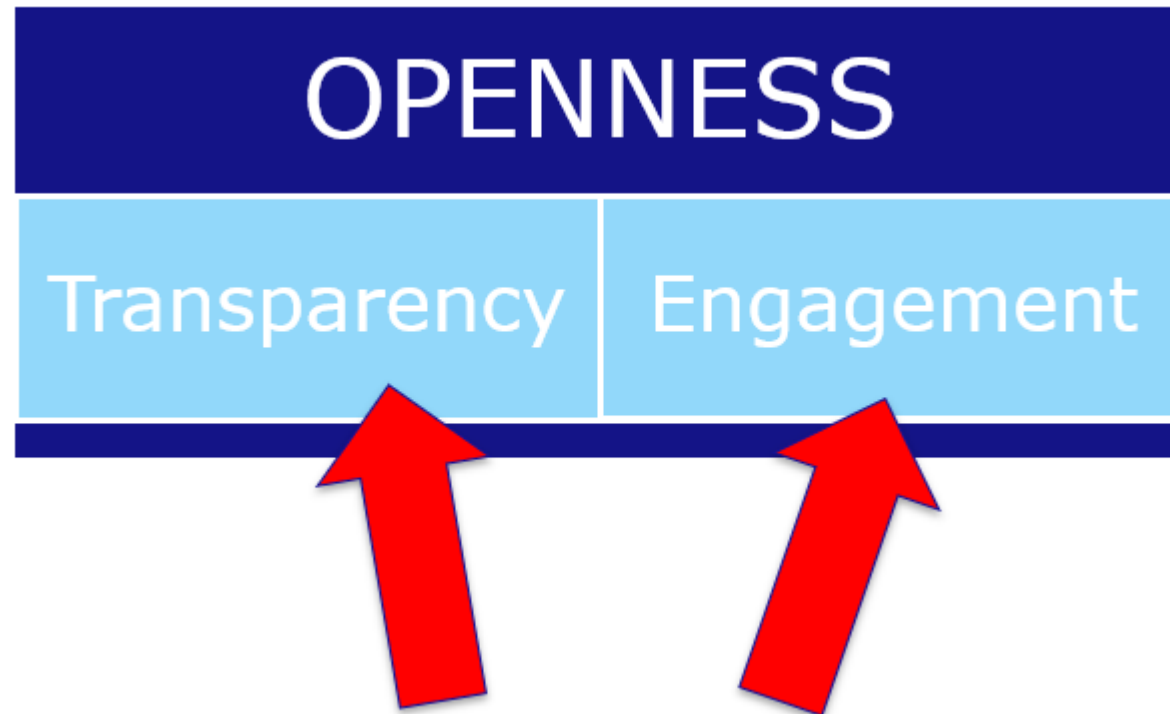


24 November 2022



# Welcome to the Open Session of the 164<sup>th</sup> Plenary of the FEEDAP Panel

Trusted science for safe food



24 November 2022



# 164<sup>th</sup> Plenary of the FEEDAP Panel

Chair: Prof. Vasileios Bampidis

Trusted science for safe food

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24 November 2022



# Guidelines for Observers for online open plenary meetings

FEEDAP Panel Open plenary

Trusted science for safe food



## Observers may:

- submit questions upon registration
- ask questions during the meeting online, when the Chair grants the opportunity
- gain insights on scientific discussions and procedures at EFSA
- witness collegial decision-making first-hand online
- report on the proceedings of the meeting, while any reference to participants should respect their reputation and professional integrity



## Observers may not:

- hinder the work of the Panel
- engage in the discussion, drafting, deliberation of the scientific output at hand
- attempt to influence the meeting participants, in particular members of the Panel
- distribute or request the circulation of any documents
- make a written transcript or record the meeting

The minutes of the **online** open plenary meeting are published on the EFSA website following the open plenary.

No audio/video-recordings of the open plenaries are made hence, if not followed live online, the information regarding the meeting discussions and outcomes can be only obtained through the meeting minutes that will be published on the EFSA website.

EFSA does its best to ensure the quality of the its web-casted open plenaries, however, due to the reliance on internet and other technical systems outside EFSA's control, streaming can be disrupted.

EFSA would like to inform all the registered online observers that **the link** you receive to connect to the EFSA meeting via Teams is RESERVED FOR YOU IN PERSON to connect online. **PLEASE DO NOT SHARE OR FORWARD** the link to anyone else, as this may lead to unauthorized remote access.

Should you notice anything abnormal or unexpected in the course of your connection to the EFSA meeting, please contact EFSA staff who confirmed your registration or the Meeting Moderator in the chat available throughout the meeting.

- Chair may grant observers the opportunity to ask questions either after they have observed a discussion on a given topic or at the end of the open plenary meeting on other topics which fall within the remit of the Panel in a dedicated Q&A session.
- If members of the Scientific Panel are unable to answer questions from observers during the meeting, observers may resubmit their questions to EFSA through the #AskEFSA service on the EFSA website.

- To allow all Observers to participate the number of interventions per observer may be limited
- Express your interest in asking a question/comment by raising hand or writing “floor please” in the meeting chat box. For those in EFSA premises, floor can be requested by raising the hand
- Please state your name and affiliation when introducing the question/comment
- Keep it simple – short and concise

Keep your **microphone muted and camera off** at all times unless specifically asked by the Chair or an EFSA staff

Keep the **meeting chat box clean**. Use it only to signal technical problems or when indicated by the Panel Chair

Use “raise hand” function to ask the floor to submit questions or comments **when indicated by the Chair**

If you have problems with the connection, exit the meeting and rejoin

Use of headset recommended for better sound quality



Enjoy the meeting

Trusted science for safe food

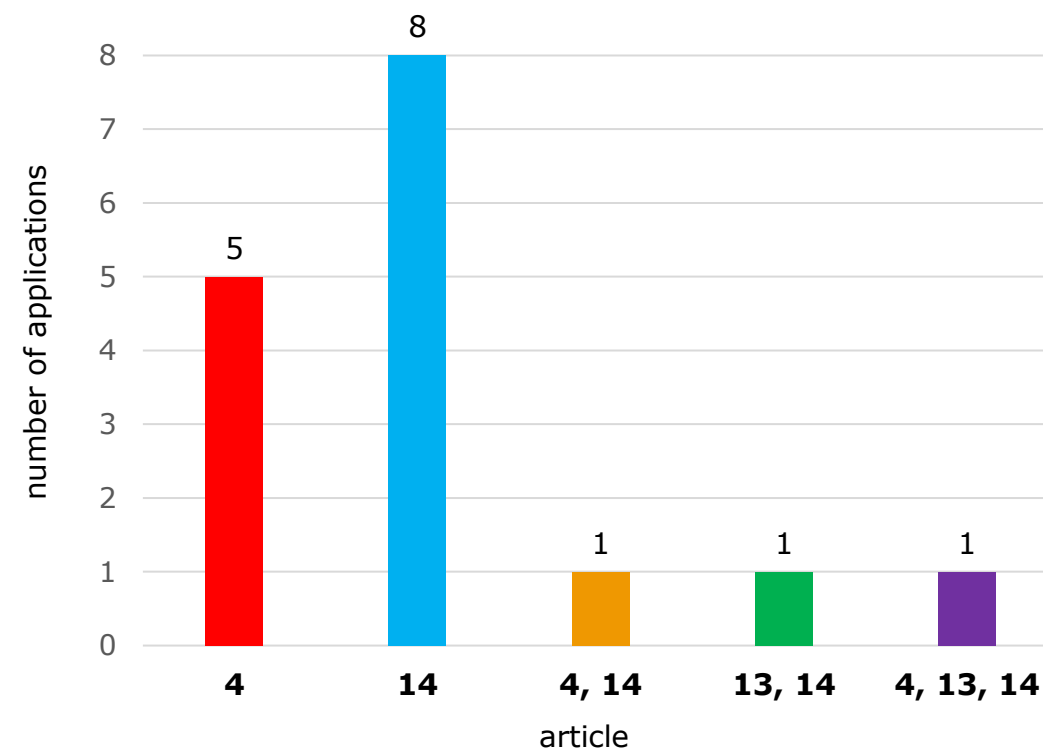


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# New applications under Reg. 1831/2003

EFSA-Q-Number	FAD/FEED number	Subject	Article
EFSA-Q-2022-00624	FEED-2022-9491	Iron (II) - betaine complex for all animal species	4
EFSA-Q-2022-00745	FEED-2022-7951	Coated granulated cobalt (II) carbonate (3b304) for herbivore reptiles and zoo mammals, ruminants with functional rumen, lagomorphs, equidae, rodents	13, 14
EFSA-Q-2022-00746	FEED-2022-7310	PB6 ( <i>Bacillus velezensis</i> ATCC PTA-6737) for all growing poultry	4, 13, 14
EFSA-Q-2022-00778	FEED-2022-8790	<i>Lentilactobacillus (Lactobacillus) buchneri</i> LN4637 / ATCC PTA-2494 for all animal species	14
EFSA-Q-2022-00779	FEED-2022-7830	Tartrazine (2a102) for freshwater fish	4
EFSA-Q-2022-00780	FEED-2022-8671	<i>Lentilactobacillus (Lactobacillus) buchneri</i> LN40177 / ATCC PTA-6138 for all animal species	14
EFSA-Q-2022-00781	FEED-2022-7910	Ponceau 4R (2a124) for freshwater fish	4
EFSA-Q-2022-00789	FEED-2022-9191	<i>Lentilactobacillus buchneri</i> DSM 22501 (formerly <i>Lactobacillus buchneri</i> ) for all animal species	14
EFSA-Q-2022-00791	FEED-2022-3990	L-Cystine (3c391) for all animal species	14
EFSA-Q-2022-00792	FEED-2022-10233	Cobalt (compounds: cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate) for bovines with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	4
EFSA-Q-2022-00793	FEED-2022-10090	BIOMIN® BBSH® 797 (microorganism strain DSM 11798) for pigs and all avian species	14
EFSA-Q-2022-00799	FEED-2022-10750	Bentonite for ruminants, poultry and pigs	14
EFSA-Q-2022-00800	FEED-2022-10230	AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by <i>T. longibrachiatum</i> (MUCL 49755 and 49754)) for pigs for fattening, minor porcine species for fattening other than <i>Sus scrofa domesticus</i> , and turkeys for fattening	14
EFSA-Q-2022-00801	FEED-2022-11091	Bentonite (1m558i) for all animal species	14
EFSA-Q-2022-00810	FEED-2022-8730	Fumaric Acid for all animal species	4, 14
EFSA-Q-2022-00811	FEED-2022-7610	NITTEN DFAIII (difructose anhydride III) for all female adult ruminants in the periparturient period, all neonatal ruminants fed colostrum and milk/milk replacer in early life	4

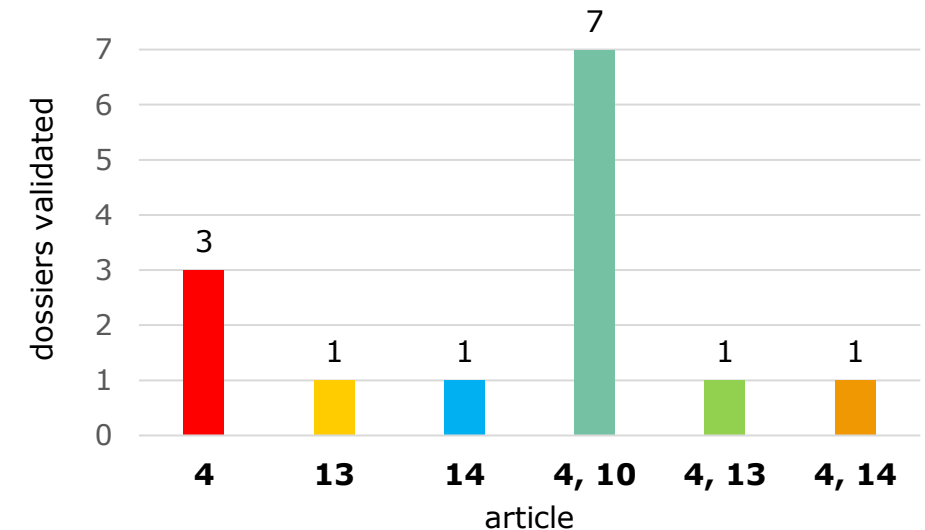
16 new applications received



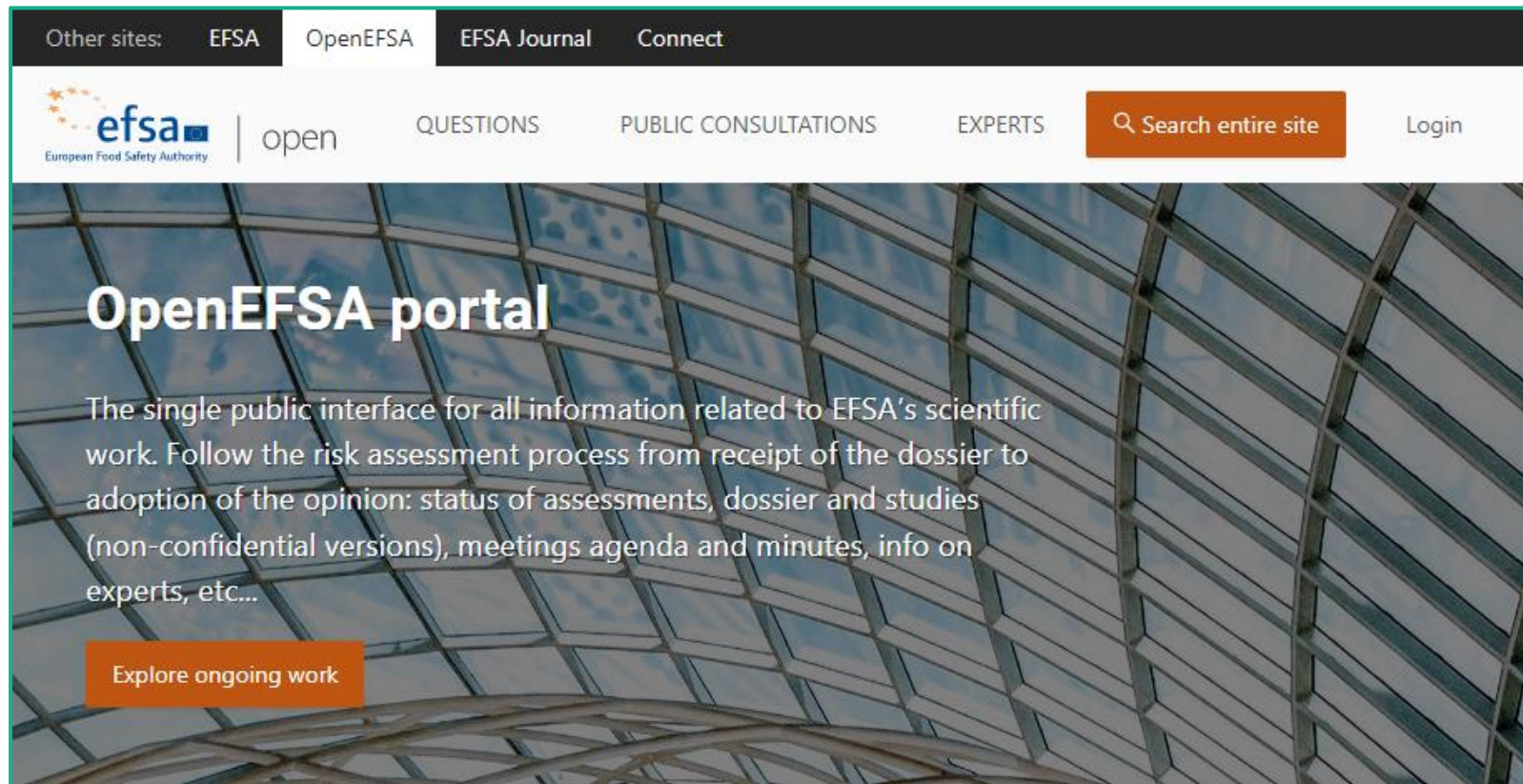
# Valid applications under Reg. 1831/2003

EFSA-Q-Number	FAD/FEED number	Subject	Valid on	Article
EFSA-Q-2022-00565	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Anise tincture	16/09/2022	4, 10
EFSA-Q-2022-00566	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Cumin oil	16/09/2022	4, 10
EFSA-Q-2022-00567	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dill tincture	16/09/2022	4, 10
EFSA-Q-2022-00568	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dong quai tincture	16/09/2022	4, 10
EFSA-Q-2022-00569	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Fennel tincture	16/09/2022	4, 10
EFSA-Q-2022-00570	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Parsley tincture	16/09/2022	4, 10
EFSA-Q-2022-00571	FAD-2010-0221	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Star anise tincture	16/09/2022	4, 10
EFSA-Q-2022-00320	FEED-2022-4933	PB6 <i>Bacillus velezensis</i> ATCC PTA-6737 for all pigs	30/09/2022	4, 14
EFSA-Q-2022-00340	FEED-2022-5091	<i>Pediococcus acidilactici</i> CNCM I-4622 for all insect species and categories	30/09/2022	4
EFSA-Q-2022-00350	FEED-2022-6191	KemTRACE Chromium (Chromium propionate) for all growing birds	11/10/2022	4, 13
EFSA-Q-2022-00375	FEED-2022-6070	Hydroxy-analogue of Selenomethionine (3b814) for all animal species	20/10/2022	14
EFSA-Q-2022-00318	FEED-2022-4411	Balancius® Muramidase (EC 3.2.1.17) for laying hens	21/10/2022	4
EFSA-Q-2021-00130	FAD-2021-0011	Cannabidiol for cats and dogs	09/11/2022	4
EFSA-Q-2022-00325	FEED-2022-3273	GalliPro® Fit ( <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840) for all poultry species for fattening or reared for laying or reared for breeding	16/11/2022	13

7 applications validated  
+ 7 created for Botanical Group 02



For information on the status of dossiers assessments:  
[open.efsa.europa.eu](https://open.efsa.europa.eu)



The screenshot shows the OpenEFSA portal website. At the top, there is a navigation bar with links for 'Other sites: EFSA', 'OpenEFSA', 'EFSA Journal', and 'Connect'. Below this is a header section with the EFSA logo, the word 'open', and navigation links for 'QUESTIONS', 'PUBLIC CONSULTATIONS', and 'EXPERTS'. A search bar with the text 'Search entire site' and a 'Login' link are also present. The main content area features a large background image of a glass and steel dome structure. The text 'OpenEFSA portal' is prominently displayed in white. Below this, a paragraph describes the portal as 'The single public interface for all information related to EFSA's scientific work. Follow the risk assessment process from receipt of the dossier to adoption of the opinion: status of assessments, dossier and studies (non-confidential versions), meetings agenda and minutes, info on experts, etc...'. An orange button labeled 'Explore ongoing work' is positioned at the bottom left of the main content area.

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- Review of the existing health-based guidance values for copper and its exposure assessment from all sources – adopted
- Draft protocol of the opinion on bromide- endorsed for public consultation
- Technical report to assess reliability and relevance of the genotoxicity studies – endorsed for publication
- Applicability of the margin of exposure in the risk assessment of botanicals preparations used as feed additives

- Notice of call for expressions of interest – Scientific and technical support – various profiles

Notice of call for expressions of interest - Scientific and Technical Support - Various Scientific and Communication Profiles

🔍 Italy, Emilia-Romagna, Parma

NEW

📁 Science Professionals

📁 EO/EFSA/2022/01

📅 Oct 24, 2022

Apply for Job

Share this Job

Sign Up for Job Alerts

Individuals with scientific expertise to assist EFSA in carrying out **preparatory work** (including data related activities) in support of EFSA's scientific and risk communication activities with the main focus on the areas of generic risk assessments and the assessment of applications for the authorisation of regulated products.

The delivered preparatory work will be reviewed by EFSA staff and/or ad hoc experts for **its use in EFSA scientific outputs** and communications

[Link to the Call](#)



# EFSA – Panel Renewal - Mandate 2024-2029

**Call for expressions  
of interest - online**

Feb-Mar '23

**Appointment by  
Management Board**

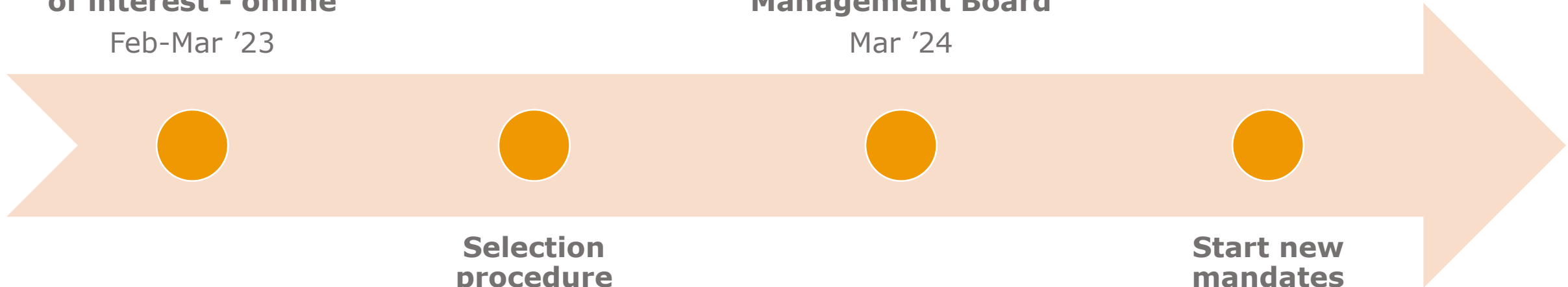
Mar '24

**Selection  
procedure**

Apr '23-Feb '24

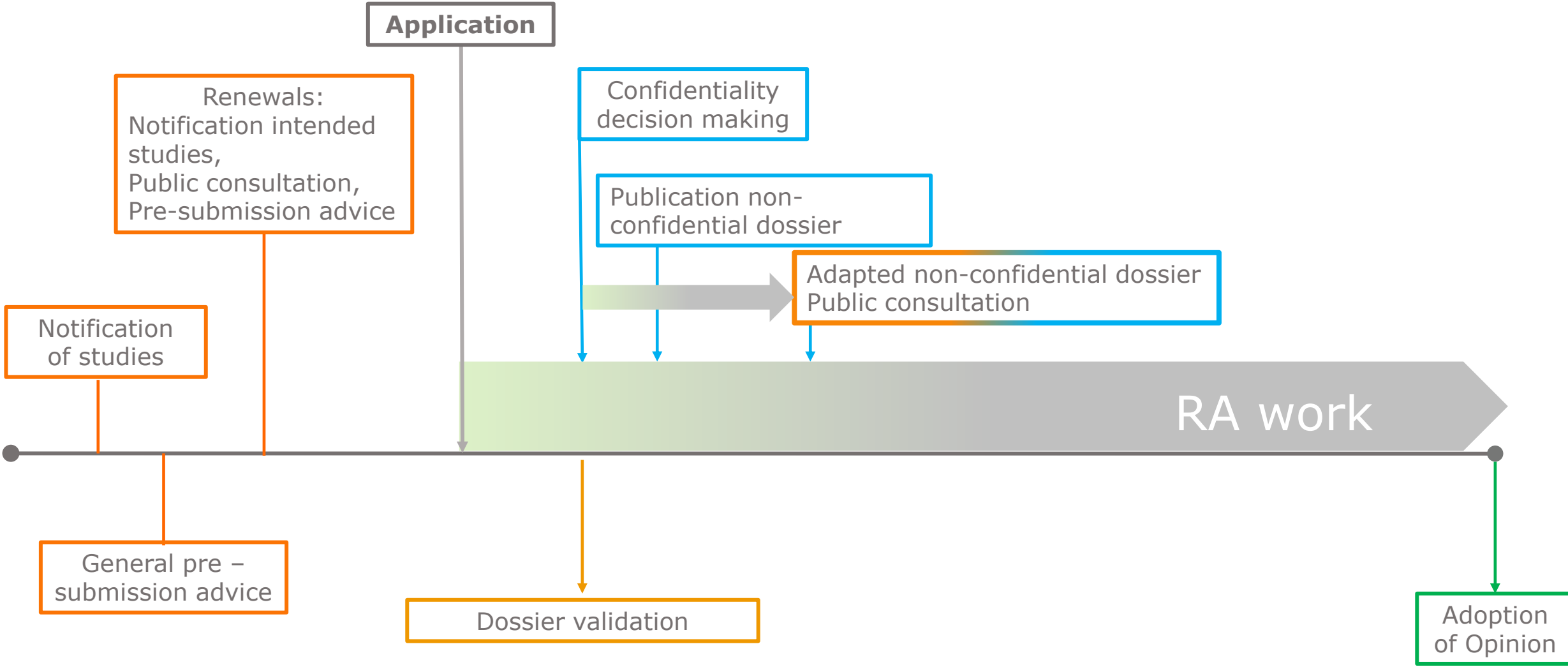
**Start new  
mandates**

July '24

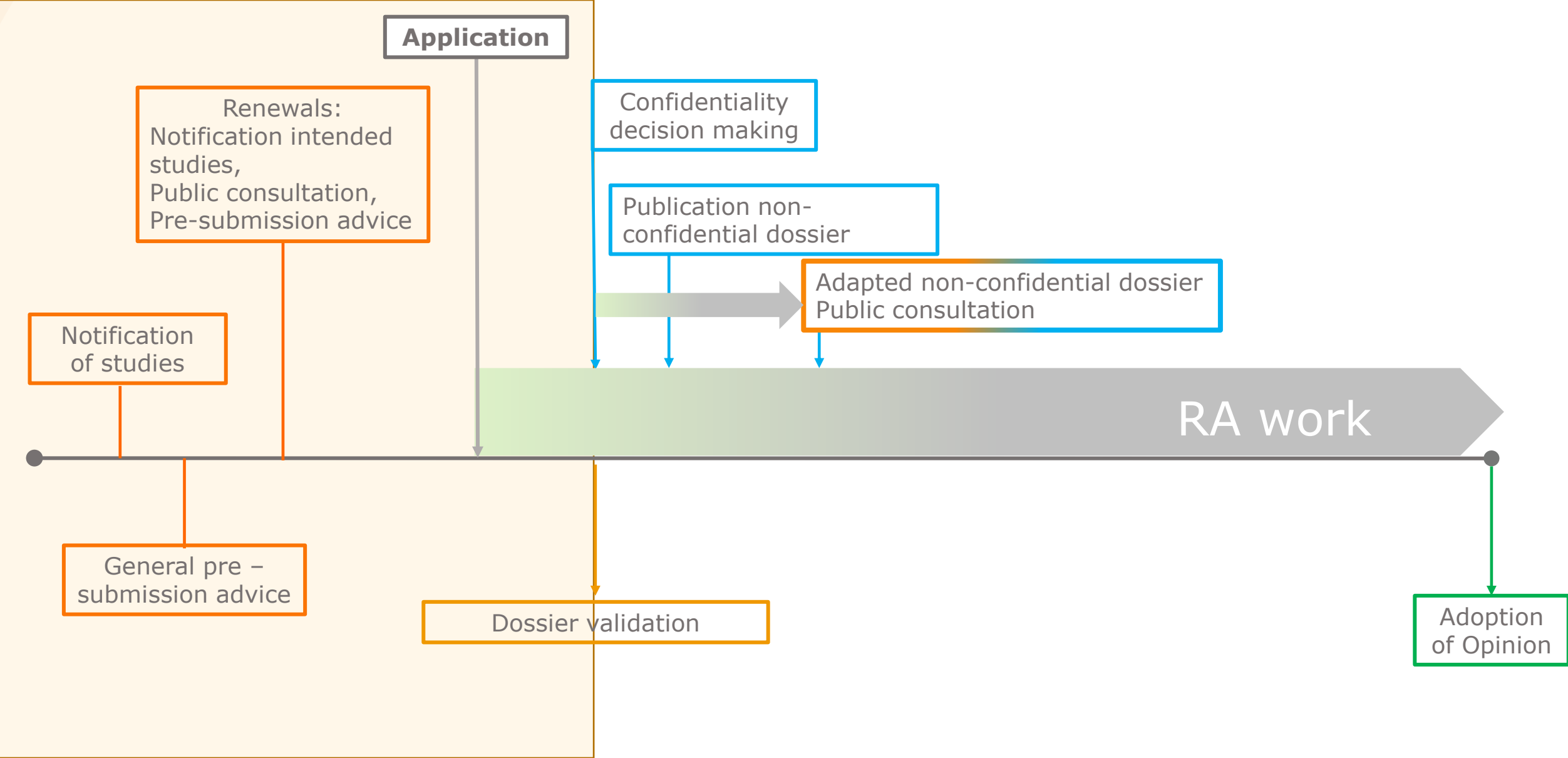


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# Life-time of an application



# Life-time of an application



24 November 2022  
FEEDAP 164th Plenary meeting



# Pre-submission Activities and Completeness Check: Challenges and achievements in the implementation of the Transparency Regulation

**Irene Baratto and Oscar Gonzalez**  
Front-Desk and Workforce Planning Unit

Trusted science for safe food

## 4 pillars

### Transparency

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

### More reliable independent studies

- EFSA will have more access to relevant scientific evidence in requests for authorisation

### Better governance

- Member States will contribute more to EFSA's governance and scientific Panels

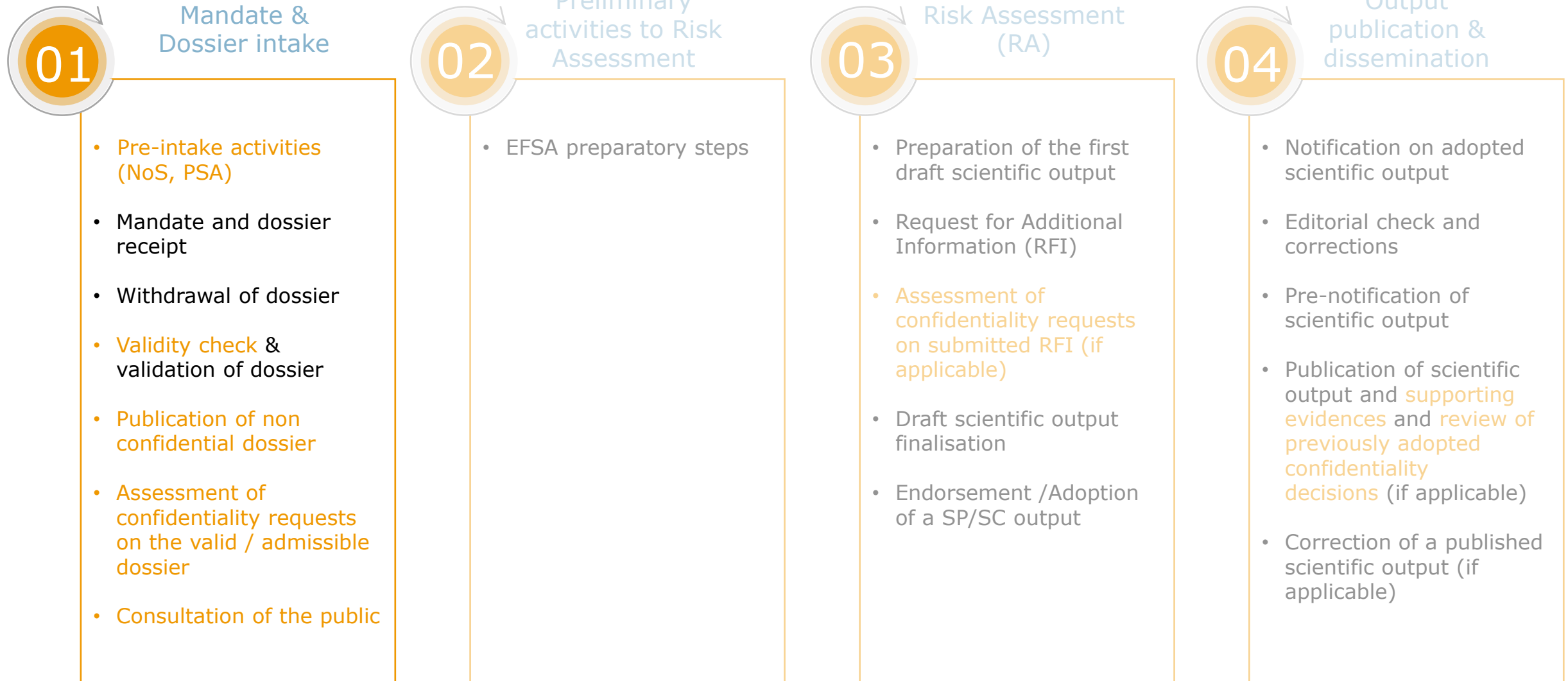
### Effective risk communication

- Improve coordination between risk assessors and risk managers to ensure better communication to stakeholders and general public

**Applicable For** - New dossier/applications submitted on or after 27<sup>th</sup> March 2021



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



Confidentiality



# Pre-Submission Activities and Public Consultations

- General Pre-submission Advice

	Received	Accepted	% Rejected
<b>FEED</b>	20	10	50%
<b>total</b>	68	39	42%

- Public Consultations:

The participation has been scarce so far

- Renewal Pre-submission Advice

	Received	Processed	Ongoing
<b>FEED</b>	47	47	0
<b>total</b>	104	103	1

*Many RPSA are received short before the deadline for submitting the renewal: studies are notified but few questions are received*

## **Advice on** the rules applicable to the content required for an application

- **Non-mandatory** (but recommendable to solve the applicant's doubts)
  - **Non-committal** for the applicants nor for EFSA and its Scientific Panels
  - Available for **all kind of applications**: new authorisations, modifications and renewals
  - Can be requested **any time** before sending the application (recommended > 6 months in advance)
  - **Up to two requests** per pre-application ID - each request can contain **several questions**
  - Answer prepared by EFSA staff and **provided in written (meeting if necessary)**
  - 15 working days to accept the request, 15 wd to answer (20 wd if meeting)
  - Only a **succinct summary is published** together with the application upon its validation
  - **At no cost to** the potential applicant
- 
- **How to request a GPSA:** at [Connect.EFSA](https://connect.efsa.europa.eu) following the [User Guide](#)
    - Potential applicant [registers in the system](#) – create a [pre-application ID](#) – requests [the GPSA](#)

## In the Admitted Scope

- Questions on Applications
  - Rules applicable
  - Content
- Explaining the relevant requirements contained in:
  - Rules
  - Guidance Documents
  - Guidelines

## Out of the Scope (rejected)

- Questions to be addressed to the Risk Managers (EC, MS)
- Questions on content of future submission of complementary information following inconclusive opinions [*Ask EFSA*]
- Requests for pre-assessment
- Unclear or non-precise questions, mistakes (i.e. wrong food domain)

## Study Design

General explanations  
if the Study Design is addressed  
in EFSA Guidance Documents

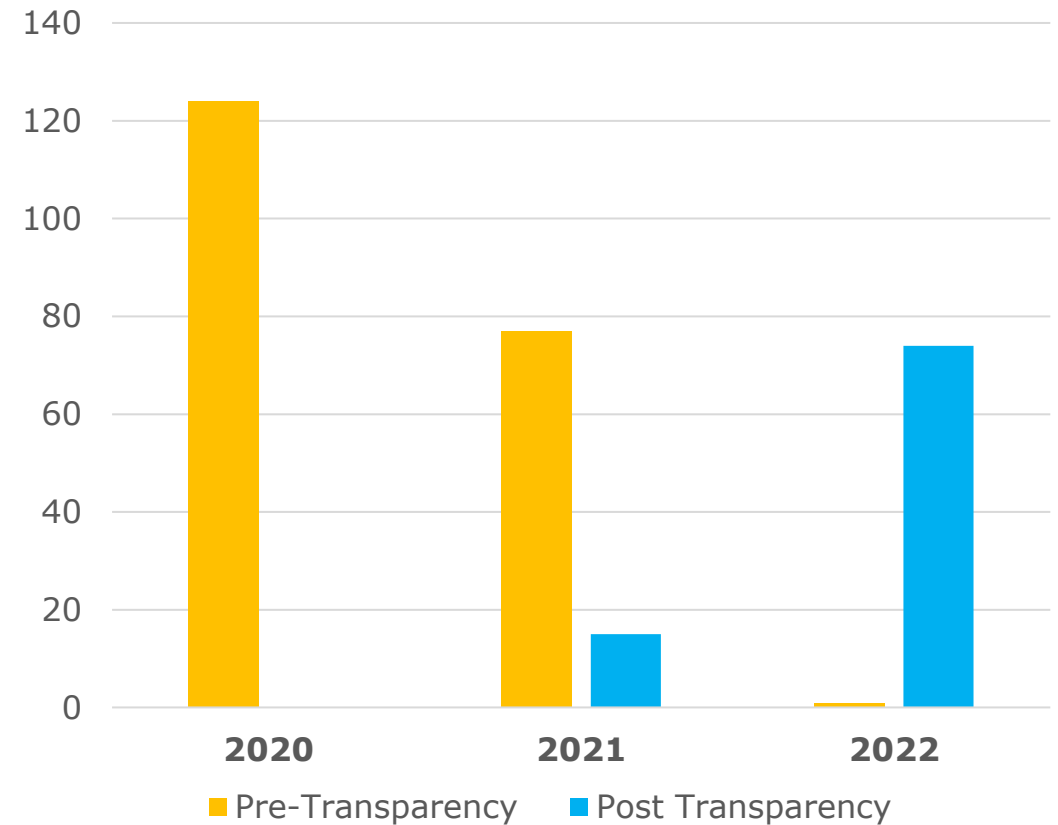
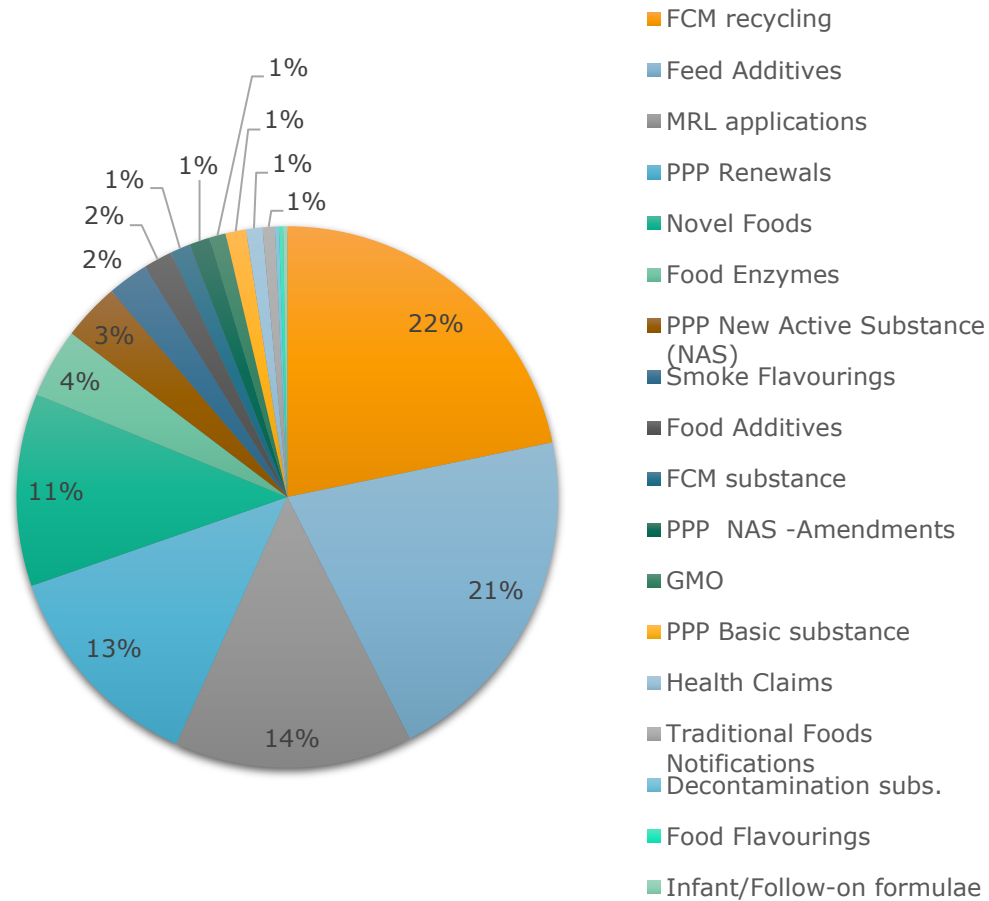
- How to develop or manage a study
- Hypothesis to be tested
- Validation of protocols

- **Pre-submission activities are well in place**
  - Tools running properly
  - Training and supporting documents available for users
- **GPSA and RPSA**
  - Increase the number and quality of the PSAs received
  - Make this services better known and better understood – promote the use
  - Special focus on SMEs
- **Public consultations:**
  - Increase the participation of stakeholders to ensure that all relevant info is taken into account in the assessment

# Completeness Checks

# FEED Applications trend over the years

## Post-TR applications (n=409)



Year	Pre TR	Post TR
2020	124	-
2021	77	15
2022	1	74



## Scope

- Guarantee high quality application dossiers
- Compliance with administrative and scientific minimum requirements (EFSA guidance docs)
- Compliance with NoS obligations
- Information complete, consistent and accessible for the RA

## Main interactions with applicants

- Requests of missing information (RFI)
- Clarification teleconferences

### Administrative compliance

Administrative guidance for the preparation of applications on additives for use in animal nutrition

- Administrative data complete and correct
- Dossier correctly structured
- IPR information
- Documents word searchable, accessible and correctly categorised

### Scientific compliance

EFSA scientific guidance documents

- Scientific data complete and in line with the relevant minimum requirements
- Consistency of scientific data

### Sanitization of confidential and personal data

- Permanent sanitization of documents
- Personal data sanitized

### Compliance with NoS obligations

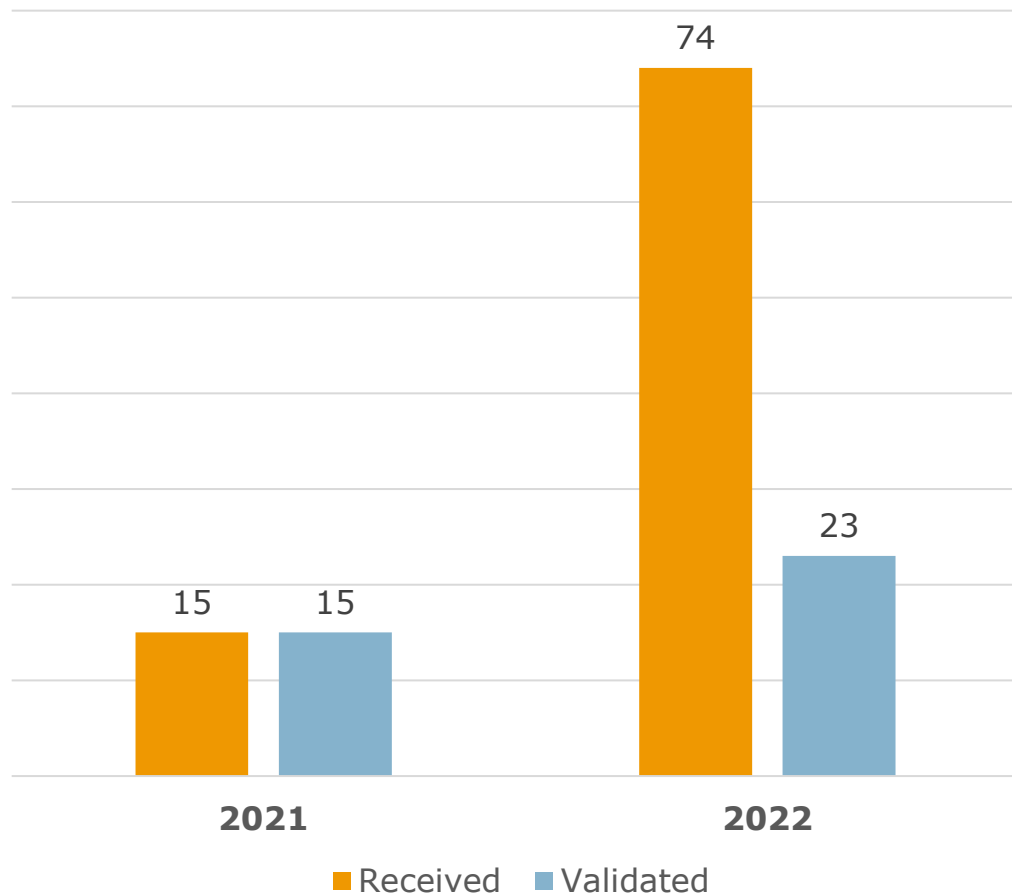
Article 32b of the GFL Regulation

- Information consistent with data in EFSA NoS database
- Pre application ID
- Notification of Post-TR studies
- Notified studies not included or withdrawn
- Post TR studies not notified or notified in delay
- Admissibility of justifications

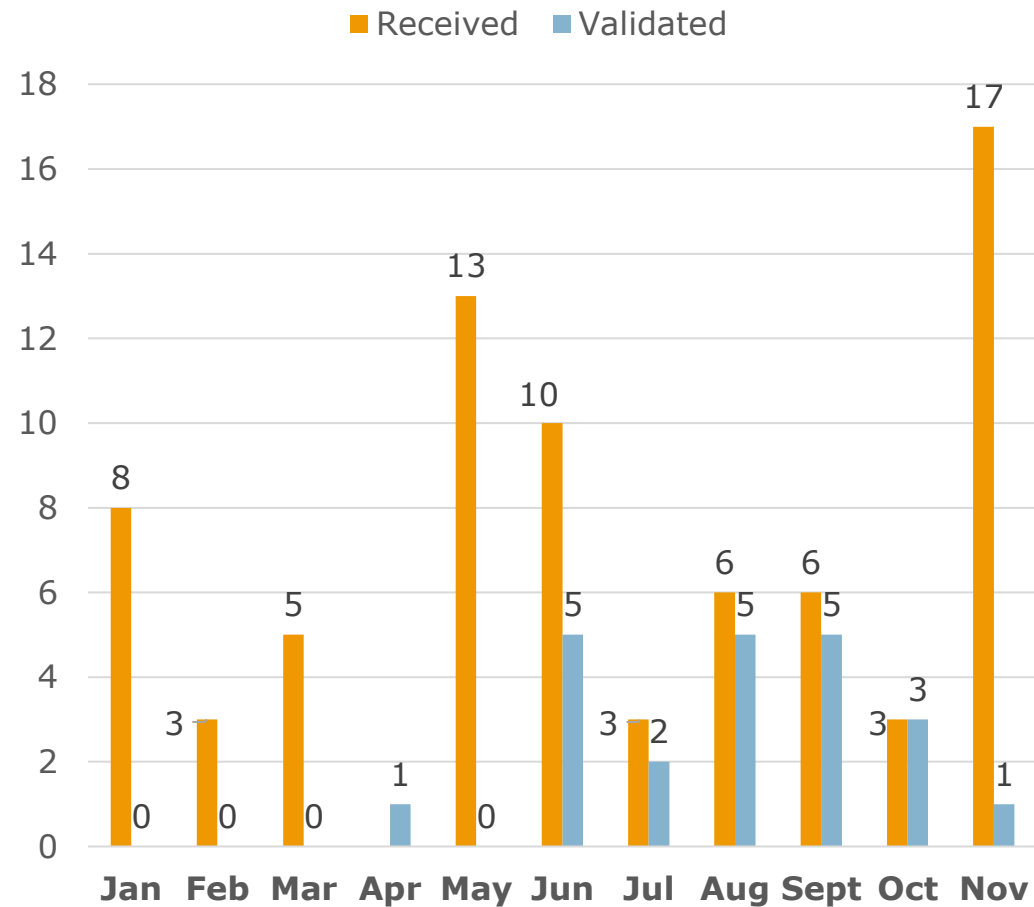
# Post Transparency FEED applications

## How is it going?

Post-TR Applications received and validated  
(2021-2022)



Post-TR Applications received and validated in  
2022 - Zoom



## Timelines from reception to validity of an application

### Pre-Transparency (Year 2020-21)

- Average: **98.6 days**
- Shorter: 30 days
- Longest: 293 days

### Post-Transparency (Year 2021-22\*)

- Average: **114 days**
- Shorter: 47 days
- Longest: 197 days

Time to validate an application has slightly increased

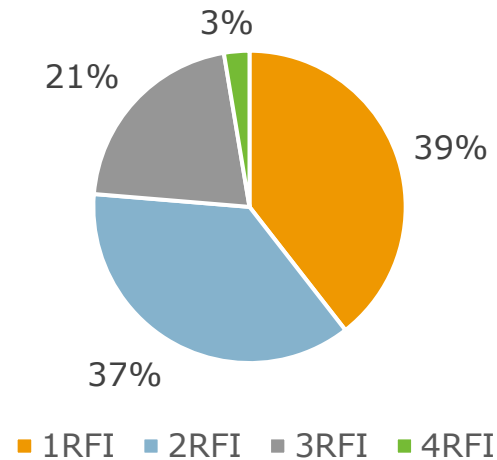
Main reasons:

- Increased number of request for information per application due to TR new measures
- More time needed for applicants to reply to RFI

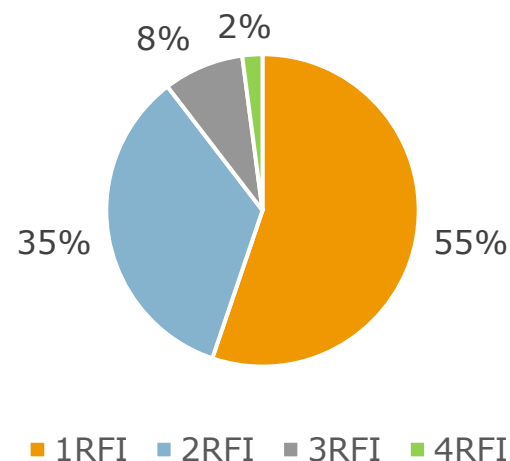
# Requests for information - Overview

Data representative of all the Post-TR applications received in 2021 and 2022, validated or still under completeness check.

2021	
Total RFI sent	38
1 <sup>st</sup> RFI	15
2 <sup>nd</sup> RFI	14
3 <sup>rd</sup> RFI	8
4 <sup>th</sup> RFI	1



2022*	
Total RFI sent	96
1 <sup>st</sup> RFI	53
2 <sup>nd</sup> RFI	33
3 <sup>rd</sup> RFI	8
4 <sup>th</sup> RFI	2

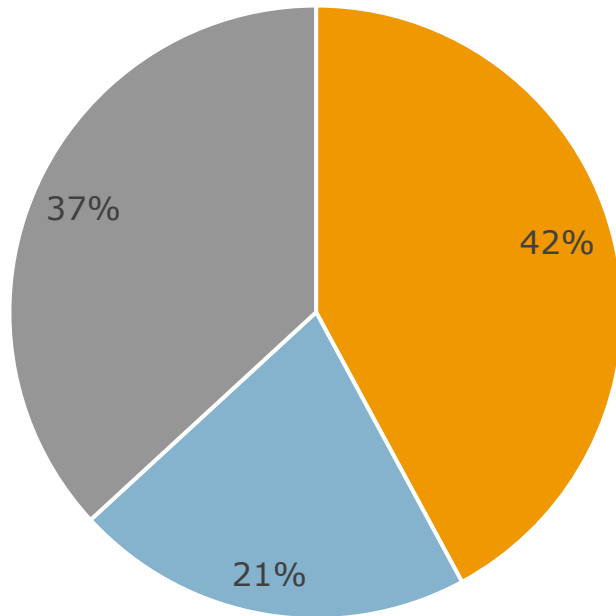


- 100% of completeness checks ended with at least 1 RFI
- Currently no Post-TR applications have been validated after the first completeness check (i.e. without RFI)

\*Information updated as of 11<sup>th</sup> November 2022

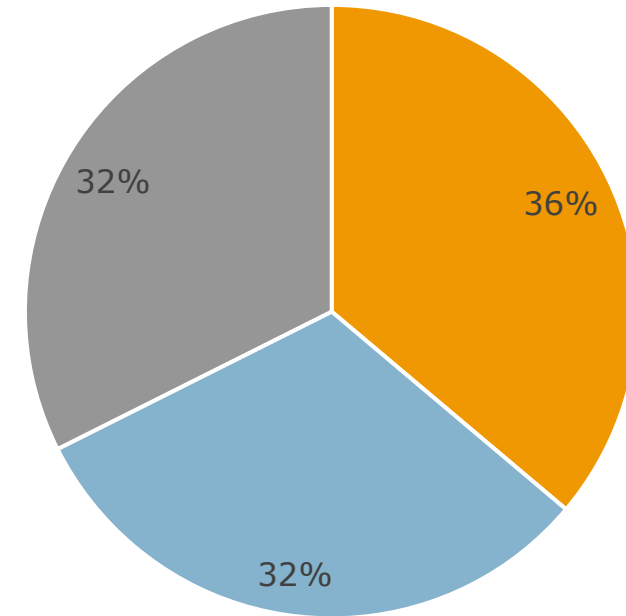
# Requests for information Most frequently asked topic?

## RFI sent on 2021



- Requests on sanitisation of documents
- Requests on NoS
- Requests on guidance docs

## RFI sent on 2022\*



- In 2021 and 2022, the requests related to the **sanitisation of documents** are the most asked in RFI, even if the number is decreasing in 2022.
- The requests related to the compliance with the **NoS** obligations is increasing in 2022, reaching the same number of requests related to compliance with EFSA Guidance documents.

## **Guidance documents**

- Lack of data and information on the presence of nano-particles in the feed additives
- Documents not word-searchable
- Documents in different languages without translation
- Missing/unclear information on IPR of publications
- Documents not properly categorised

## **Sanitisation of documents**

- Personal data not sanitised
- Mismatches between confidential and public version of documents

## **NoS**

- Mismatches between the information in the database and the information provided in the dossier
- Justification for delay in notification not provided
- Justification for not having notified a study not provided
- Justifications not clear/exhaustive for a proper evaluation

# Submission of complementary information following EFSA inconclusive/negative opinion

Applicants, after receiving the request to provide additional data from the EC, must upload the new data in **Portalino** platform.

The submission should consist in two versions:

- **Confidential version:** with personal and confidential data highlighted.
- **Public version:** same content of Confidential version but with personal and confidential data permanently sanitized.

After the acceptance, the public version is published in OpenEFSA.

PSA activity **does not** cover submissions of complementary information

## Light check

### Administrative guidance for the preparation of applications on additives for use in animal nutrition:

- The complementary information should consist of a main document and its annexes accompanied by a signed cover letter listing the content of the submission.

### Sanitisation of documents:

- Permanent sanitization of documents
- Personal data sanitized
- Consistence between confidential and public version of the submission

- Webinars
  - Webinar on application procedure for feed additives and intended renewal applications
  - Webinar on Notification of Studies (NoS)
  - Webinar on confidentiality assessment and content sanitisation in the context of the Transparency Regulation
- Improvements on EFSA website
  - Toolkit for applicants
  - FEED additives applications dedicated page (Eg updated workflow including presubmission steps)
- Update of EFSA guidance documents
- Update of EFSA catalogue\* (currently on-going)
- Implementation of Portalino for submission of complementary information

\*Clarification teleconferences can be requested by applicants or proposed by EFSA during completeness checks to clarify any outstanding issues on the application or when the RFI is not clear to the applicant. In 2021 and 2022, no applicants requested a clarification teleconference for FEED applications.



# Take-home messages

## Useful information

### Q&A

- Send us your questions when preparing a new application via the **GPSA and RPSA** services
- Ask for a **Clarification Teleconference** after receiving a Request for Information during the Completeness Check, if there are doubts on the EFSA request
- You are kindly invited to **participate in the Public Consultations** on the Lists for Intended and Studies and dossiers
- Contact us via Ask EFSA for any other questions

## Legal documents:

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- Consolidated text of Regulation (EC) No 1831/2003 on additives for use in animal nutrition
- Consolidated version Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives
- TR: Practical arrangements
- Q&A on Practical arrangements

## Guidance/training material:

- Administrative guidance for the processing of applications for regulated products (update 2021)
- Updated administrative guidance for the preparation of applications on additives for use in animal nutrition
- Guidance on the renewal of the authorisation of feed additives
- Training programme on Transparency regulation
- Feed additive applications: regulations and guidance web section
- Catalogue of services (update 2021)
- Webinar on application procedure for feed additives and intended renewal applications
- Webinar on Notification of Studies (NoS)
- Toolkit page: <https://www.efsa.europa.eu/en/applications/toolkit>
- User Guide - Notification of Studies (NEW since 01 July)
- User Guide - Pre-application ID (NEW since 01 July)



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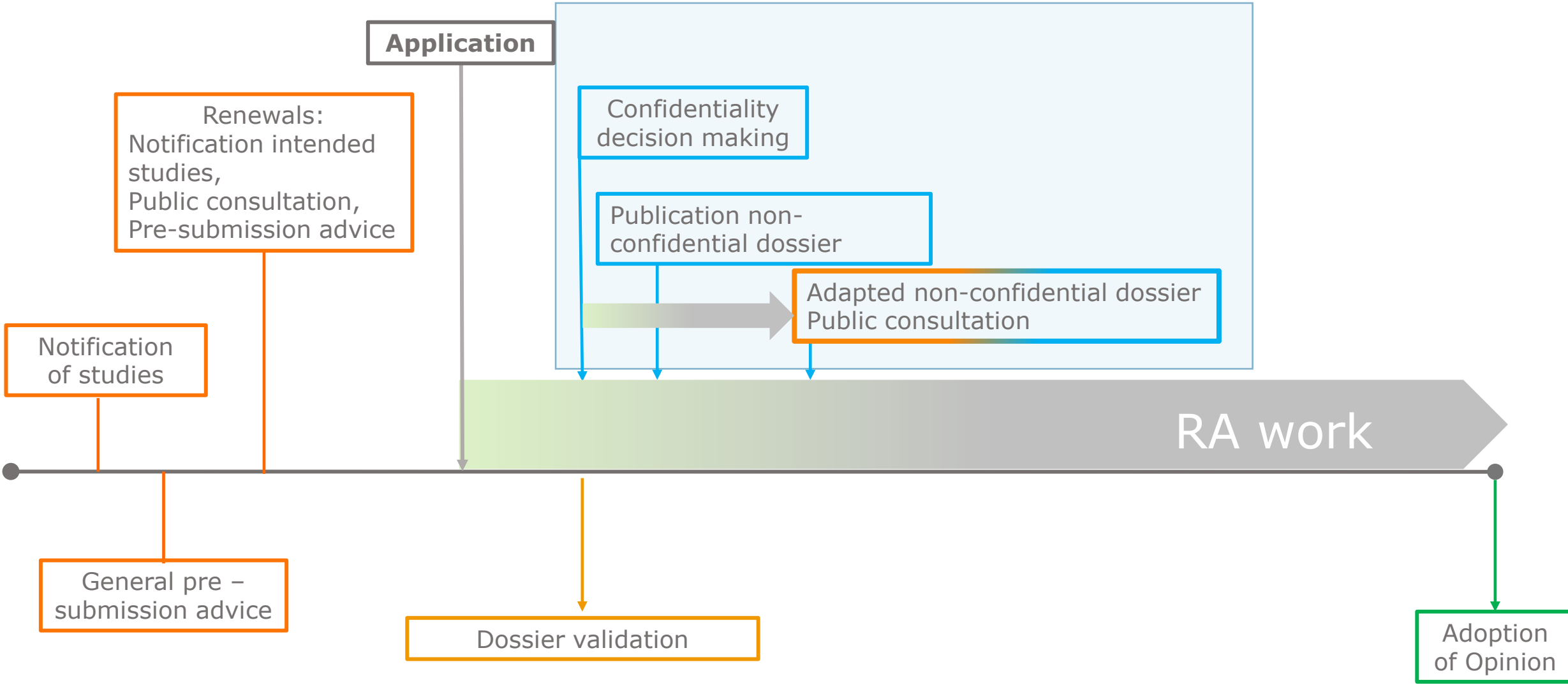


## Contact us


[efsa.europa.eu/en/contact/askefsa](https://efsa.europa.eu/en/contact/askefsa)

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# Life-time of an application



*Open Plenary Session*  
*24 November 2022*



# Confidentiality assessment in the context of feed additives

**Simone Gabbi**

Legal & Assurance Services

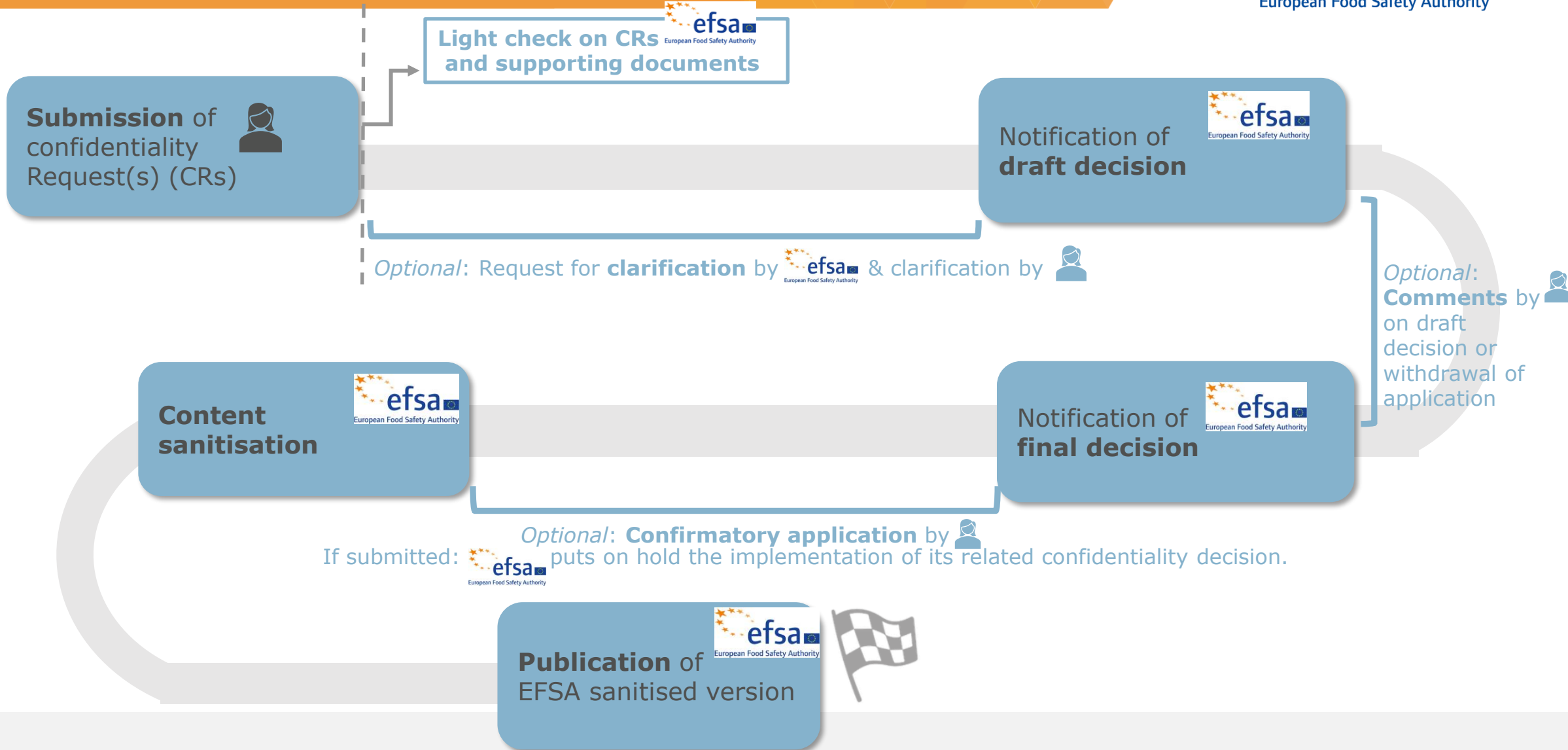
Trusted science for safe food

## Assessment of confidentiality requests

- Proactive disclosure of application dossiers
- Confidentiality as exception to transparency
- Burden of proof on applicants
- Non-disclosure of information claimed confidential pending decision-making



# EFSA confidentiality assessment & sanitisation | Procedural steps



## Confidentiality requests only on items on closed positive list

For the feed additives sector:

### **Article 18(3) of Regulation 1831/2003**

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

## **Article 39(2) of Reg 178/2002**

- a. 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;
- b. commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- c. commercial information revealing sourcing, market shares or business strategy of the applicant;
- d. quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;

# 'Personal data' broad concept (GDPR & EUDPR)

Regulation (EU) 2018/1725 (the EUDPR)

Regulation (EU) 2016/679 (the GDPR)

1

**Definition** of personal data: **wide and open-ended scope**

2

**Examples:** name of individuals, study authors, personal contact details, handwritten signatures, in specific circumstances: names of test facilities, GPS coordinates of trial sites, pictures of people.

3

The **rules apply to personal data regardless** the level of confidentiality: Personal data can be public (e.g.: 39e(1) GFL), internal or sensitive.

## ○ **Masking 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

## ○ **Masking of personal data is not included** in the submission of **confidentiality request**



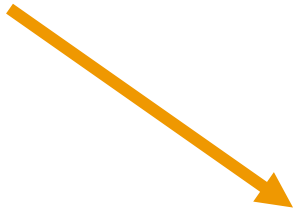
Personal data remains visible in the non-confidential version published online  
Applicant may be held accountable for any infringement of the rules

# ESFC - Building a Confidentiality Request

- Provide non-confidential file, with **permanent** and **visible** blackening
- Define your request:
  - Legal ground
  - Justification
  - Excerpt
  - Location in file
- Add requests, as required

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

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



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

**Step 4/4: Confidentiality requests** \* = Mandatory field

Zip files

Full version \*

Non confidential version \*

Confidentiality Request

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

File name 1 \*

Ground \*

Justification \*  19 / 4000

Excerpt of the text \*  333 / 4000

Related section \*  8 / 4000

Potential harm \*  Yes  No

Worthiness of legal protection \*  Yes  No

Provide non-confidential file with **permanent** and **visible** blackening





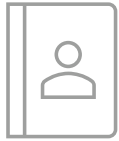
Confidentiality requests shall be **introduced at the time of the submission of documents/data** and can **only** be **modified or complemented upon EFSA request**

1

**One confidentiality request per document per legal ground**



**Quote the excerpt, or at least precise identification** of the location(s) of the information item(s) claimed confidential in the confidentiality request, at least by referring to the **name of the document, page** and **number of the paragraph**



Provide functioning e-mail address and ensure **business continuity** (e.g. referring to **functional mailbox**)



**Faster replying** to and addressing of EFSA`s requests for clarifications = **faster processing** of your confidentiality requests



If you **agree with EFSA`s draft decision** + **reply immediately** to EFSA expressing explicitly your agreement = **faster issuance of the final decision**

## Legal documents

- TR: [Regulation \(EU\) 2019/1381](#)
- General Food Law: [consolidated text of Regulation \(EC\) No 178/2002](#)
- Consolidated text of [Regulation \(EC\) No 1831/2003 on additives for use in animal nutrition](#)
- PAs on transparency and confidentiality: [Practical Arrangements concerning transparency and confidentiality](#)
- [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](#)

## Guidance/training materials

- Q&As on PAs: [Questions and Answers on the EFSA Practical Arrangements](#)
- Updated administrative guidance for the [preparation of applications on additives for use in animal nutrition](#)
- Guidance on the [renewal of the authorisation of feed additives](#)
- Administrative guidance for the [processing of applications for regulated products](#)
- 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](#)

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24 November 2022

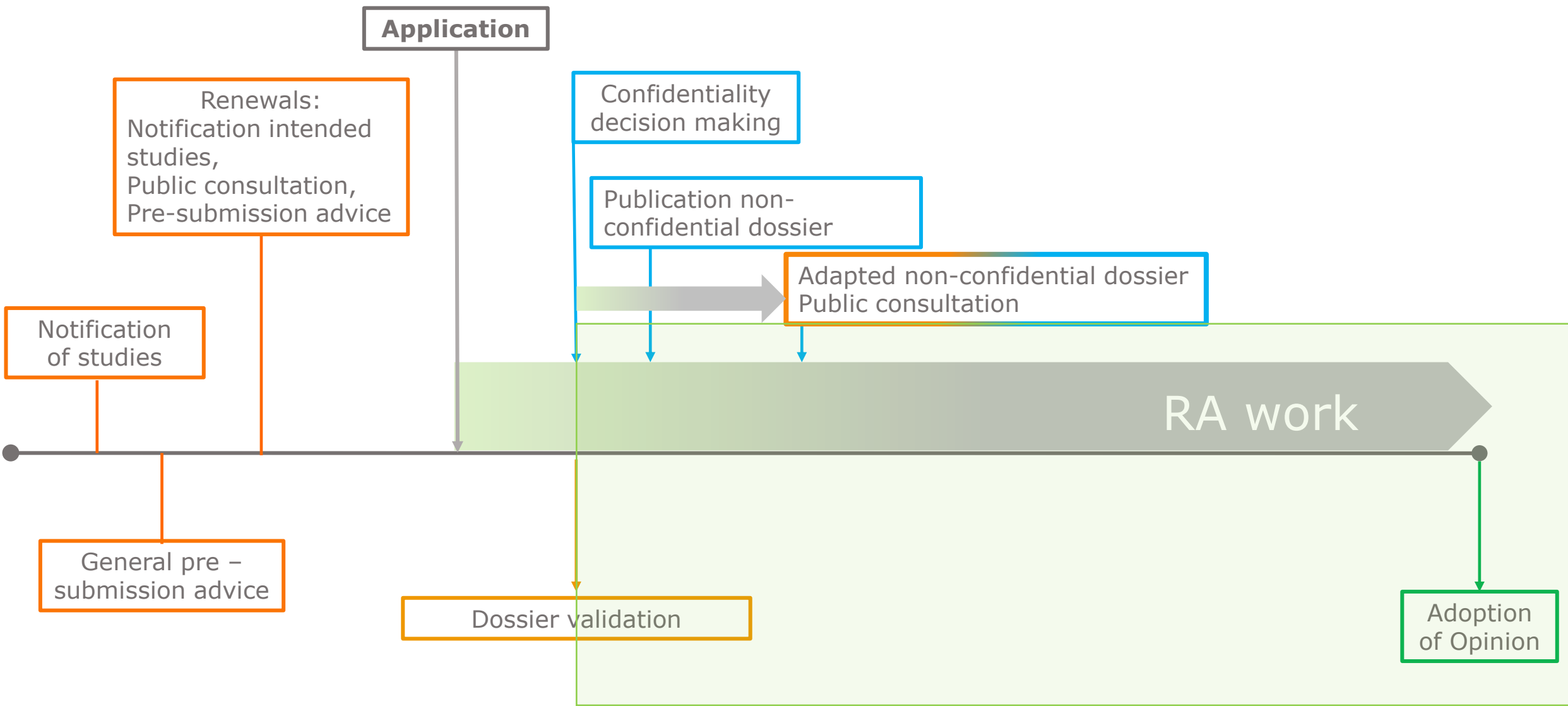


# FEEDAP Panel and FEED Team – general planning

**FEED TEAM**

Trusted science for safe food

# Life-time of an application

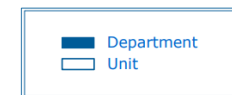
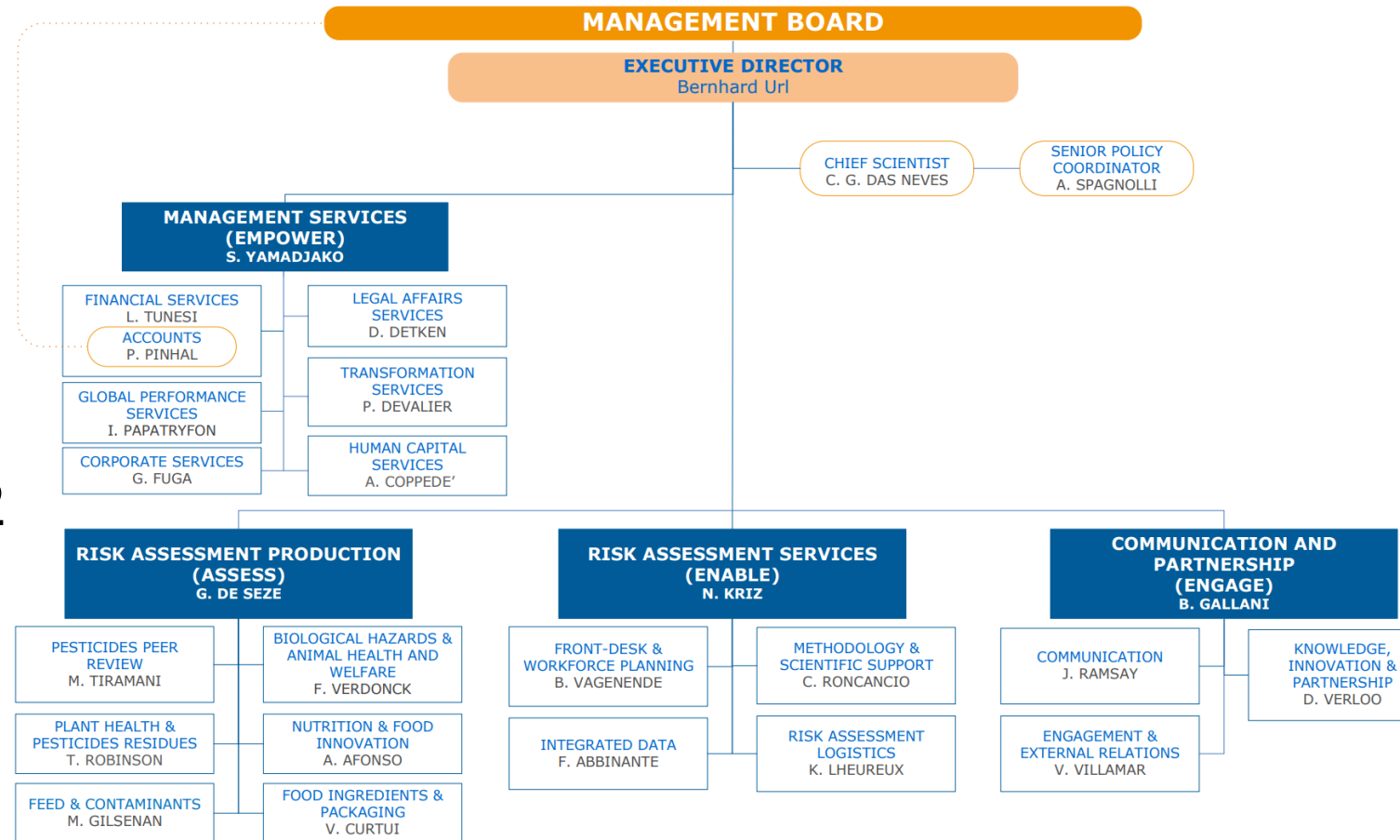


- FEEDAP - FEEDCO
  
- Work ahead 2022-2023
  - Applications – current work
  - Guidance update
    - Safety for the user
    - Guidance on Efficacy
    - Guidance on Micro – Statement and pipelines
  - Other on-going work

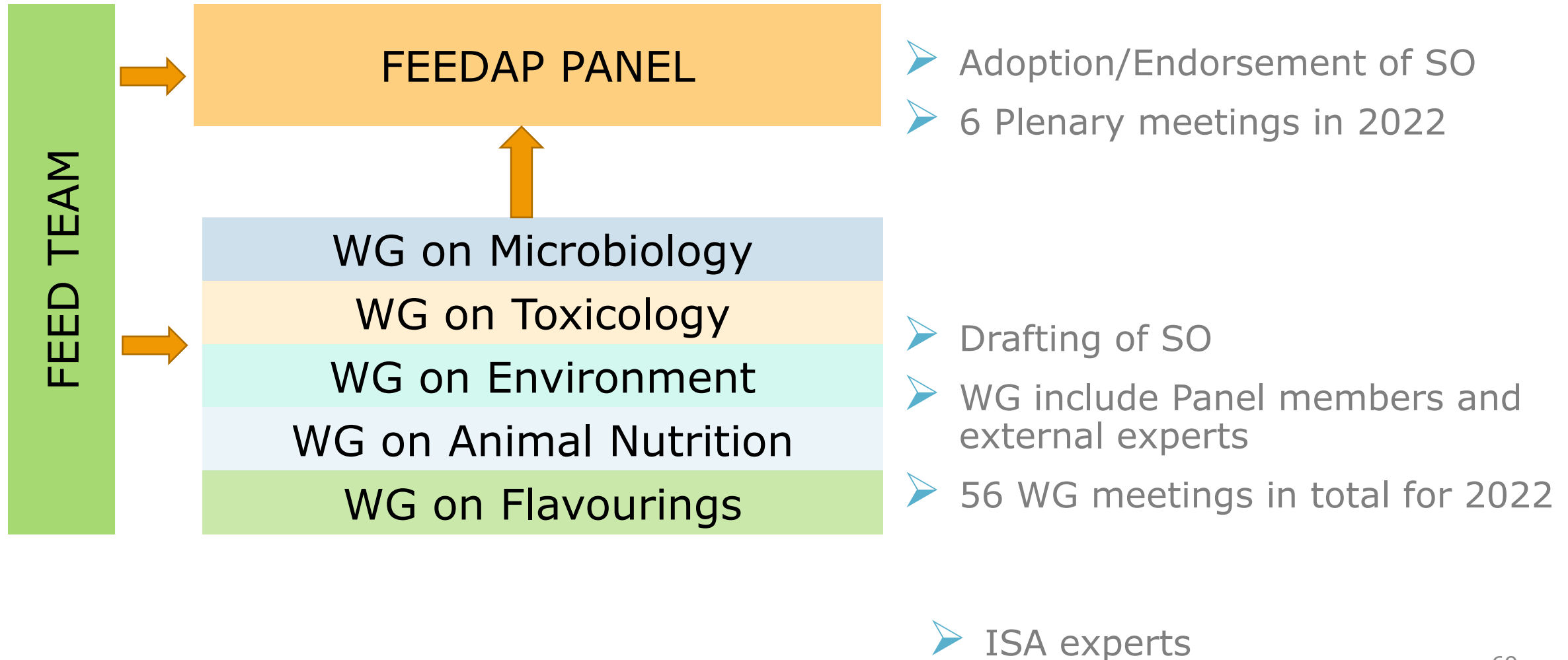
- FEEDAP Panel: Substances/products that are intentionally added to feed

- FEEDCO Unit as of 1/1/2022
  - Two teams
  - Providing support to two Panels (FEEDAP – CONTAM)
  - Mary Gilsean - HoU

Organisational Structure on 01/11/2022



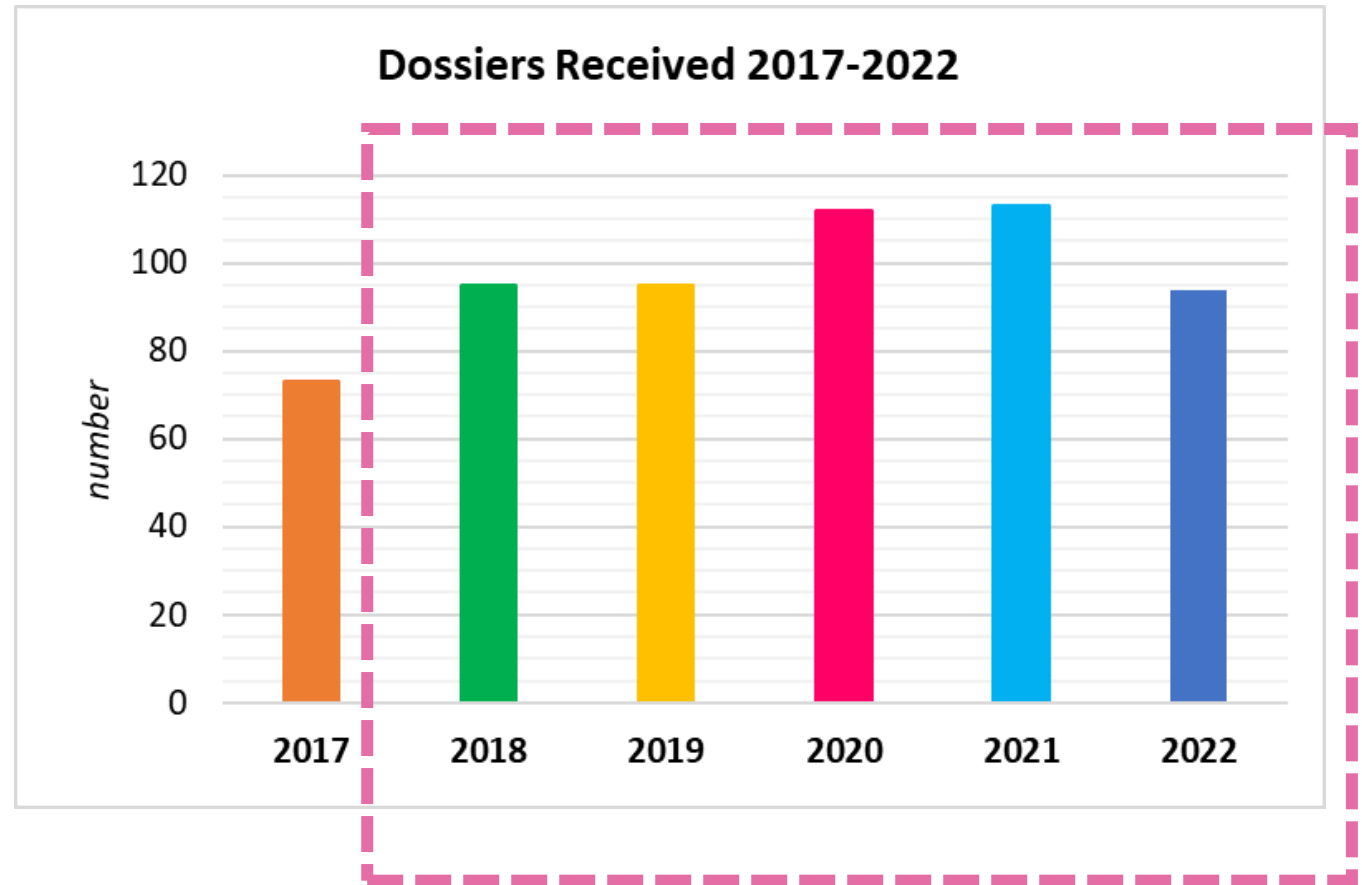




- FEEDAP - FEEDCO
  
- Work ahead 2022-2023
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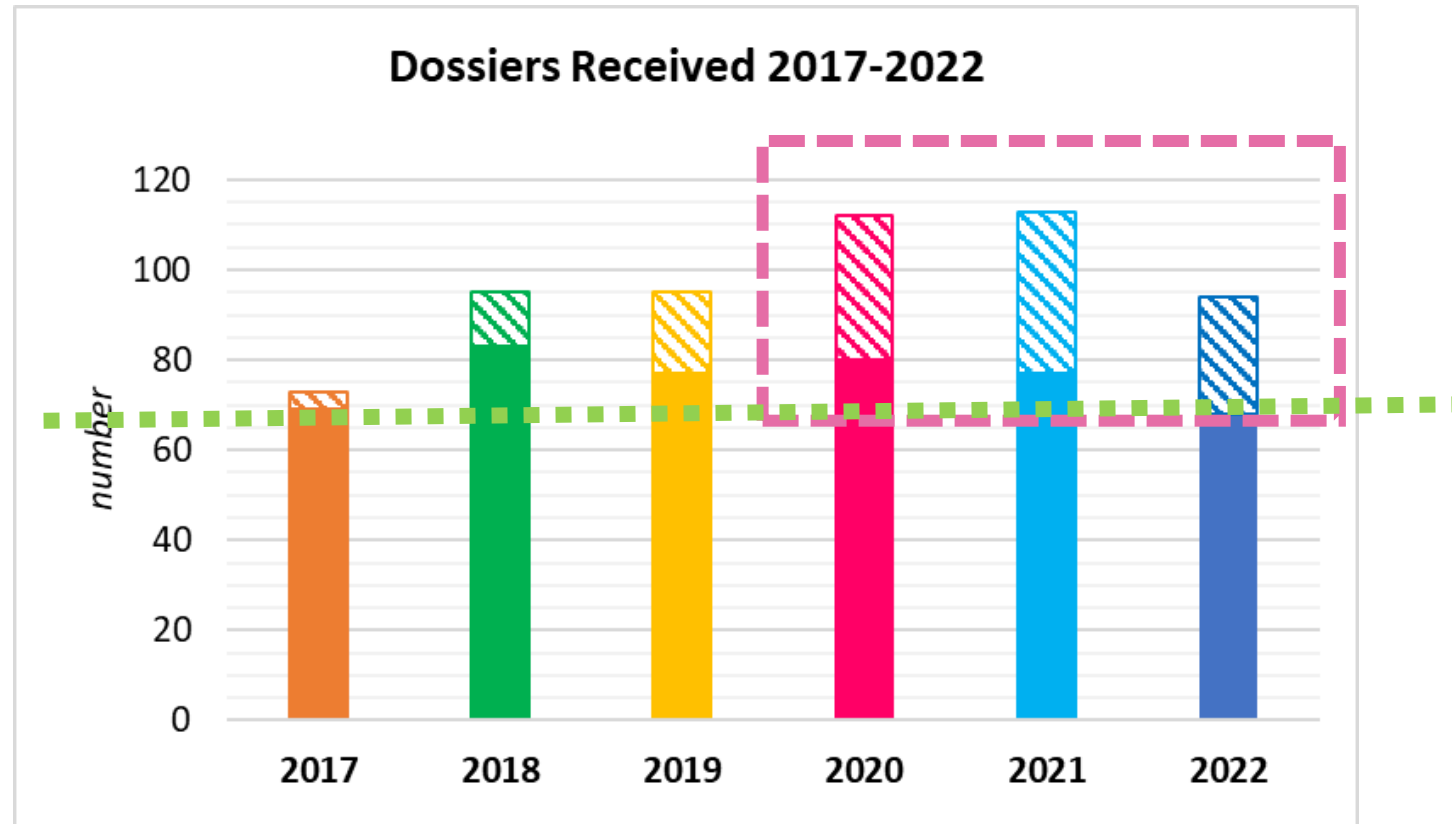
## Assessment of applications under Regulation (EC) No 1831/2003

- New additives, new uses, modifications of the authorisation, renewals
- Last 5 years – ca 100 dossiers per year



## Assessment of applications under Regulation (EC) No 1831/2003

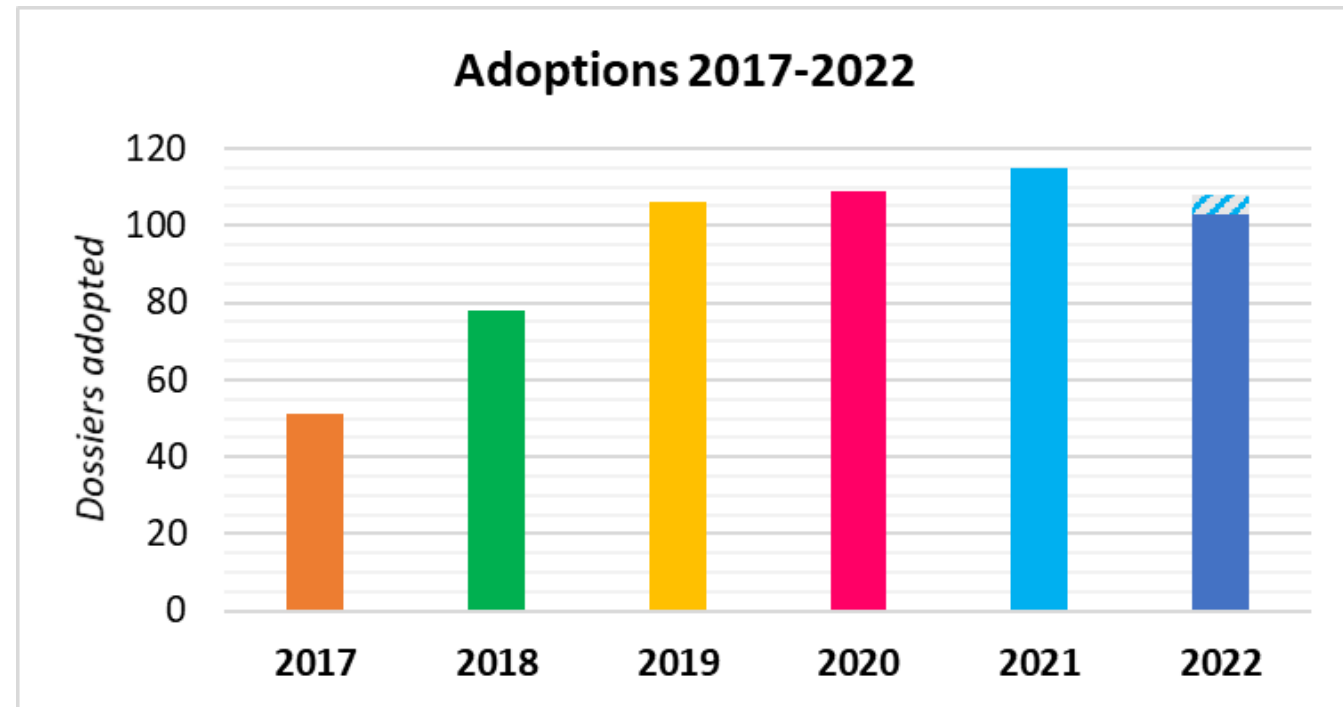
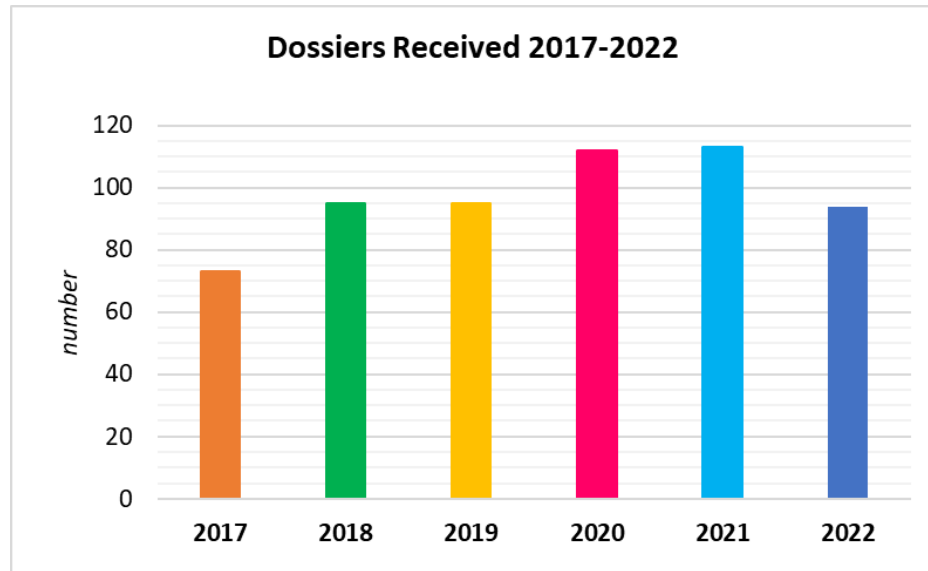
- New additives, new uses, modifications of the authorisation, **renewals**
- Last 5 years – ca 100 dossiers per year
- **Renewal applications** in last three years - 30% of the dossiers received
- 33 post-transparency in 2021



## Assessment of applications under Regulation (EC) No 1831/2003

- Re-evaluation dossiers?
  - Number of dossiers/questions not closed ca 75
  - Most of them sensory additives - flavours
- Re-evaluation of Flavourings
  - Assessment of chemically defined (CD) substances was done first
    - A total of 596 substances to be assessed – 592 assessed
    - Circa 200 may require follow up opinions
  - Assessment of Botanically defined (BD) substances followed
    - A total of 188 substances to be assessed– 52 assessed
    - Work plan to finish the assessments in 2026

# From dossier to Opinion



Ca 1,300 opinions adopted 2003-2022

- FEEDAP - FEEDCO
  
- Work ahead 2022-2023
  - Applications – current work
  - **Guidance update**
    - Safety for the user
    - Guidance on Efficacy
    - Guidance on Micro – Pipelines
  - Other on-going work

Identity and Characterisation  
Characterisation of Microorganisms

Safety for the Target species

Safety for the Consumer

Safety for the User

Safety for the Environment

Efficacy

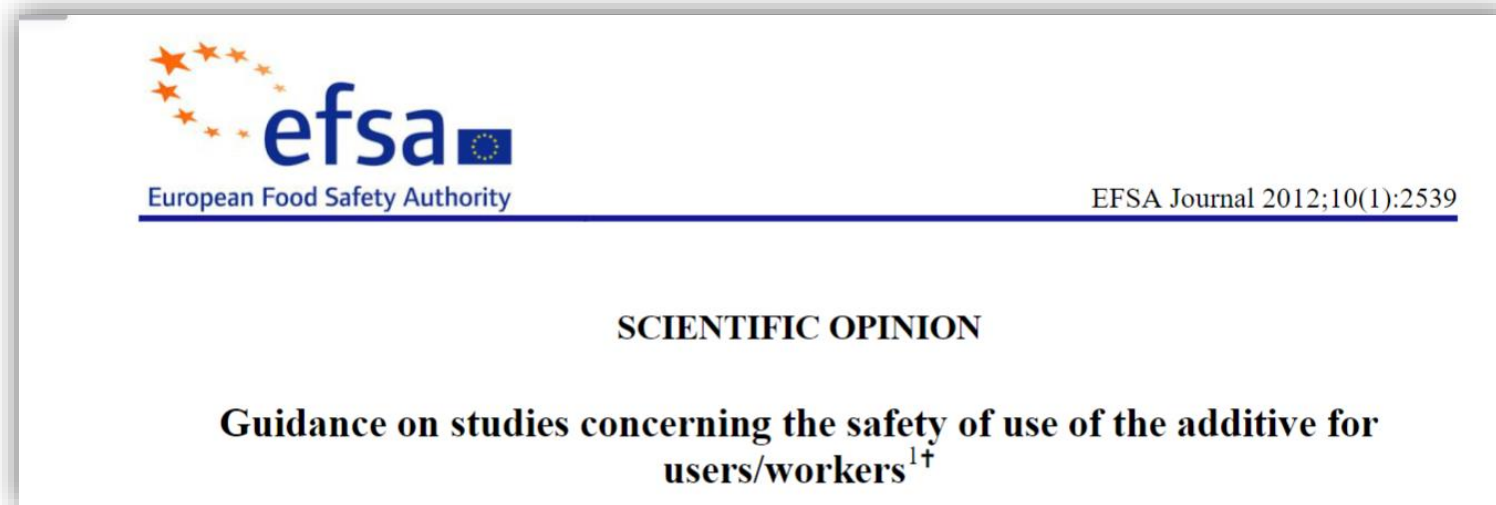
Renewal



Identity and Characterisation	2017
Characterisation of Microorganisms	2018
Safety for the Target species	2017
Safety for the Consumer	2017
Safety for the User	2012
Safety for the Environment	2019
Efficacy	2018
Renewal	2021

- Last Guidance update 2016-2019
- Need to update?

## Safety for the User

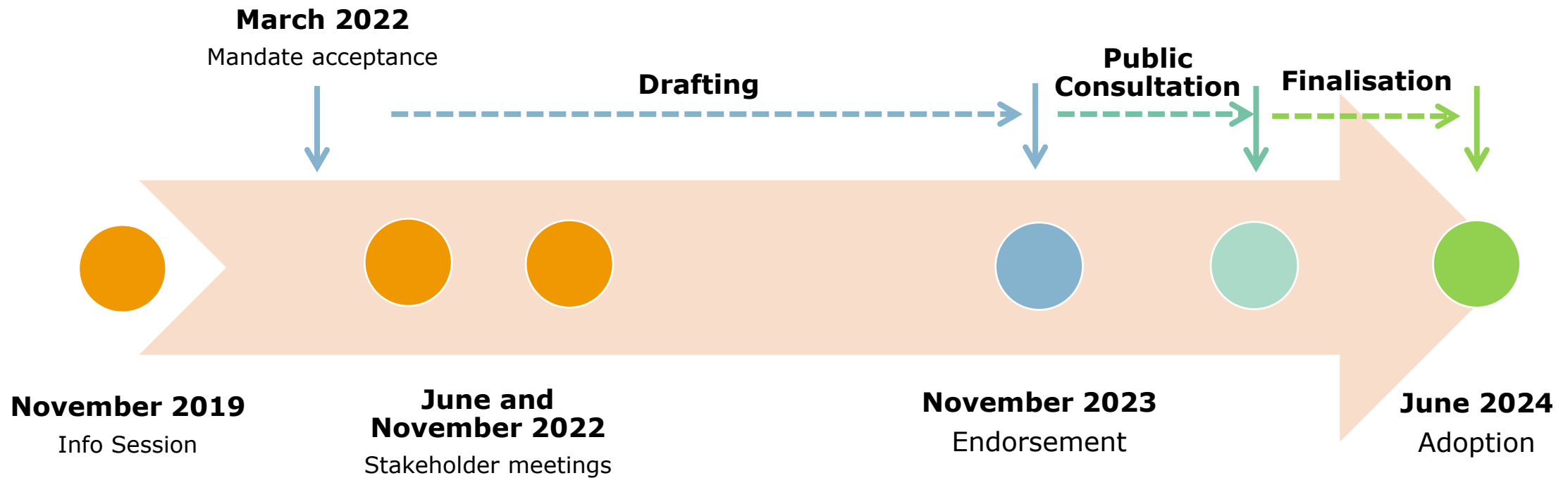


- Last update 2012
- Effects on the respiratory system, skin and eyes – systemic –
- Exposure assessment


## Safety for the User – Update to...

- Scientific developments/practices
  - Harmonisation with other frameworks
  - Use of existing data
  - Step-wise approach
- 
- ✓ Fit for purpose – risk assessment – risk manager – proportionate requirements

## Safety for the User – timeline



## Characterisation of microorganisms



**GUIDANCE**

ADOPTED: 21 February 2018  
doi: 10.2903/j.efsa.2018.5206

**Guidance on the characterisation of microorganisms used as feed additives or as production organisms**

Update in 2018:

- Introduction of new requirements for the data – WGS, thresholds for DNA detection
- Comprehensive merging of well-established guidances

Statement  
WGS 2021

## Characterisation of microorganisms – Update to...

- Current practices and most frequent questions
- Phenotypic antimicrobial susceptibility

**Table 2:** Microbiological cut-off values (mg/L)

	Ampicillin	Vancomycin	Gentamicin	Kanamycin	Streptomycin	Erythromycin	Clindamycin	Tetracycline	Chloramphenicol	Tylosin	Ciprofloxacin	Colistin	Fosfomycin
<i>Lactobacillus</i> obligate homofermentative <sup>(a)</sup>	2	2	16	16	16	1	4	4	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus acidophilus</i> group	1	2	16	64	16	1	4	4	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus</i> obligate heterofermentative <sup>(b)</sup>	2	n.r.	16	64	64	1	4	8 <sup>(c)</sup>	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus reuteri</i>	2	n.r.	8	64	64	1	4	32	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus</i> facultative heterofermentative <sup>(d)</sup>	4	n.r.	16	64	64	1	4	8	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus plantarum/pentosus</i>	2	n.r.	16	64	n.r.	1	4	32	8	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus rhamnosus</i>	4	n.r.	16	64	32	1	4	8	4	n.r.	n.r.	n.r.	n.r.
<i>Lactobacillus casei/paracasei</i>	4	n.r.	32	64	64	1	4	4	4	n.r.	n.r.	n.r.	n.r.
<i>Bifidobacterium</i>	2	2	64	n.r.	128	1	1	8	4	n.r.	n.r.	n.r.	n.r.
<i>Pediococcus</i>	4	n.r.	16	64	64	1	1	8	4	n.r.	n.r.	n.r.	n.r.
<i>Leuconostoc</i>	2	n.r.	16	16	64	1	1	8	4	n.r.	n.r.	n.r.	n.r.
<i>Lactococcus lactis</i>	2	4	32	64	32	1	1	4	8	n.r.	n.r.	n.r.	n.r.
<i>Streptococcus thermophilus</i>	2	4	32	n.r.	64	2	2	4	4	n.r.	n.r.	n.r.	n.r.
<i>Bacillus</i>	n.r.	4	4	8	8	4	4	8	8	n.r.	n.r.	n.r.	n.r.
<i>Propionibacterium</i>	2	4	64	64	64	0.5	0.25	2	2	n.r.	n.r.	n.r.	n.r.
<i>Enterococcus faecium</i>	2	4	32	1,024	128	4	4	4	16	4	n.r.	n.r.	n.r.
<i>Corynebacterium</i> and other Gram-positive	1	4	4	16	8	1	4	2	4	n.r.	n.r.	n.r.	n.r.
Enterobacteriaceae	8	n.r.	2	8	16	n.r.	n.r.	8	n.r.	n.r.	0.06	2	8

- Bacteria - yeasts
- Where possible/needed at species level
- List of antibiotics

## Characterisation of microorganisms – Update to...

- Current practices and most frequent questions
- Check the need for update on the phenotypic antimicrobial resistance thresholds
- EFSA statement on WGS data requirements
  - In use in the risk assessment – not in the guidance
  - Document subject to update to consider:
    - New developments/uses in the technologies/tools
    - Knowledge gained in the initial implementation and during the development of pipelines

## Microorganisms Pipelines Service - MoPS

Develop and implement 3 pipelines (**bacteria, yeasts/filamentous fungi and viruses**) to support the risk assessment of WGS data

### How?

- ✓ Build a **secure and confidential environment**;
- ✓ Perform the **sequence quality check** of the WGS data;
- ✓ Use the WGS data to **taxonomically identify** and **characterise** the microorganism;

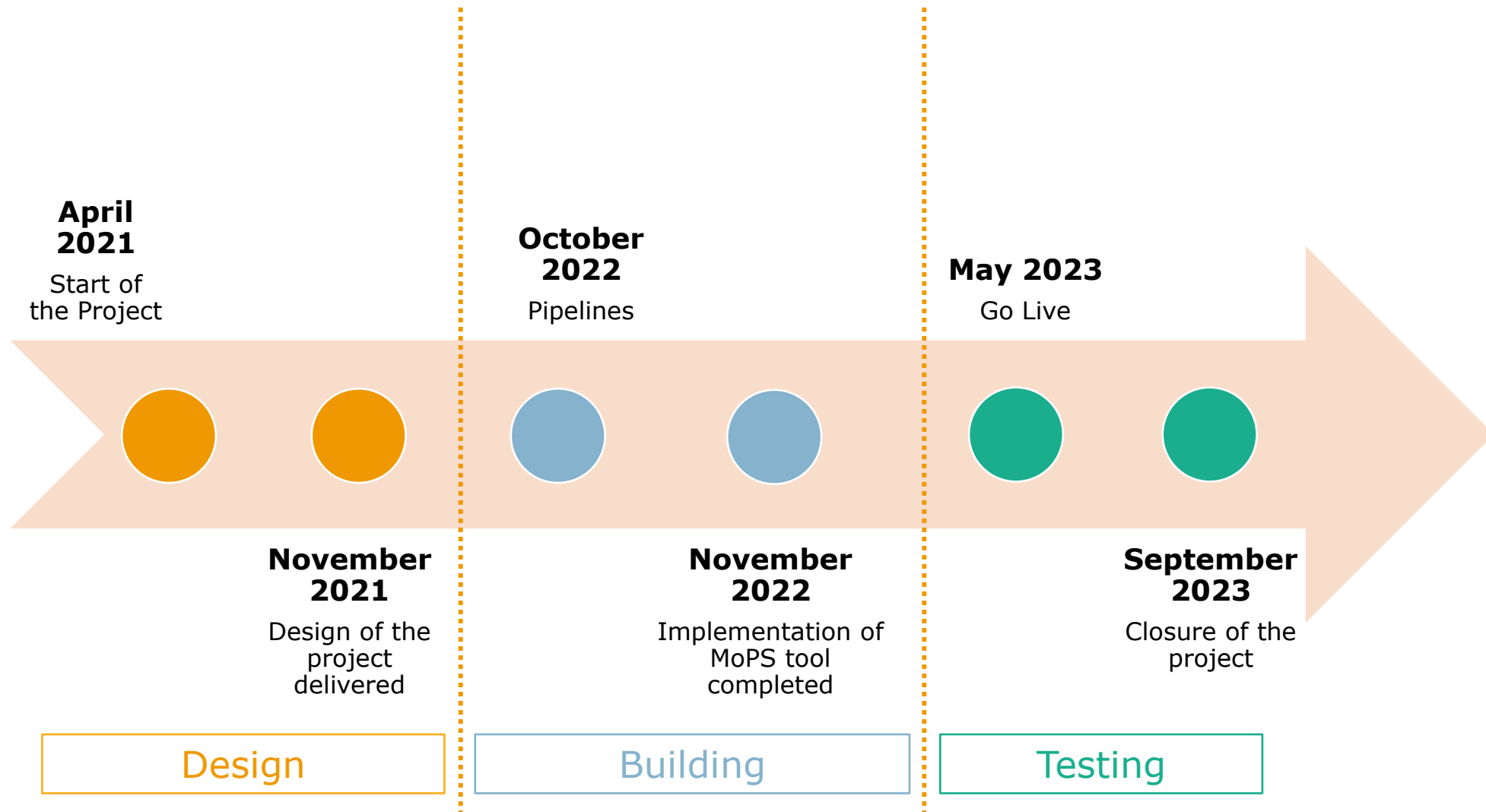
### Why?

- ✓ Address the needs of **different risk assessments domains**;
- ✓ **Comprehensive** microorganisms risk assessment;
- ✓ **Standardised** microorganism WGS based analysis;

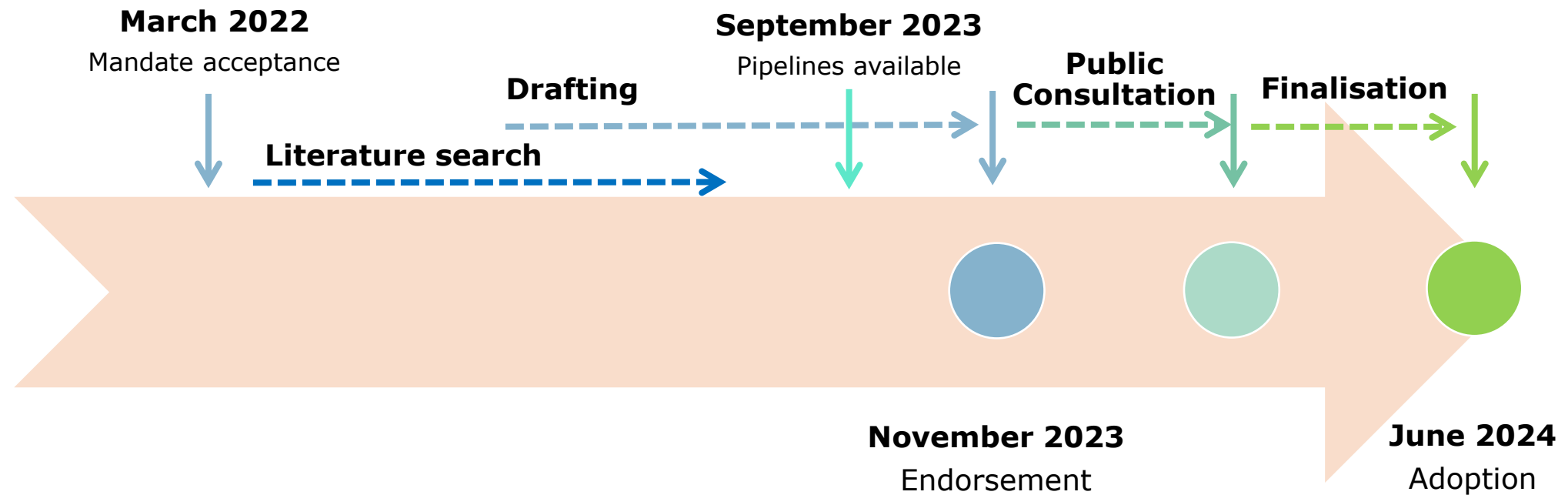


- Microorganisms Pipelines Service – codes
- Pipelines
  - Develop pipelines for microorganisms not already covered;
  - Keep abreast with the latest tools/databases.


# Pipelines - Timeline



## Characterisation of microorganisms – timeline



## Efficacy



**GUIDANCE**

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ADOPTED: 17 April 2018  
doi: 10.2903/j.efsa.2018.5274

**Guidance on the assessment of the efficacy of feed additives**

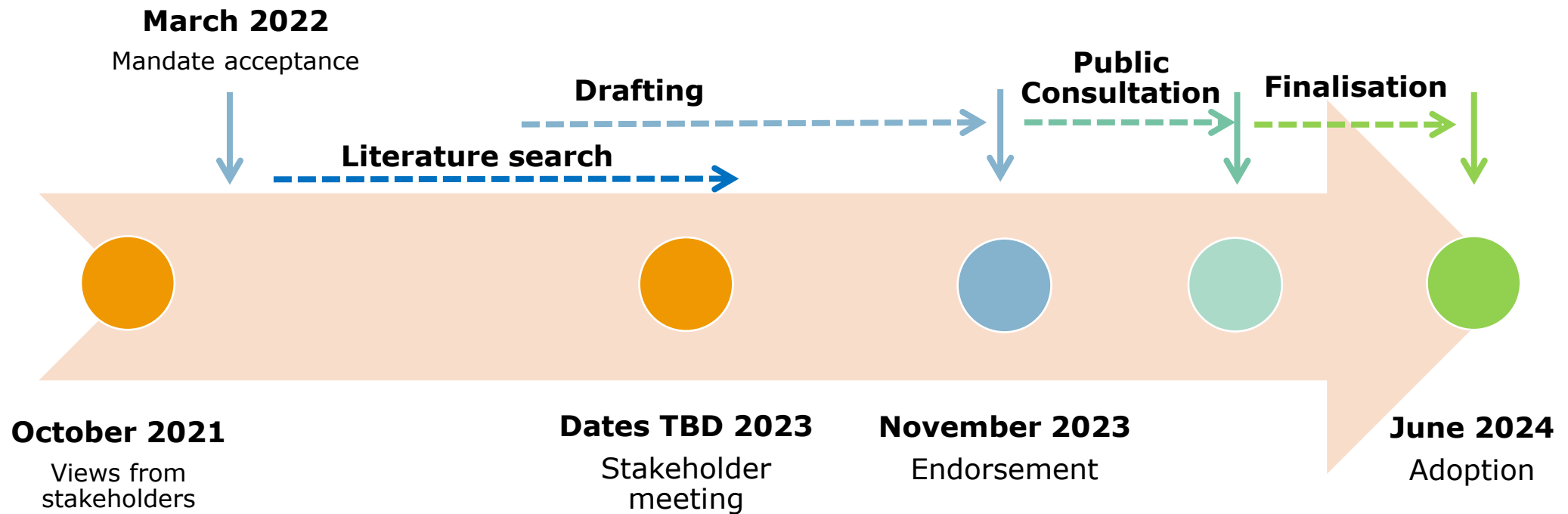
Update in 2018:

- All-in-one guidance: category/functional group requirements and guidance on the conduct/reporting of studies
- Number of studies required and extrapolation of data

## Efficacy – Update to...

- Update in some functional groups
  - Introduced in Regulation 1831/2003 - physiological condition stabilisers
  - Substances which favourably affect the environment
  - In use in the risk assessment – not in guidance (e.g., hygiene condition enhancers)
- Update in the Regulatory framework (ideally should be first)
- Consideration for further refinements/reduction
- ✓ Fit for purpose - innovations

## Efficacy – timeline



Identity and Characterisation  
Characterisation of Microorganisms

Safety for the Target species

Safety for the Consumer

Safety for the User

Safety for the Environment

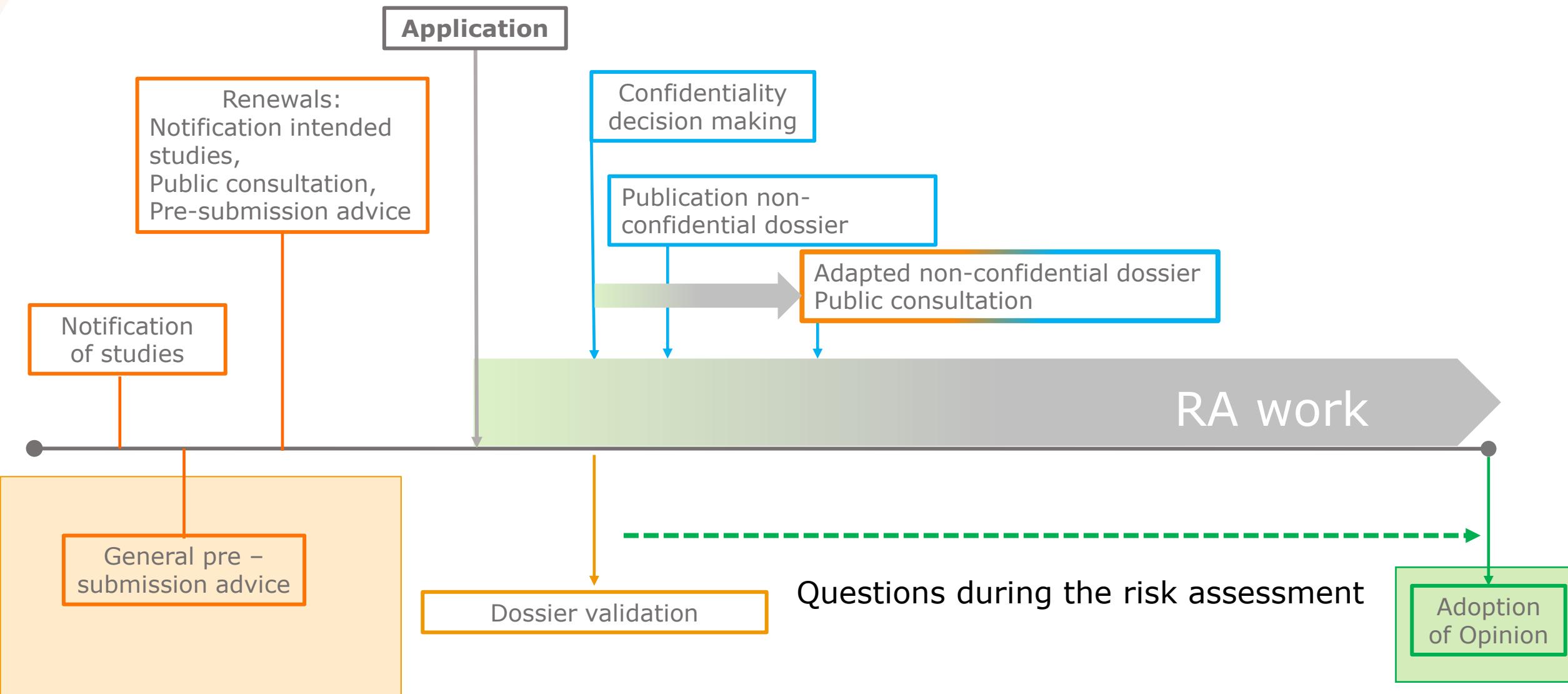
Efficacy

Renewal

## Guidance improvements

- ✓ Fit for purpose;
- ✓ Up-to-date methods/tests/data;
- ✓ Clear requirements - predictability;

# Life-time of an application





- FEEDAP - FEEDCO
  
- Work ahead 2022-2023
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    - Safety for the user
    - Guidance on Efficacy
    - Guidance on Micro – Pipelines
  - **Other on-going work**

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<b>Plenary</b>	<b>Dates</b>
<b>165</b>	31 January-2 February
<b>166</b>	21-23 March
<b>167</b>	11-12 May
<b>168</b>	4-6 July
<b>169</b>	26-28 September
<b>170</b>	14-16 November (tentative open)



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