1 December 2022

Webinar ABP applications

Webinar on animal by-products applications

Trusted science for safe food

efsa
European Food Safety Authority

Welcome and introduction

Who we are

Presenters of this webinar

Frank Verdonck
Angel Ortiz-Pelaez
Laura Paltrinieri
Vasileios Migkos
Avelino Álvarez-Ordóñez

Q&A contributors

Costanza Casiraghi
Pietro Stella
Angel Ortiz-Pelaez

Webinar moderator

Ernesto Liebana

Goals

What is the goal of this webinar? The webinar will outline the procedures concerning the implementation of the transparency regulation, the submission of applications, the confidentiality assessment and content sanitization in place at EFSA.

It will also provide practical guidance based on lessons-learnt and principles to consider when submitting applications on alternative methods for the processing of animal by-products (ABP) or derived products.

Out of scope: Regulatory and risk management aspects of animal by-products will not be addressed.

Webinar guide for attendees

- You are **automatically connected** to the audio broadcast. One-way oral communication (listen only mode).
- You can submit questions throughout the webinar via the **dedicated Q&A chat box** 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 at the end of the webinar, will be addressed via email after the webinar.
- The webinar **is being recorded.**

Tentative agenda

Time	Topic	Speaker
14:00 – 14:10	**Webinar outline and agenda**	**BIOHAW:** **Ernesto Liebana (Chair)**
14:10 – 14:35	**Introduction:** The role of EFSA in the ABP area. Applications and mandates. Legislation, EFSA Statement. Transparency regulation: application Q&A	**BIOHAW:** **Frank Verdonck** **Angel Ortiz-Pelaez**
14:35 – 15:00	**Life cycle of the application until validation:** Pre-submission activities and submission of the application: tools to be used and resources for the applicants on how to use them EFSA guidance documents Completeness check and timeline from submission to validation Q&A	**FDP:** **Laura Paltrinieri**
15:00 – 15:25	**Life cycle of the application after validation:** Confidentiality (Legal) Working group, BIOHAZ Panel Timeline Public consultation studies/dossier Adoption, publication Q&A	**LEGAL/BIOHAW:** **Vasileios Migkos** **Angel Ortiz-Pelaez**
15:25 - 15:50	**Standards and scientific issues of the assessment:** Hazard identification Risk reduction Standards Q&A	**BIOHAZ Panel Member:** **Avelino Álvarez-Ordóñez**
15:50 – 16:00 **16:00**	**Q&A** **End of the info session**	**Chair**

1 December 2022

Webinar ABP applications

1. Introduction: EFSA role

Frank Verdonck

Biological Hazards & Animal Health and Welfare Unit (BIOHAW)

Angel Ortiz-Pelaez

BIOHAW

Trusted science for safe food

efsa

European Food Safety Authority

Contents

- Transparency Regulation
- EFSA remit in the ABP area
- Legislation. EFSA statement.
- Format ABP applications

Transparency Regulation 27 March 2021

- **Regulation (EU) 2019/1381** on the transparency and sustainability of the EU risk assessment in the food chain amends the General Food Law (Regulation 178/2002) and other related pieces of legislation

- Transparency: better access to scientific studies
- More reliable independent studies
- Better governance
- Effective risk communications

New dossier/applications submitted on or after 27 March 2021

Transparency Regulation – Practical Arrangements

1. Public Access to Documents (Reg. 178/2002, Art. 41)

Adopted in March 2020 by MB
Published on EFSA website

2. Pre-submission advice and Public Consultation (Reg. 178/2002, Art. 32a, b, c)

3. Transparency and Confidentiality Assessment by EFSA (Reg. 178/2002, Art. 38 and 39d(5)

4. Consistency of MS confidentiality assessments (PPPs) (Reg. 1107/2009, Art. 7 and 16)

Adopted in December 2020 by ED
Published on EFSA website

"Questions and Answers on EFSA Practical Arrangements" has been published on EFSA's website (here).

Transparency Regulation – Application workflow

Business operators

EFSA staff

Business operator notifies studies (NOS) via Connect EFSA

Business operator can request pre-submission advice

Business operator submits the dossier to the competent authority of a MS

Competent authority MS sends the application to EFSA
EFSA asks applicant to submit application via Portalino

EFSA performs completeness/suitability check of the application +
EFSA performs notification of studies (NOS) check

EFSA validates the application

Transparency Regulation – Application workflow

EFSA initiates confidentiality decision

EFSA publishes non confidential valid dossier + summary Pre-submission advice

EFSA issues a Confidentiality Decision of the valid dossier and sanitises accordingly the relevant documents

EFSA launches Public Consultation of the valid dossier

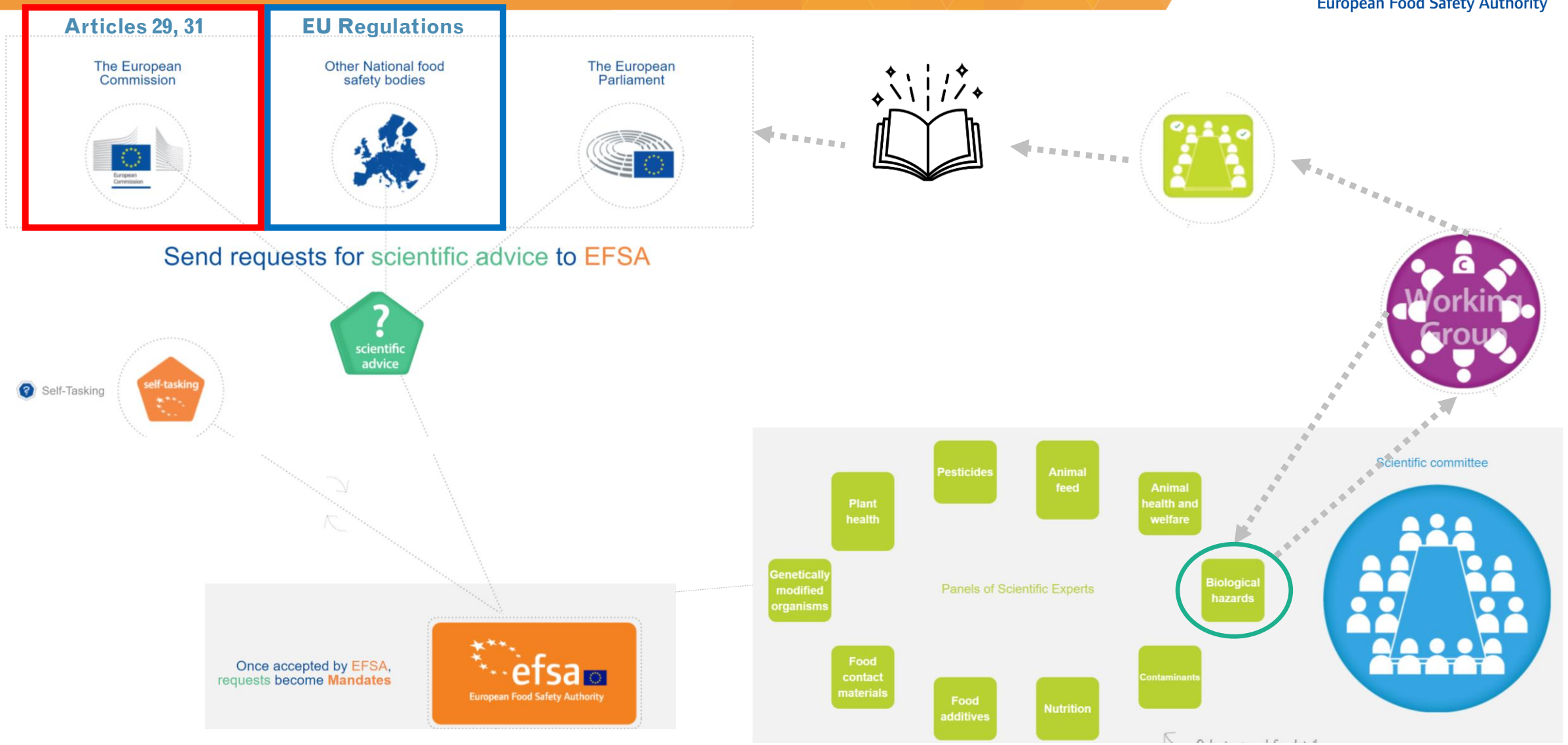
EFSA publishes comments received from Public consultation

EFSA performs thorough risk assessment

EFSA Panels adopt scientific output

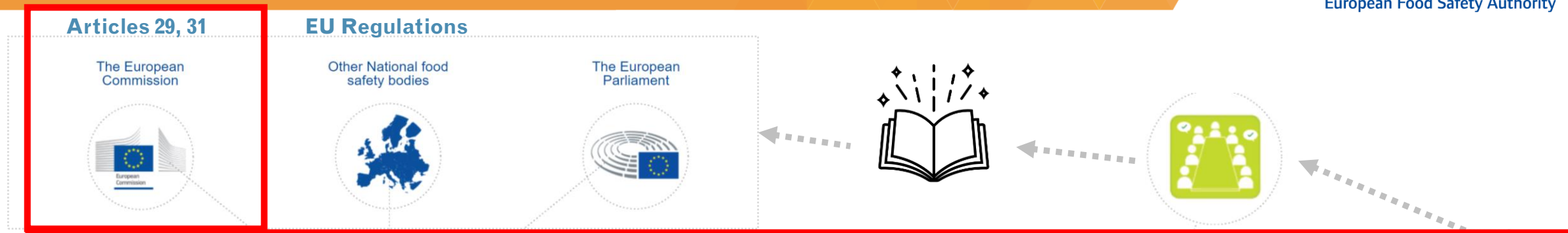
EFSA publishes scientific output + evidences + assessment of comments from Public consultation

EFSA remit



https://multimedia.efsa.europa.eu/fieldtofork/index.htm

EFSA remit



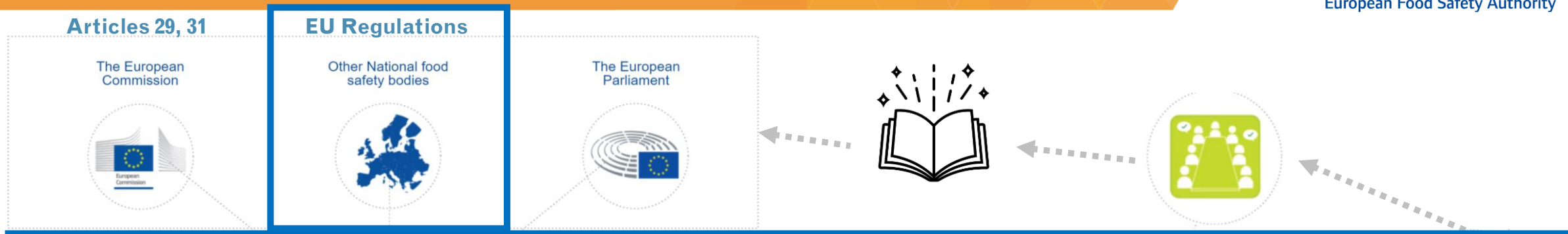
Articles 29, 31 Regulation (EC) 178/2002 :

Generic mandates. Multiple topics. The EC: requestor.

- Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers (2021)
- Potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminant farmed animals (2020)
- Updated quantitative risk assessment (QRA) of the BSE risk posed by processed animal protein (PAP) (2018)
- Scientific Opinion on the capacity of oleochemical processes to minimise possible risks linked to TSE in Category 1 animal by-products (2011)

https://multimedia.efsa.europa.eu/fieldtofork/index.htm

EFSA remit



Article 20 Regulation (EC) 1069/2009 :

Evaluation of alternative methods for use and disposal

- Application for a new alternative biodiesel process for rendered fat of Cat. 1 (BDI-RepCat Process, AT) (2021)
- An alternative method for production of biodiesel from processed fats derived from Cat. 1, 2 and 3 ABP (College Proteins) (2020)
- Evaluation of Alternative Methods of Tunnel Composting (submitted by the European Composting Network) (2020)
- New alternative biodiesel production process for rendered fat of Cat 1 (BDI-RepCat process, AT) (2017)
- Scientific Opinion on an alternative method for the hygienic treatment of bovine colostrum through a series of filtration steps (2015)

https://multimedia.efsa.europa.eu/fieldtofork/index.htm

ABP legislation

Regulation (EC) 1069/2009. The ABP Regulation

- Public health and animal health rules for animal by-products and derived products.
- Rules…to prevent and minimize risks to human and animal health, and to ensure the food and feed chain is kept safe.
- Driven by the BSE epidemic and TSE legislation: Com. Reg (EC) 999/2001

Commission Regulation (EU) 142/2011. Implementing regulation

- Standard/Alternative processing methods
- Disposal, use, trade, import/export, official controls, certification, derogations

EFSA remit: legal mandate

Regulation (EC) 1069/2009 Article 20 (ABP Regulation)

2. 4. EC or interested party to competent authority of the member state

2. 3. Within two months, the competent authority assesses compliance with standard format and send to EFSA and informs the EC

- ✓ EFSA's Statement on technical assistance on the format for applications for new alternative methods for animal by-products (2010). EFSA Journal 2010; 8(7):1680

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.1680

- ✓ Chapter II of Annex VII **Com. Reg. (EU) 142/21011.** Standard format for applications for alternative methods


European Food Safety Authority

EFSA Journal 2010; 8(7):1680

SCIENTIFIC OPINION

Statement on technical assistance on the format for applications for new alternative methods for animal by-products[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABP applications: format

Chapter II of Annex VII **Com. Reg. (EU) No 142/2011:** standard format for applications for alternative methods

Content of Applications: CONFIDENTIALITY?

a) **description of the process:** entire process. Material flow including end-products, co-products and by-products. Critical parameters (e.g., temperature, pressure, exposure time, pH, particle size)

b) **material to be treated:** ABP category, physical status (e.g., water content, particle size), pre-treatment. Materials other than ABP.

Impact, if any, on the level of risk reduction due to interaction with ABP.

a) **hazard identification:** identify and characterize biological hazards for human and animal health represented by the categories of ABP

b) **level of risk reduction:** most resistant biological hazards reduced at least to the degree achieved by method/processing standard approved. Valid direct measurements / modelling or comparisons

ABP applications: format

Content of Applications:

e) HACCP plan: flow diagram,

- Critical limits and critical parameters (e.g., temperature, pressure, time, microbiological threshold values).
- Key technical parameters specifically related to the equipment used, monitoring (either continuously or intermittently) and recorded.
- It should reflect normal and abnormal/emergency operating conditions and specify possible corrective actions to be applied

e) Risk associated with interdependent processes:

- Transport and storage of end-products and by-products as well as safe disposal of by-products.

f) Risk associated with the intended use of the products:

- Additional risks (human, animal, environment)

e) Documentary evidence: flow diagram, evidence (references)

f) Contact address: name, full address, email, fax/telephone

Themes EFSA ABP RA

Safety of ABP:

- manure (2005, 2010)
- tallow (2005, 2011)
- hides and skins (2006, 2011)
- blood (2007)
- hatchery waste (2011, 2015)

Safety of derived products (TSE):

- MBM (2003, 2007, 2008)
- PAP (2007, 2011, 2018)
- Hydrolyzed proteins (2000)
- Gelatine (2000, 2005, 2006)
- Collagen (2005)
- Collagen/gelatine (2020)
- DCP-TCP (2000, 2003)
- Glycerin (2010),
- Biogas/compost (2005, 2007, 2009)
- Organic fertilizers (2001, 2004)
- Petfood (hatchery waste) (2011)
- Colostrum (feed) (2015)
- Fishmeal (2007, 2011)

Themes EFSA ABP RA

Methods for safe disposal:

- Dead animals (2008, 2011, 2012a. 2012b)
- Carcasses (2008,2011)
- Cat 1 (2003)
- Cat 1-2 (2004)
- Cat 2-3 (2009)
- Cat 3 (2018)
- Fish waste (2011)

Processing methods for:

- Biofuel/biodiesel (2004, 2006 2010, 2017, 2020, 2021)
- Compost, fertilizers (2011a, 2011b, 2020, 2021)
- Renewable fuels (2015)
- Feed, petfood (2011, 2015, 2018)

Sources

ABP topic page in EFSA website:
https://www.efsa.europa.eu/it/topics/animal-by-products

ABP applications page in EFSA website.
https://www.efsa.europa.eu/it/applications/biologicalhazard

EFSA journal.
https://efsa.onlinelibrary.wiley.com/journal/18314732

Info mandates and applications: Open EFSA:
https://open.efsa.europa.eu/

European Food Safety Authority

Thank you

Questions?

2. Life cycle of the application until validation

Laura Paltrinieri

Front-Desk & Workforce Planning (FDP)

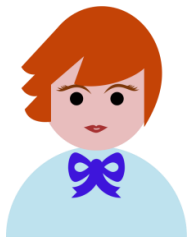
Content

- Pre-submission activities
- Submission of the Dossier (Portalino)
- Completeness check and timeline from submission to validation
- Information (Ask EFSA a Question)

Pre-submission activities:

- **General pre-submission advice**
- **Notification of Studies**

Registration Process



Sarah

Business Operator
Potential Applicant

John

Laboratories
Testing facilities

Martin

Third Parties

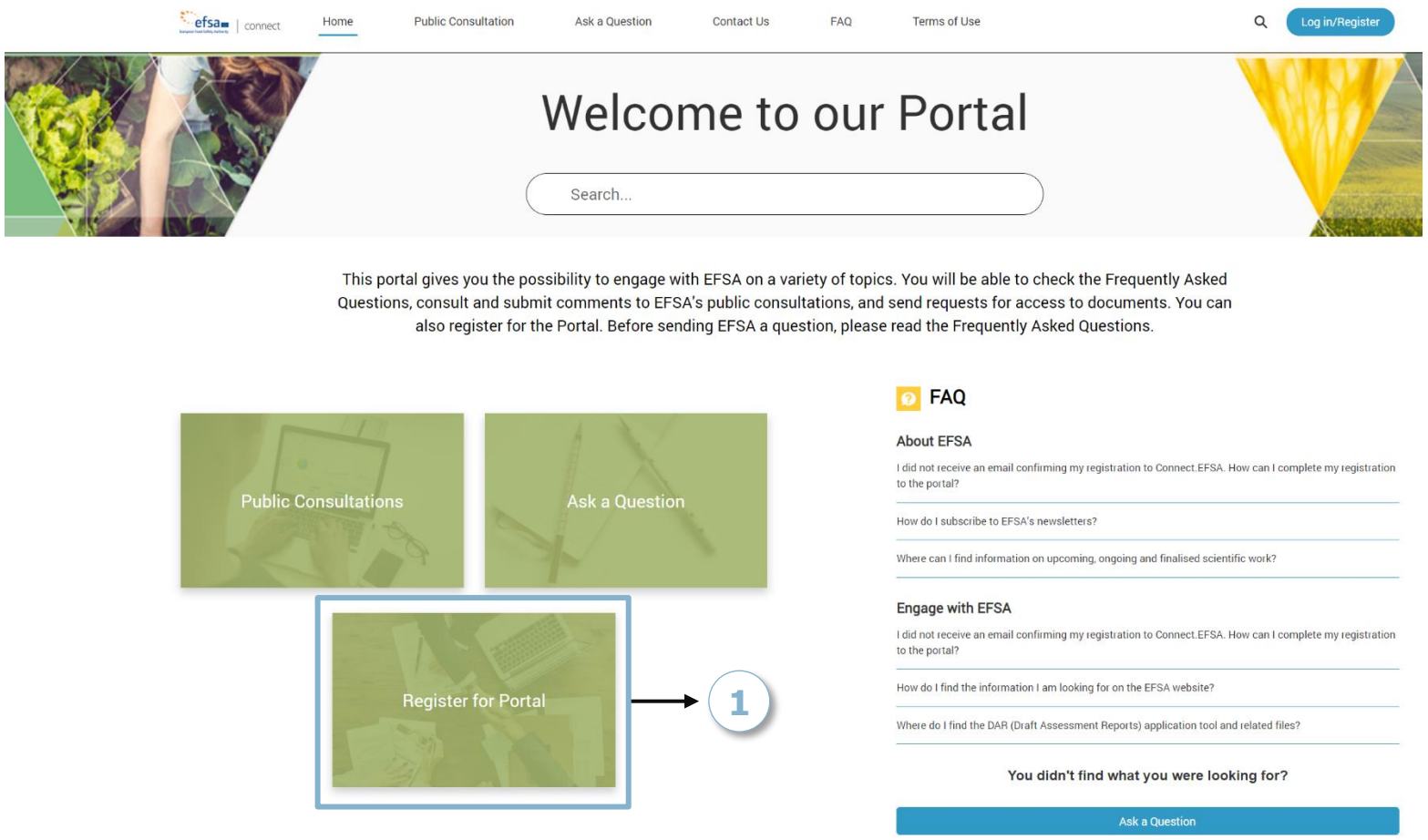
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

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

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

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

Connect.EFSA Portal - Account Registration



Sarah

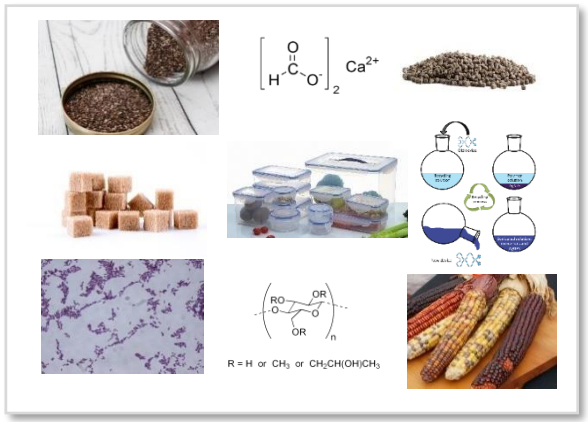
The potential applicant starts the registration in the portal.

The potential applicant must register as the entity he/she is representing (e.g., a company).

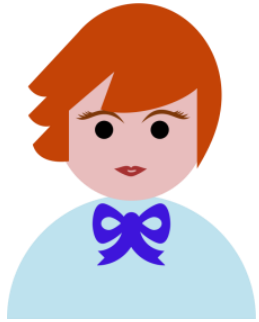
The account name will then be the entity (company) name

1 Click here to register

Pre-Application Identification



Subject
of the application



Sarah
Business Operator(s)

Intended Area

General Pre-Submission Advice

General pre-submission advice (GPSA)

Upon request of a potential applicant (GPSA is optional)

Filling in the dedicated 'GPSA form' in Connect.EFSA.
After having created a pre-application ID

Indication on the relevant requirements located in the applicable rules or guidance documents or guidelines to prepare an application

Anytime.
Preferably at least six months before submission

Frequently Asked Questions

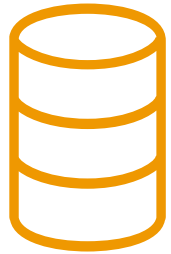
General Pre-Submission Advice

General Pre-Submission Advice

Sarah

The potential applicant gets the pre-application-ID

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



Pre-Submission Advice tool

General Pre-Submission Advice

EFSA provides advice

Step 3
Validation of application

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

Notification of Study

According to Article 2 of EFSA Practical Arrangements on pre-submission phase and public consultations[1] a study is defined as:

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

- Only new studies commissioned/started after March 27th 2021 must be notified;
- Studies need to be notified before the starting date;
- In case of delay of notification (i.e. after the starting date) a justification for delay should be provided.

[1] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

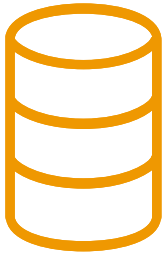
Notification of Studies for new application

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 (e.g., delay notification)

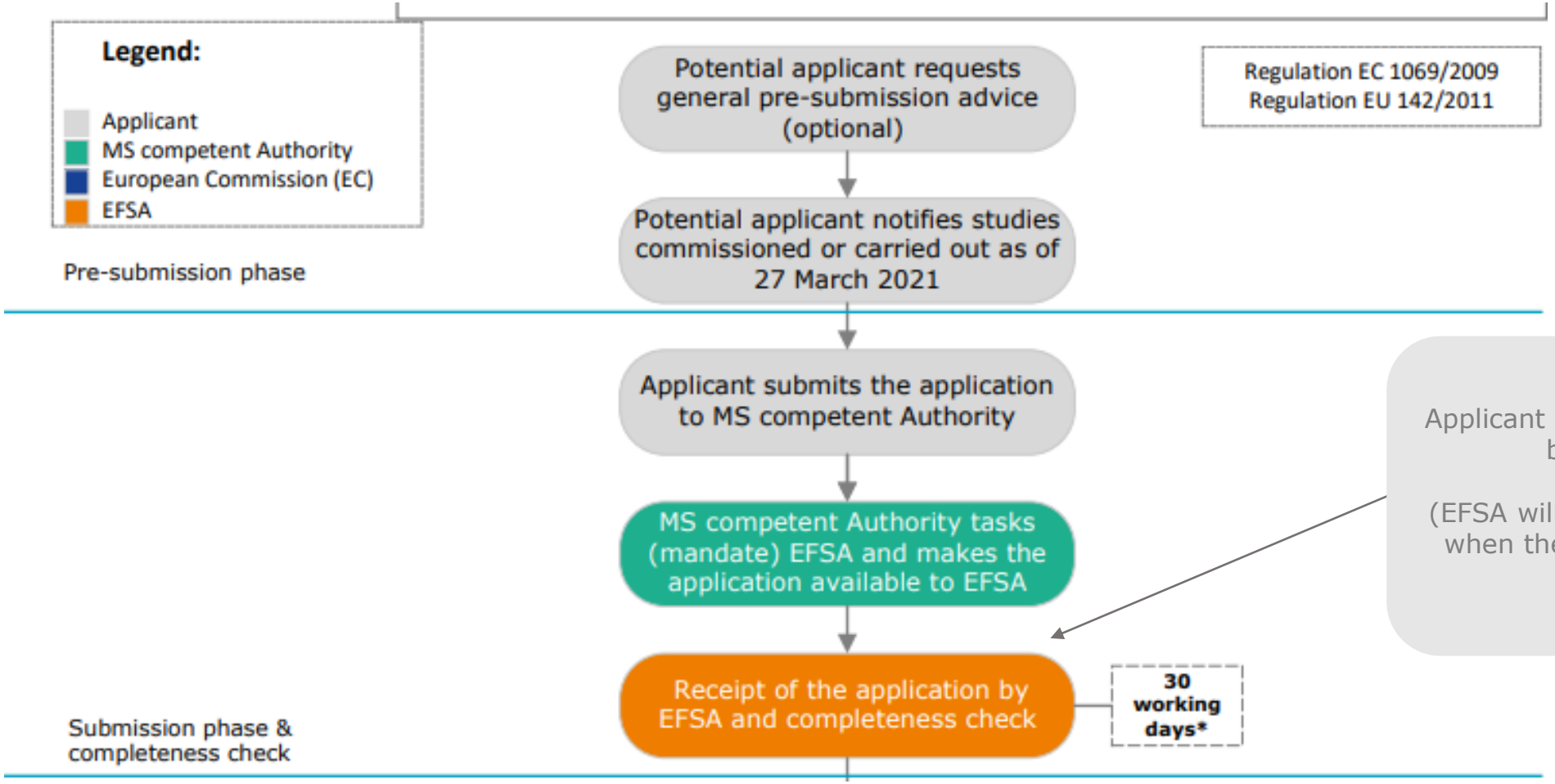
Step 3
Validation of application

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

Submission of a Dossier:

- Portalino

Dossier intake workflow



Applicant submits the application to EFSA by using **PORTALINO.**

(EFSA will notified the applicant by email when the dossier can be submitted via Portalino)

Register to Portalino

Sarah
Potential Applicants

Send registration request
servicedesk@efsa.europa.eu

EFSA validates the request and provides credentials

Portalino https://confportal.efsa.europa.eu/

To specify:

Organization details

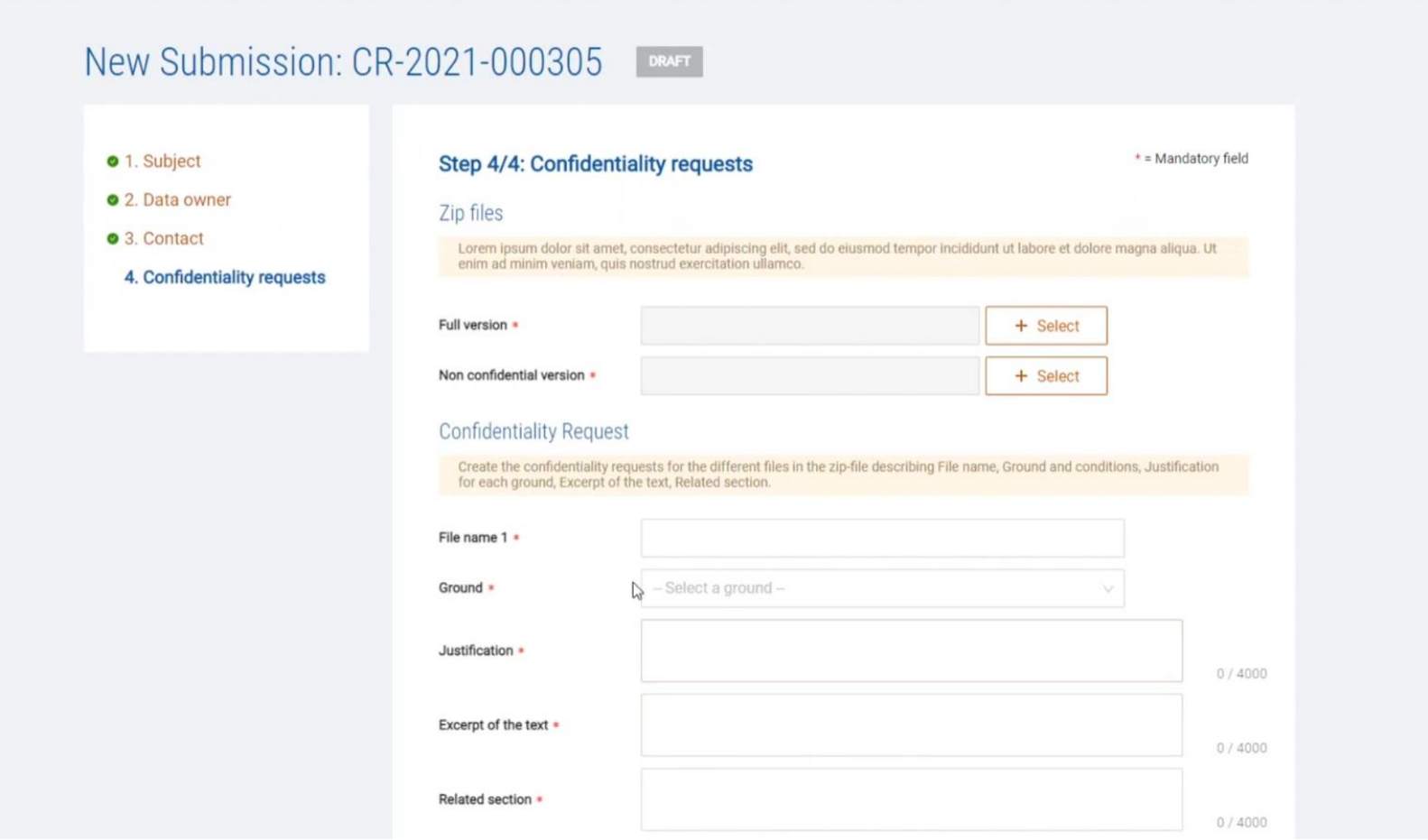
- Organization Name
- Organization email (corporate domain)
- Website (optional)
- Phone number
- Address
- City/Place of residence
- Country
- First and Last name of the user requesting access

Registration request

- If your organization is already registered in Connect.EFSA
- The scope of your submission

Submission of the two versions of the dossier

Applicant submits two versions of the dossier:
Confidential (full version) and Non-confidential



User guides to Portalino

- Quick guide

https://www.efsa.europa.eu/sites/default/files/2021-05/portalino-quick-guide-business-users.pdf

- Video tutorial

https://www.youtube.com/watch?v=PognKycrYUQ

For any technical issue related to the IT tool
Please contact

servicedesk@efsa.europa.eu

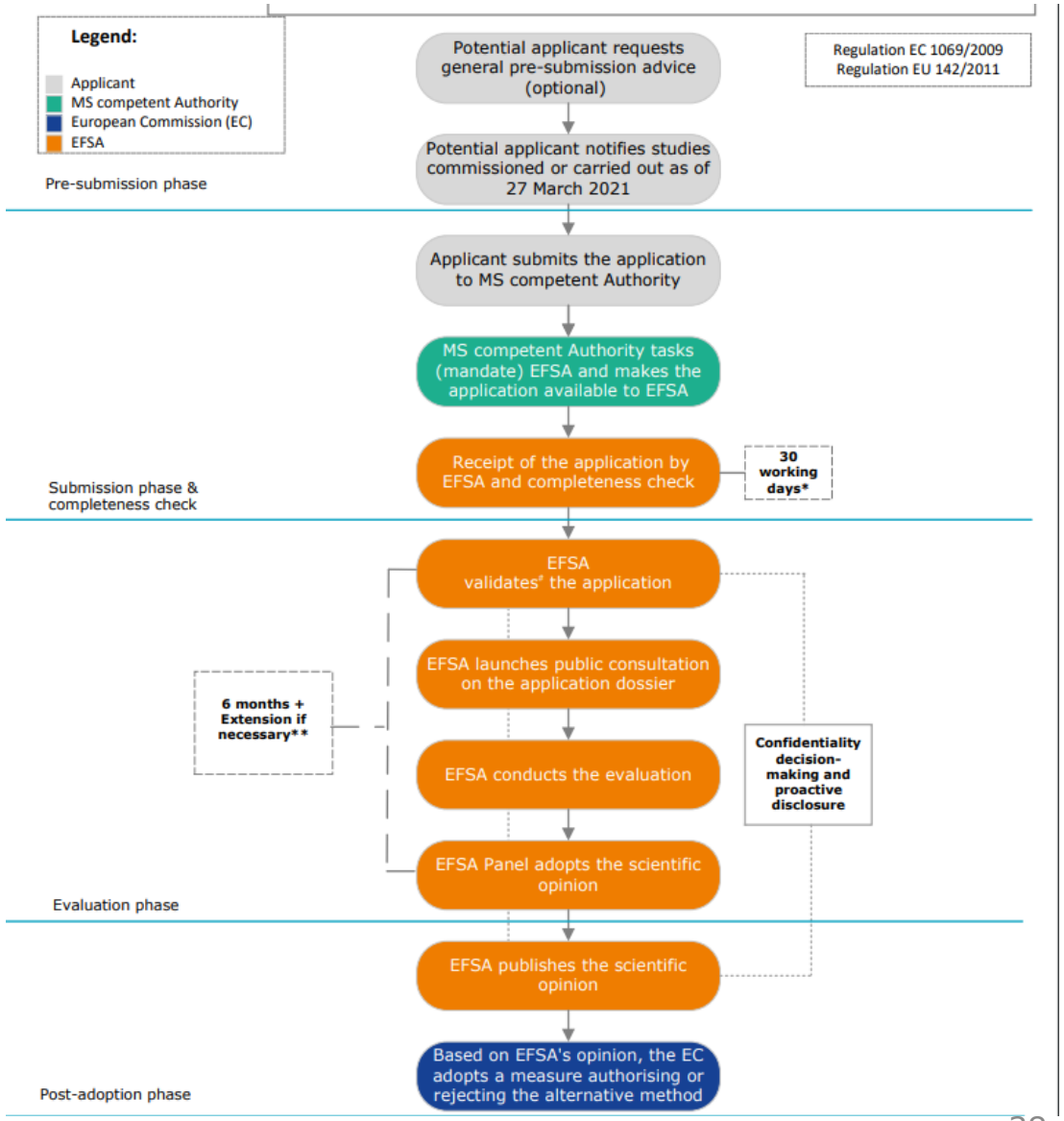
Completeness check and timeline from submission to validation

Completeness check

Applications on ABPs should be according to **Regulation EC 1069/2009** and **Regulation EU 142/2011**.

FDP Completeness check is based on **Annex VII of Regulation EU 142/2011** includes provisions on the format, language and content of the application.

*In case certain parts of the application need modification or completion in order to be considered valid, EFSA requests the missing information (RFI) to the applicant.



https://www.efsa.europa.eu/sites/default/files/2022-05/apdeskapplworlflowanimalbyprod.pdf

Questions:

- **Ask EFSA a Question**
- **Useful links**

Questions

Ask EFSA a Question

EFSA Stakeholders.
For regulated products select as area: questions about scientific application process

Fill in the dedicated form on the website Connect.EFSA

Administrative and scientific issues, the regulatory framework on specific scientific areas, guidance documents, procedural steps, status of specific applications, IT tools to be used in the pre-submission phase or for the preparation and submission of applications

Anytime.
Responses to web form requests are provided within 15 working days

Ask EFSA a Question

Useful Links

- TR: Regulation (EU) 2019/1381
- Training programme on Transparency regulation
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- 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

- Catalogue of services (update 2021)
- Toolkit page: https://www.efsa.europa.eu/en/applications/toolkit
- User Guide - Notification of Studies
- User Guide - Pre-application ID
- Ask EFSA a Question
- Connect.EFSA
- Portalino https://confportal.efsa.europa.eu/

European Food Safety Authority

Thank you

Questions?

3. Life cycle of the application after validation

Vasileios Migkos
Legal Affairs (LA) Services
Angel Ortiz-Pelaez
BIOHAW

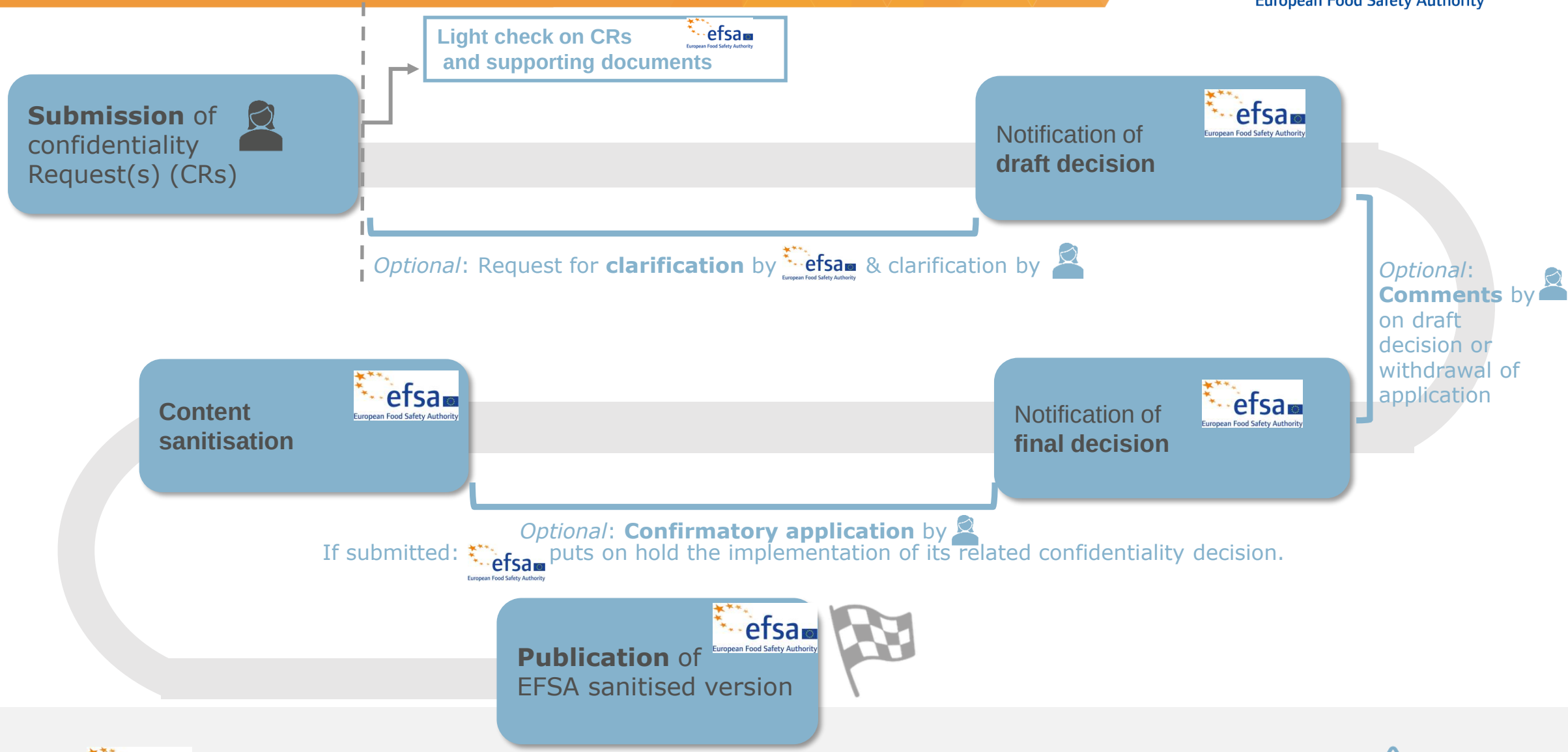
Trusted science for safe food

efsa
European Food Safety Authority

Contents

- Confidentiality
- Evaluation
- Public consultation dossier
- Timeline: stop the clock
- Adoption - publication

EFSA confidentiality assessment & sanitisation
Procedural steps



Review decision in case scientific output identifies foreseeable effects on human health, animal health or the environment

Procedural requirements

- Submission through Portalino
- Include verifiable justifications, a confidential and a non confidential version of the document
- Provide clarifications ONLY if requested to do so by EFSA
- Submit clarifications within the deadline set by EFSA
- Modifications of submitted requests not allowed, unless requested by EFSA
- No fees

Procedural requirements – Closed positive list

Confidentiality requests only on items on closed positive list

For the ANIMAL BY-PRODUCTS sector:

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;

Non-disclosure of Personal Data

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.

Responsibility of the applicant

- **Blackening of personal data included** in the submission of **confidentiality request**

Enables EFSA to support request by adopting positive decision
Personal data is sanitised in the non-confidential version published online

- **Blackening of personal data is not included** in the submission of **confidentiality request**

Personal data remains visible in the non-confidential version published online
Applicant may be held accountable for any infringement of the rules

Substantive requirements

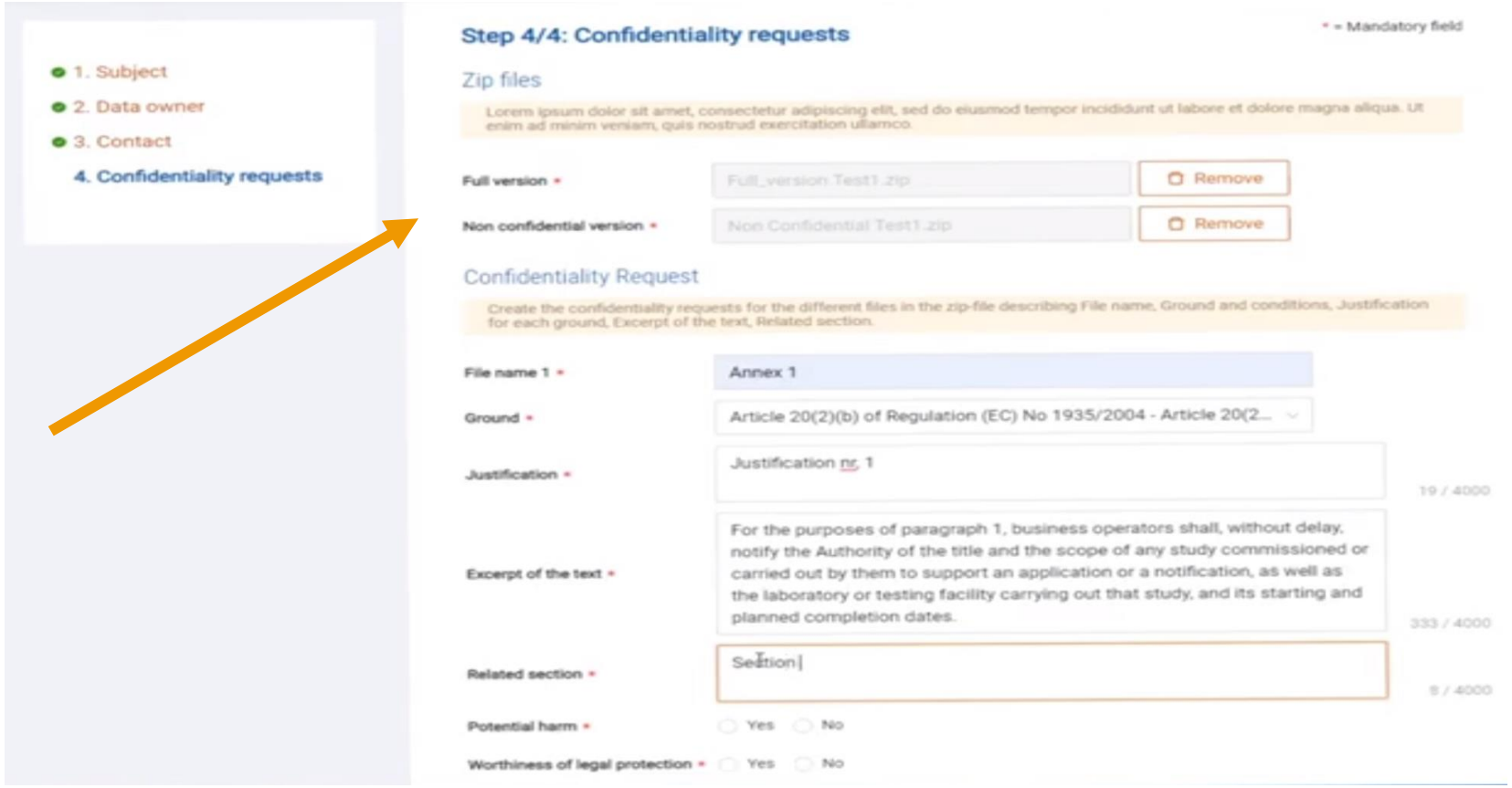
- **Identifying** clearly the information claimed confidential, by (i) referring to all elements claimed confidential (ii) locating them in the document (page/paragraph/line)
- Indicating the **legal basis (grounds)**
- Providing adequate **justification**

Ticking the relevant indicators OR explaining why the item should be kept confidential:

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

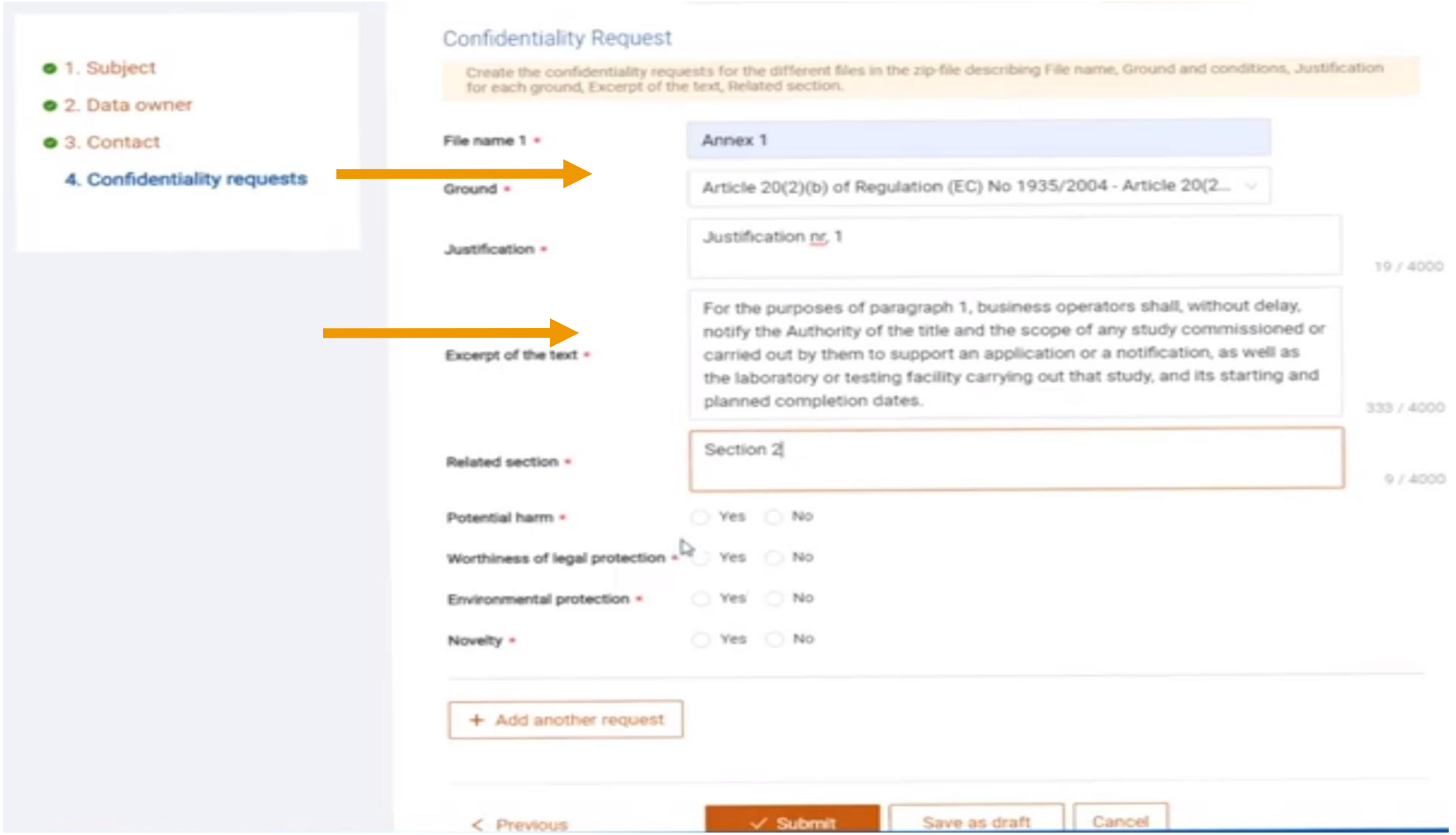
Portalino – confidentiality requests

Provide non-confidential file



Portalino – confidentiality requests

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



Useful documents

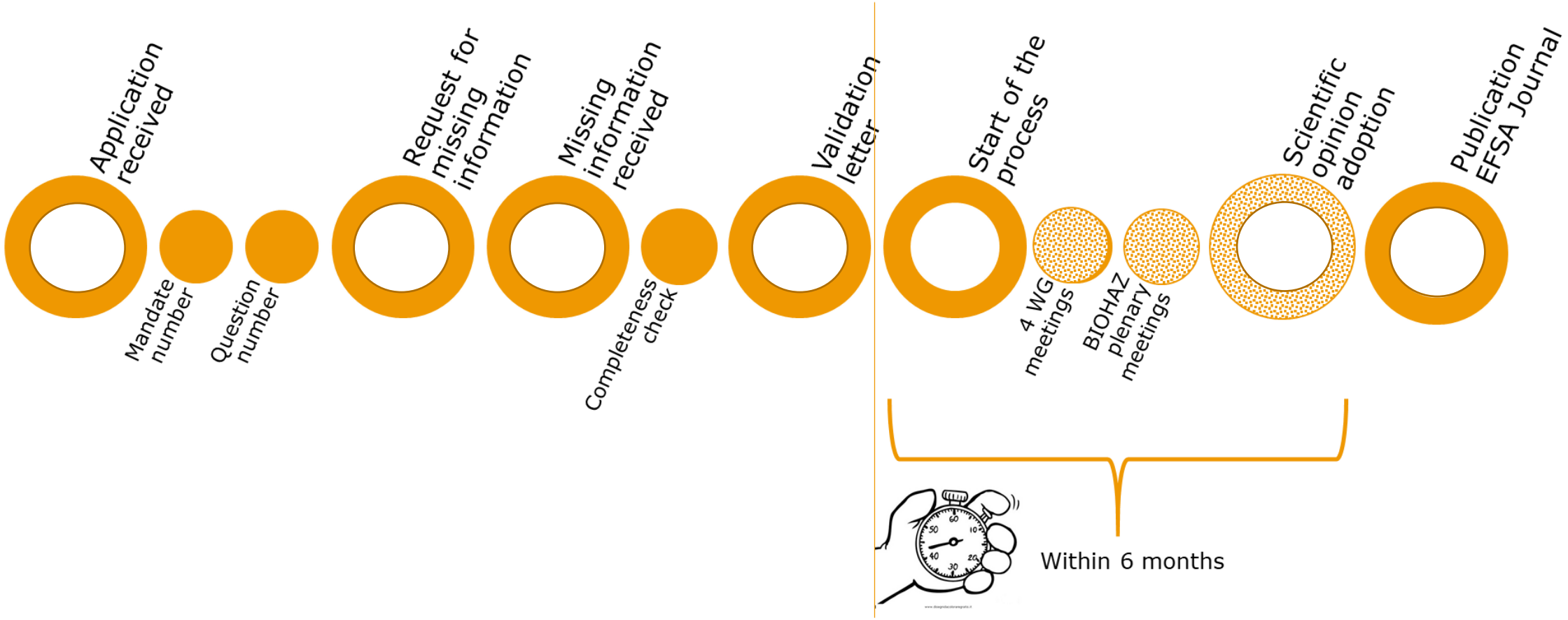
Legal documents

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- PAs on transparency and confidentiality: Practical Arrangements concerning transparency and confidentiality

Guidance/training materials

- Q&As on PAs: Questions and Answers on the EFSA Practical Arrangements
- Training material, including video introductions/tutorials and webinar recordings, are available under the dedicated section "Transparency Regulation Implementation Training Programme" on the EFSA website
- EFSA User Guide on Confidentiality

Application submission process



ABP Legal framework

Regulation (EC) 2009/1069 Article 20 (ABP Regulation)

5. EFSA shall assess, within six months following receipt of a complete application, whether the method submitted ensures that **risks to public or animal health** are:

a) controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or

b) **reduced to a degree which is at least equivalent, for the relevant category of animal by-products**, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

EFSA shall issue an opinion on the application submitted.

ABP Legal framework

Regulation (EC) 1069/2009 Article 20 (ABP Regulation)

6. In duly justified cases where EFSA requests additional information from applicants, the period provided for in paragraph 5 may be extended.

After consulting the Commission or the applicant, EFSA shall decide on a period within which that information shall be provided to it and inform the Commission and the applicant as appropriate of the additional period needed.

7. Where applicants wish to submit additional information on their own initiative, they shall send it directly to EFSA. In that case the period provided for in paragraph 5 shall not be extended by an additional period.

8. EFSA shall forward its opinion to the Commission, the applicant and the competent authority of the Member State concerned.

ABP Legal framework

Regulation (EC) 1069/2009 Article 20 (ABP Regulation)

9. Within three months following receipt of the opinion of EFSA and taking account of that opinion, the Commission shall inform the applicant of the proposed measure to be adopted in accordance with paragraph 11.

10. Following receipt of the opinion of EFSA, the following shall be adopted:

a) either a measure authorizing an alternative method of use or disposal of animal by-products or derived products; or

b) a measure rejecting the authorization of such an alternative method.

Evaluation

Applicant

Applicant
European Commission

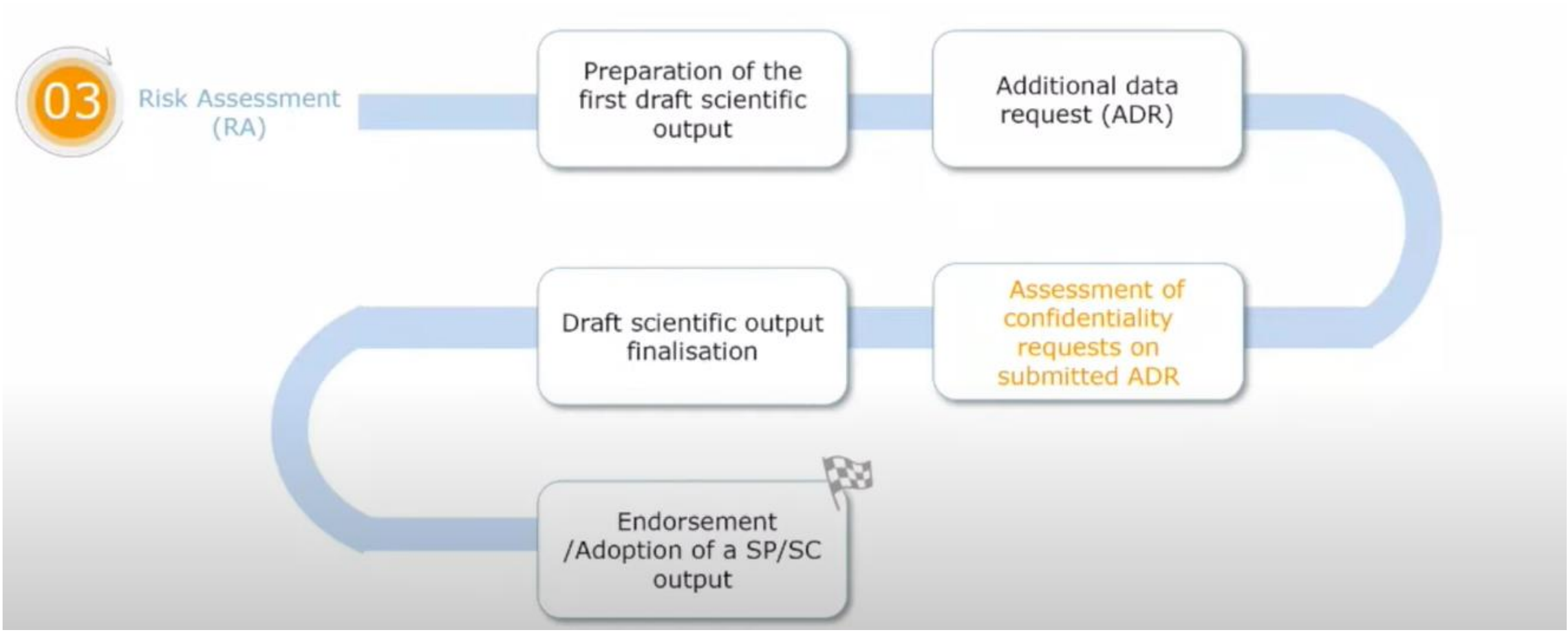
Public consultation?

Six months

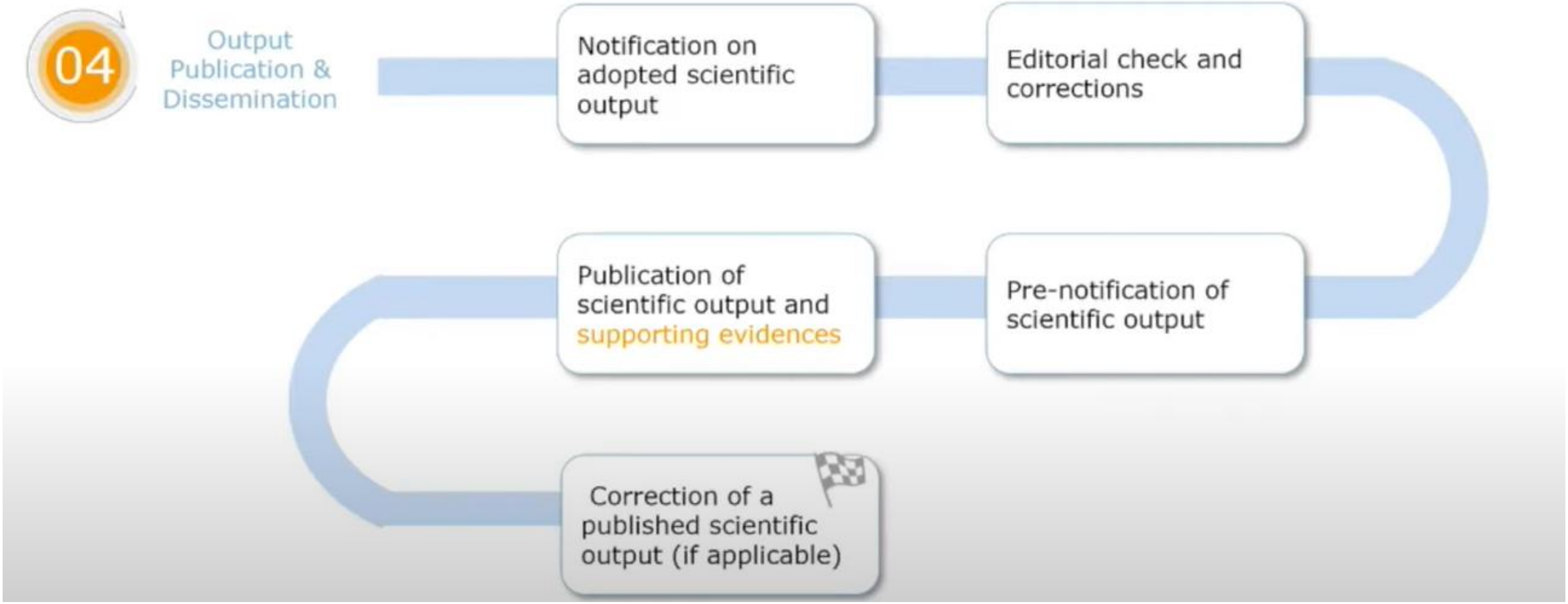
EFSA Validation

Once accepted by EFSA, requests become Mandates

Evaluation cycle



Evaluation cycle



Publication output

https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6511

Sources

ABP topic page in EFSA website:
https://www.efsa.europa.eu/it/topics/animal-by-products

ABP applications page in EFSA website.
https://www.efsa.europa.eu/it/applications/biologicalhazard

EFSA journal.
https://efsa.onlinelibrary.wiley.com/journal/18314732

Info mandates and applications: Open EFSA:
https://open.efsa.europa.eu/

European Food Safety Authority

Thank you

Questions?

4. Standards and scientific issues of the assessment

Avelino Álvarez-Ordóñez
BIOHAZ Panel Member

Trusted science for safe food

efsa
European Food Safety Authority

Contents

Hazard identification

Risk reduction

Standards

Working group

Working group´s aim

Can the method under assessment be considered at least equivalent to the processing method laid down in the legislation (e.g., for the production of 'X' from raw materials including Category 'Y' ABP)?

Working group´s approach


European Food Safety Authority EFSA Journal 2010; 8(7):1680

SCIENTIFIC OPINION

Statement on technical assistance on the format for applications for new alternative methods for animal by-products[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

The level of risk reduction must be at least equivalent to that achieved by the methods and, when available, processing standards already approved under the Regulation (EC) 1069/2009.

Main issue

- The level of risk reduction of the methods approved in the legislation is not known
- Standards are only available for very particular processes/uses

Annex V, Chapter 3, Section 2 Regulation (EU) 142/2011:

Alternative transformation parameters for biogas and composting plants

The competent authority (in a Member State) may authorize the use of parameters other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks.

The validation of the intended process must demonstrate that the process achieves the following overall risk reduction:

Thermal and chemical processes:

a reduction of 5 $\log_{10}$ of *Enterococcus faecalis* or *Salmonella* Senftenberg (775W, H_2S negative)

a reduction of infectivity titer of thermoresistant viruses such as parvovirus by at least 3 $\log_{10}$, whenever they are identified as a relevant hazard

Chemical processes:

a reduction of resistant parasites such as eggs of *Ascaris* spp. by at least 99.9% (3 $\log_{10}$) of viable stages

Standards established by the Working group experts

Category 1 ABP:

A **reduction of 6 $\log_{10}$ in prion infectivity** by the alternative method is required to consider it at least equivalent to the method approved in the legislation.

Category 3 ABP:

- A reduction of the concentration of the relevant **pathogenic bacteria by at least 5 $\log_{10}$ and the infectious titer of the relevant viruses by at least 3 $\log_{10}$**. For chemical treatments, a reduction of viable stages of resistant parasites such as eggs of ***Ascaris* spp. by at least 99.9% (3 $\log_{10}$)** is also required.
- The determination of the relevant pathogenic bacteria and viruses should be defined by the hazard identification, specific for the material to be treated.
- If the hazard identification considers spore-forming pathogenic bacteria to be relevant, the required level of inactivation will also be **a 5 $\log_{10}$ reduction of spores from these bacteria**, except for spores of *C. botulinum* for which a 12 $\log_{10}$ reduction would be required, as for processing canned petfood.
- Given their well-described high level of resistance to thermal and chemical treatments, **applicants may choose to directly use spores of pathogenic bacteria as primary indicators** without carrying out a full hazard identification exercise.

These reductions should be achieved by the process independently from the reduction provided by the standard processing methods [methods 1–5 or 7 of Commission Regulation (EU) 2011/142], should these be required.

Assessment of the dossier

Hazard identification

a) full hazard identification process detailing **all the relevant biological hazards for human and animal health related to the origin and category** of the material to be processed.

b) Comprehensive and specific for the matrix. Based on scientific evidence.

c) The biological agent/s which are the most difficult to be inactivated by the critical parameters defined in "Full description of the process" **should be retained as the primary target/s** for demonstrating the risk reduction achieved by the process.

d) Applicants may choose to directly use as primary indicators **the most resistant organisms possibly present** in the category of ABP material, without carrying out a full hazard identification exercise.

- Cat 1 ABP: TSE agents
- Cat 3 ABP: Bacterial spores

Assessment of the dossier

Level of risk reduction

- The purpose of the evaluation is not the estimation of the level of any risk, but the level of **hazard reduction**
- The level of hazard reduction can be demonstrated with **validated direct measurements:**

  a) Measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:
  - ✓ consistently present in the raw material in high numbers,
  - ✓ not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant, than the pathogens for which it is being used to monitor,
  - ✓ relatively easy to quantify and relatively easy to identify and to confirm;

  b) Using a well-characterized test organism or virus introduced in a suitable test body into the starting material.
- Adequately justified alternative **non-pathogenic indicator or surrogate organisms** with at least the same level of resistance may be used. **An explanation should be given of their relevance.**
- Key aspect: election of indicator or surrogate organisms/strains

Level of risk reduction

- Information on the **methodology** used, nature of samples that have been analyzed and evidence that samples are representative (e.g., number of samples, number of tests performed and selection of measuring points).
- **If several treatment steps are involved**, an assessment should be performed on the degree to which individual titer reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps.
- **Sensitivity and specificity** of the detection methods applied.
- Data on the **repeatability and statistical variability** of the measures obtained during the experiments.

Assessment of the dossier

Level of risk reduction

- In case no direct measurements of the risk reduction be available (i.e., no validation as defined before is feasible), **modelling or comparison with other processes may be acceptable** if:
  - the factors leading to the risk reduction are well known;
  - the model of risk reduction is well established; and
  - continuous direct measurements of the factors leading to the risk reduction are provided for the full-scale process which demonstrate that these factors are homogeneously applied throughout the treated batch.

- Adequately justified alternative **indicator organisms** with at least the same level of resistance as the hazards possibly present may be used. **An explanation should be given of their relevance.**

- Key aspects to consider:
  - **parameters** (e.g., time, pressure) used in literature
  - **matrix** used in literature
  - **No extrapolations**

Final remarks

- The Working Group assesses the method based on the information, supporting documentation, and literature included in the application.

- The Working Group **will not look** for other information to prove the risk reduction capability of the method.

- The Working Group assesses **all the sections of the application**.

- **Common mistakes:**
  - Hazard identification is not comprehensive and based on solid evidence
  - Applicant only focuses on bacterial hazards
  - Indicator/surrogate organisms used are not appropriate
  - Evidence on risk reduction has been obtained in a different matrix
  - Evidence on risk reduction has been obtained with different process parameters (temperature, pressure, time, etc.)
  - HACCP plan: CPs or critical parameters wrongly selected or not well described
  - Some by-products and/or the procedures to manage them are not well described

European Food Safety Authority

Thank you

Questions?

Stay connected

efsa
European Food Safety Authority

Subscribe to

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss

Receive job alerts

careers.efsa.europa.eu – job alerts

Follow us on Twitter

@efsa_eu
@plants_efsa
@methods_efsa
@animals_efsa

Follow us Linked in

Linkedin.com/company/efsa

Contact us

efsa.europa.eu/en/contact/askefsa

Thank you for attending our webinar!

- Feel free to submit questions via EFSA ask a question webform (EFSA.Connect at: https://connect.efsa.europa.eu/RM/s/askefsa).
- In case we did not manage to answer all your questions, we will answer them by e-mail.
- The recording of today's webinar will be available on the EFSA website in few days.