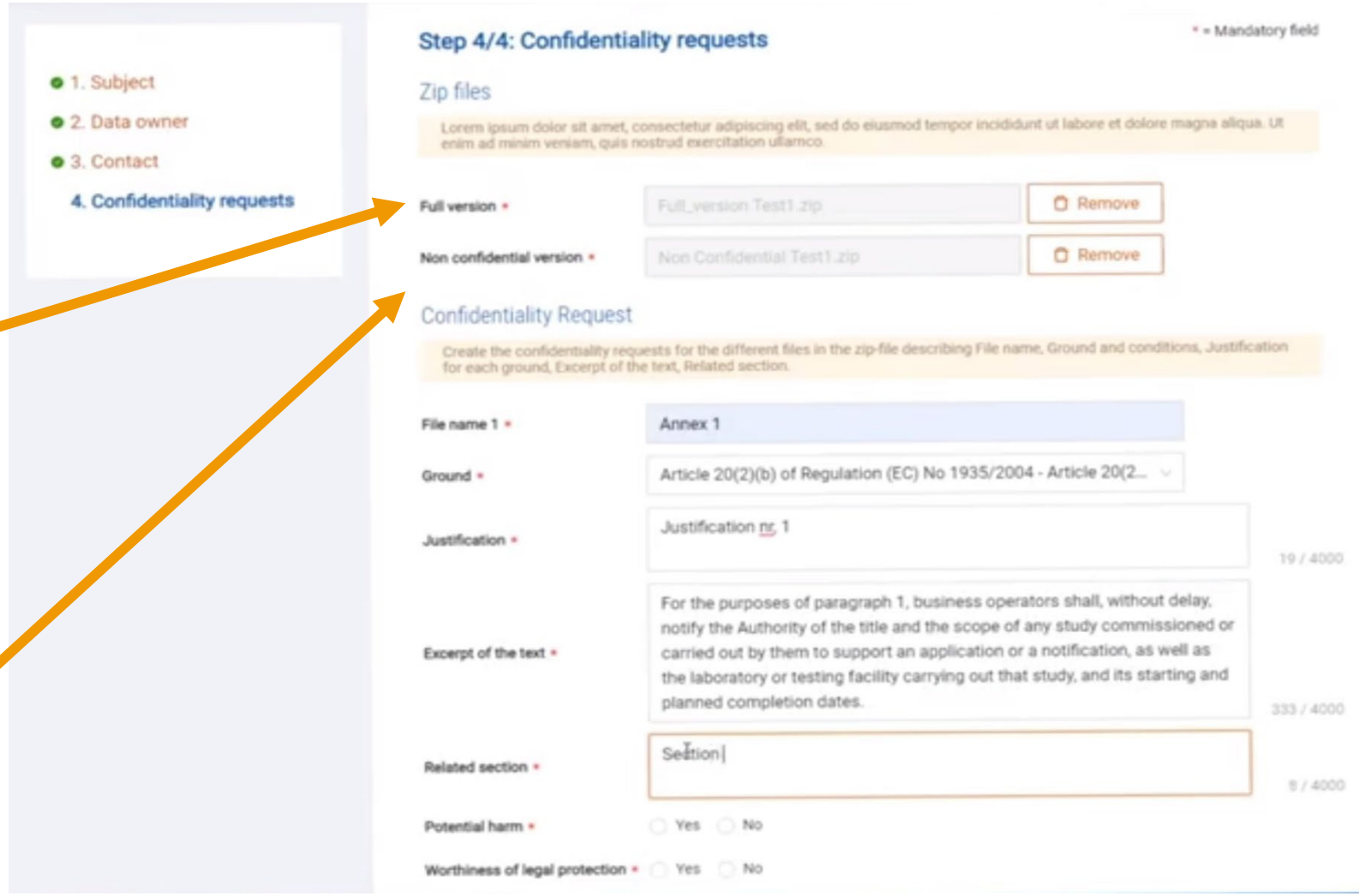
ESFC - Building a Confidentiality Request

- 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



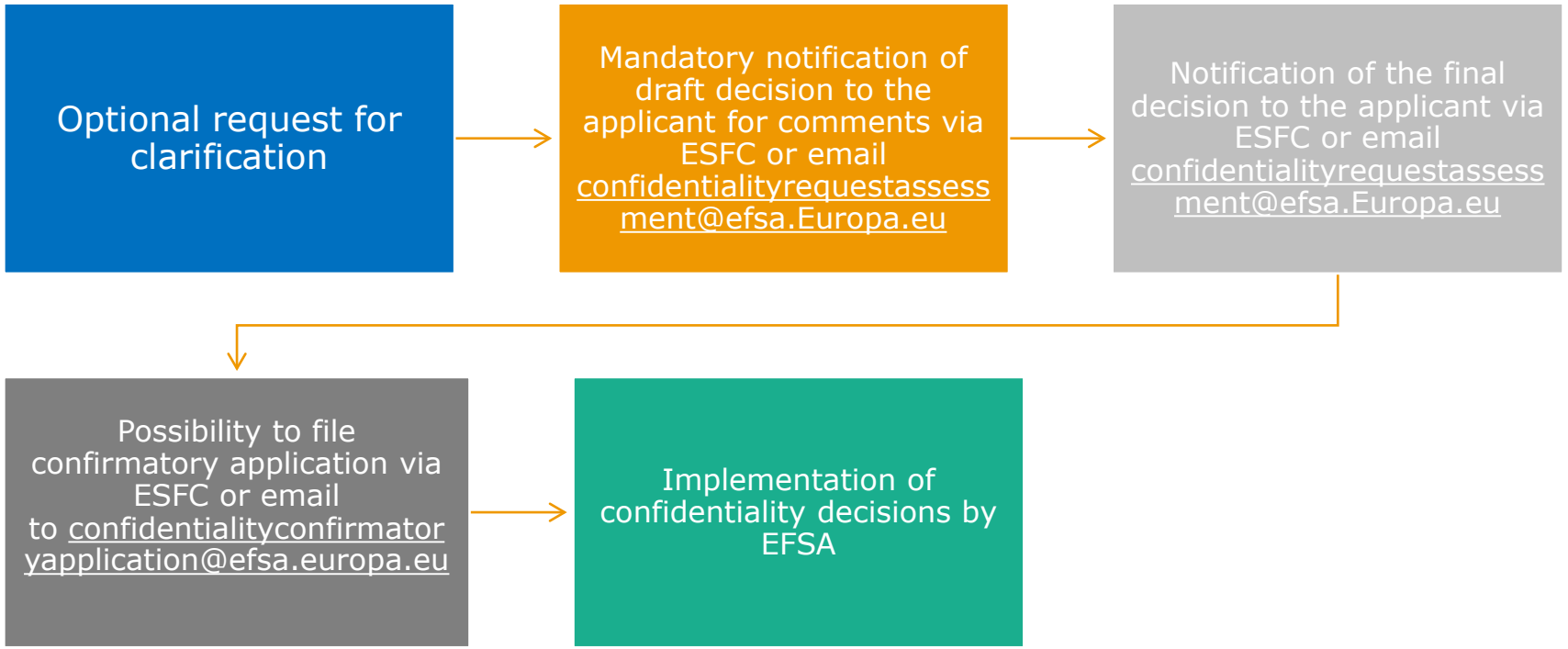
Portalino – building confidentiality requests (1)

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

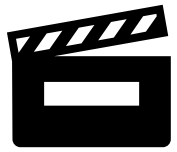


Procedural steps EFSA confidentiality assessment Article 39c of Regulation EC No 178/2002

TRIGGER: Scientific Opinion of GMO Panel identifies foreseeable effects on human health, animal health or the environment regarding items granted confidential status by NCA



"Sanitisation" and dissemination



- Implementation of EFSA's confidentiality decision by EFSA without delay
  - Information accepted as confidential is kept blackened
  - Information whose confidentiality is rejected is unblackened and published
  - Submission of a confirmatory application/Order from the General Court puts on hold the implementation

- Dissemination of information on OpenEFSA
  - Replacement of document sanitised by NCA

Contact point for Transparency and Confidentiality Team

confidentialityrequestassessment@efsa.Europa.eu for exchanges on assessment of specific files

Useful information

Legal documents:

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003R1829
- Commission Notice on the submission of notifications under Article 13 and 17 of Directive 2001/18/EC
- PAs on transparency and confidentiality: Practical Arrangements concerning transparency and confidentiality
- PA on pre-submission phase and public consultations;https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf
- Q&A on Practical arrangements: https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

Guidance/training material:

GMO guidance web section:

- Administrative guidance for the preparation of applications on genetically modified plants;
- Administrative guidance for the preparation of renewal applications on genetically modified food and feed
- Catalogue of services (update 2021)

Administrative guidance for the processing of applications for regulated products (update 2021)

Training programme on Transparency Regulation

Toolkit page (ESFC and Portalino): https://www.efsa.europa.eu/en/applications/toolkit

User Guide - Notification of Studies (updated on 4 Feb 2022)
User Guide - Pre-application ID (updated on 4 Feb 2022)

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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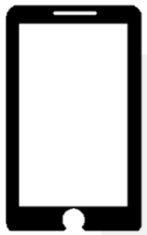

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