



Catalogue of services and the new administrative guidance for the processing of applications for regulated products

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CONTENT OF THIS PRESENTATION

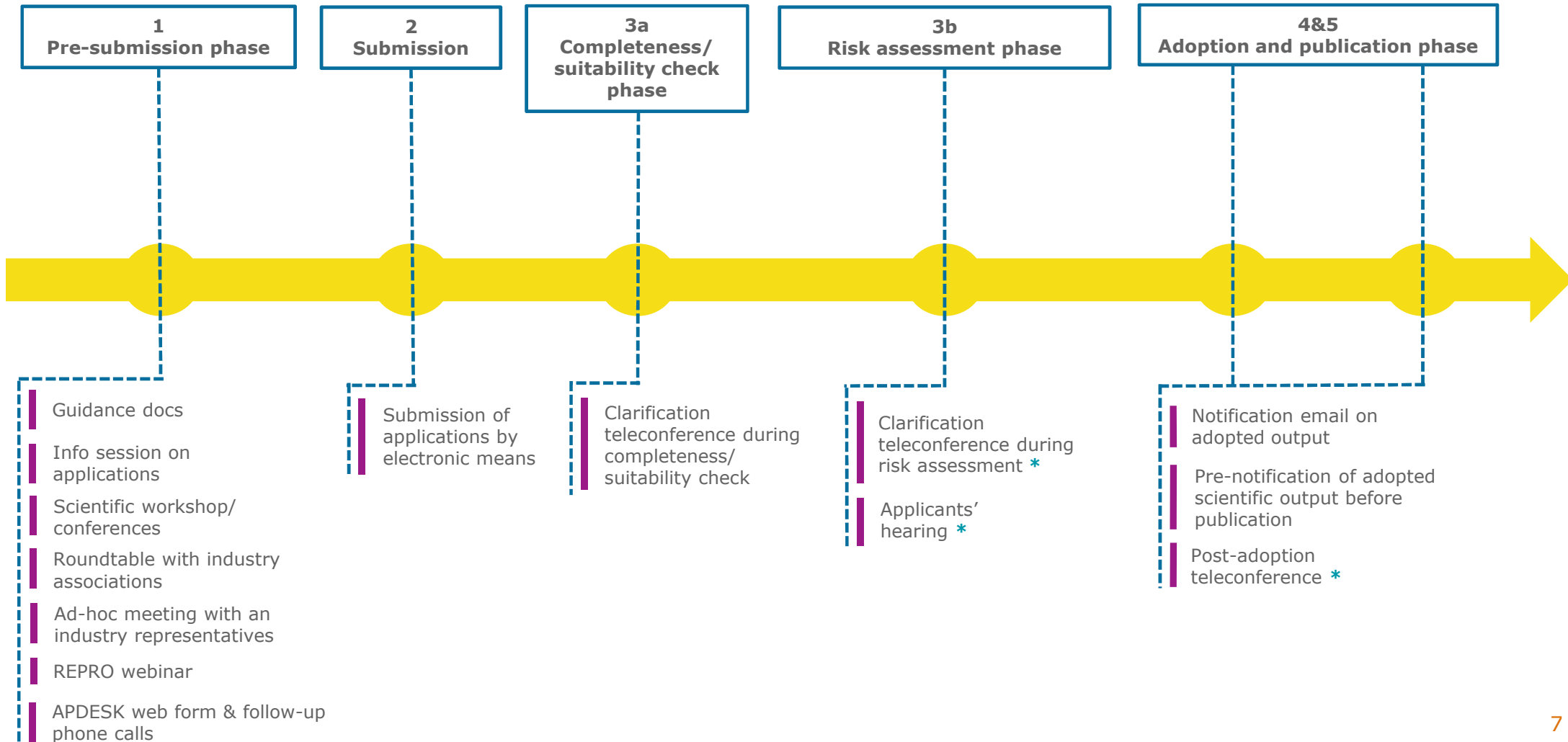
- **The EFSA Catalogue of services**
- **Administrative guidance for the processing of applications for regulated products**

INTRODUCTION TO THE CATALOGUE

Purposes of the Catalogue

- Provide an **overview of the support initiatives** currently in place for applicants, Member States, industry representatives, etc
- Set up a global **comprehensive list** of all services which can vary for type, scope and impact
- Create awareness and mutual understanding on **opportunities for dialogue** with EFSA
- Encourage applicants and other parties to **use the catalogue**

CATALOGUE OF SERVICES



CLARIFICATION TELECONFERENCE DURING RA



EFSA
staff



APPLICANT



Applicant



Telephone conference to clarify a request for additional information sent by EFSA during the Risk assessment (RA) phase



EFSA REPRO units staff, applicant



1 hour (indicative timeline)



An applicant upon reception of an EFSA letter requesting additional information

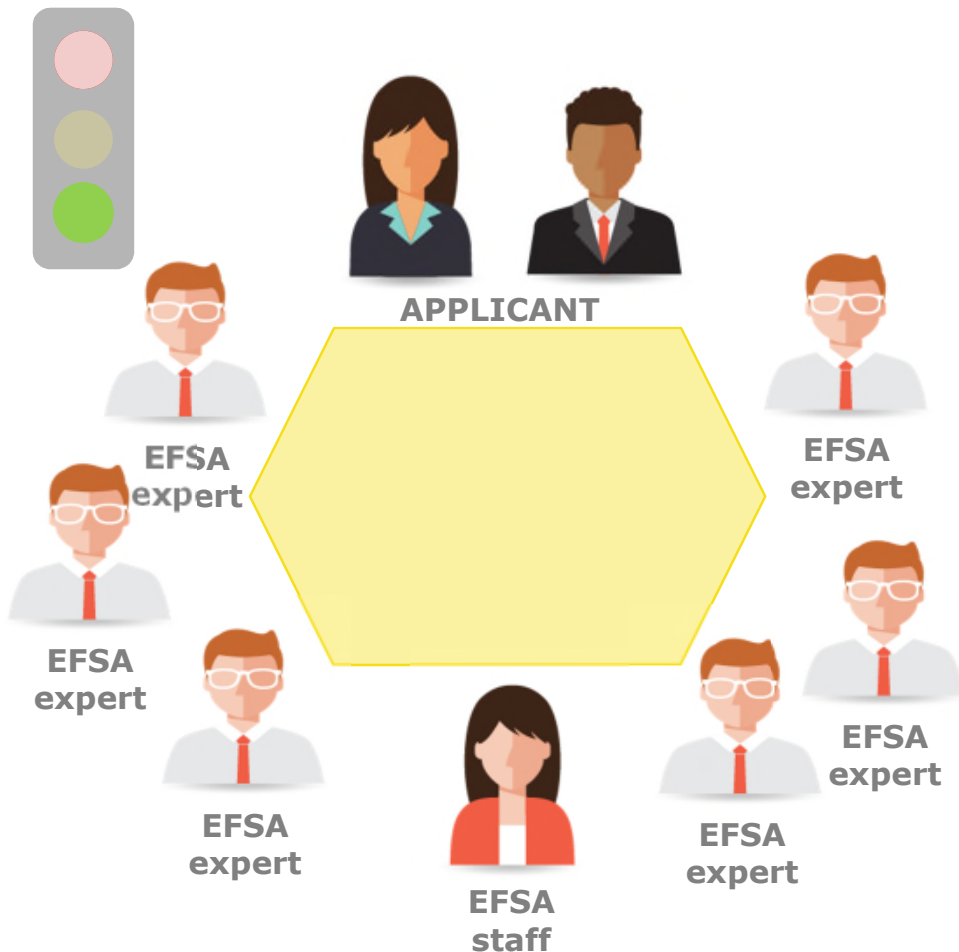


Clarify the scientific rationale of individual questions raised during RA, ensure understanding of the questions to be answered. It does not provide pre-assessment on upcoming responses



EFSA e-mail acknowledging that the teleconference took place indicating date and duration

APPLICANTS' HEARING



EFSA invites the applicant to attend a specific agenda item of working groups or Panel meetings



An applicant is invited to an applicants' hearing to answer question raised by the EFSA working groups and Panels experts



EFSA experts, EFSA staff, applicant



2 hours maximum



EFSA's working groups and/or Panels members



Clarify additional data or supplementary information provided when considered not appropriate or unclear, or to clarify any outstanding issues on the application



Participation to an applicants' hearing is reported in the meeting minutes published on EFSA website. EFSA staff sends a follow-up letter to the applicant to ensure mutual understanding

POST-ADOPTION TELECONFERENCE



EFSA
staff



APPLICANT



Applicant



Telephone conference on adopted scientific output to present the content of the final scientific output, as expressed by the Panels and/or EFSA



EFSA staff, applicant, EC



2 hours



An applicant who has filed an application to EFSA for which an EFSA scientific output was published



Explain the scientific rationale of the final output from the Panel and/or EFSA, clarify recommendations (if applicable), clarify the sources of evidence and factors that influenced the outcome. Such teleconference do not provide any scientific advice for future submissions

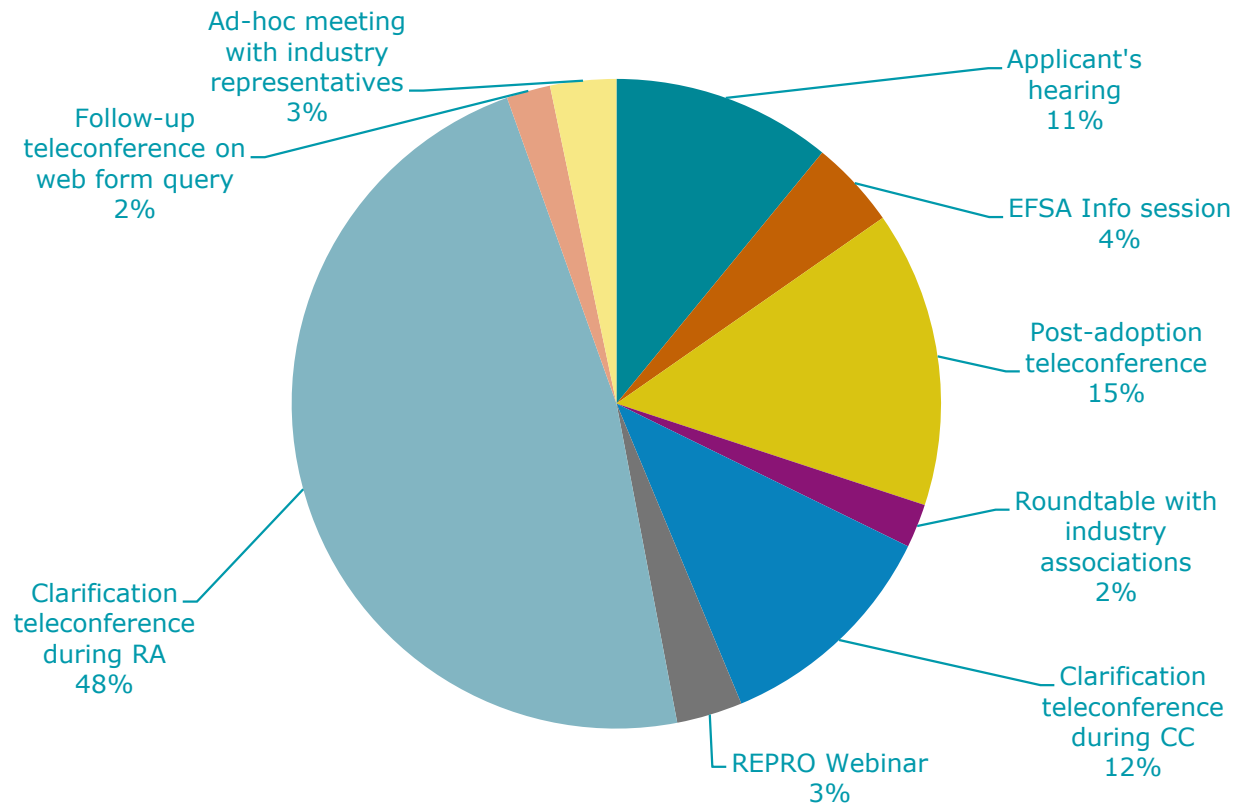


Follow-up letter including main points of discussion to keep track of what has been discussed

OVERVIEW ON SERVICES REQUESTED

Status: March 2015 – May 2018

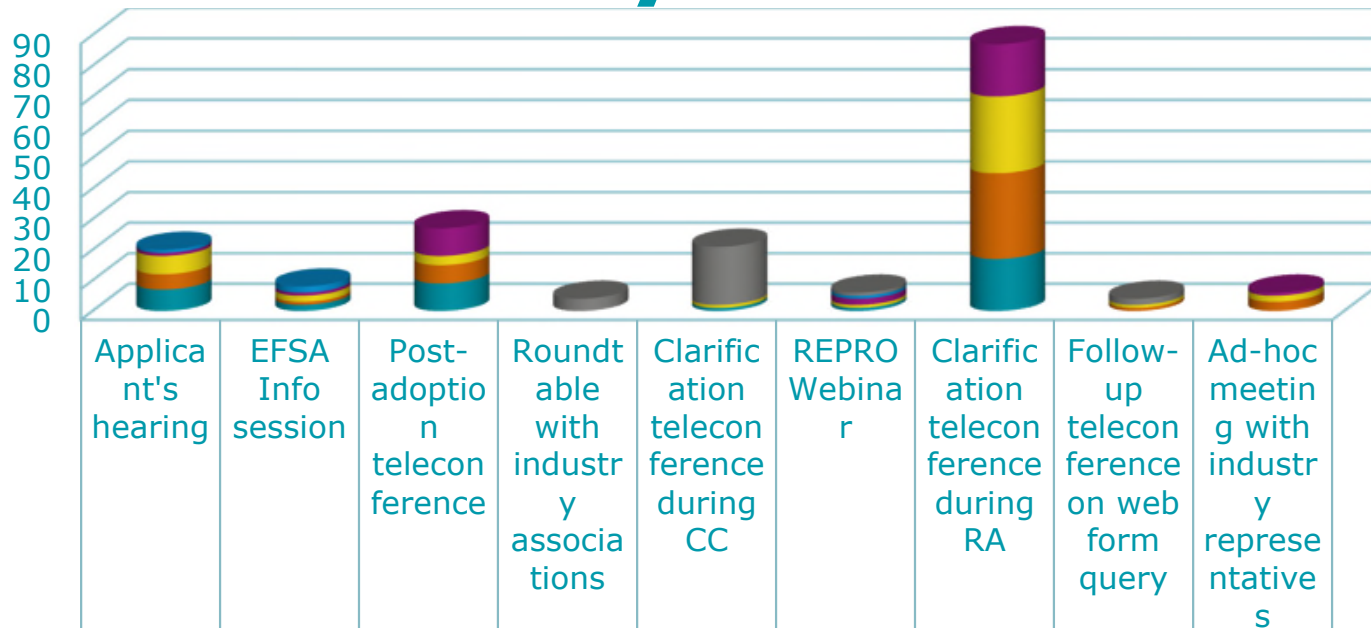
Support initiative	Number
Applicant's hearing	20
EFSA Info session	8
Post-adoption teleconference	27
Roundtable with industry associations	4
Clarification teleconference during CC	21
REPRO Webinar	6
Clarification teleconference during RA	87
Follow-up teleconference on web form query	4
Ad-hoc meeting with industry representatives	6
Grand Total	183



OVERVIEW ON SERVICES REQUESTED

Status: March 2015 – May 2018

Total: 183



	Applicant's hearing	EFSA Info session	Post-adoption teleconference	Roundtable with industry associations	Clarification teleconference during CC	REPRO Webinar	Clarification teleconference during RA	Follow-up teleconference on web form query	Ad-hoc meeting with industry representatives
■ Applications Desk				4	19	1		2	
■ Pesticides	1	2				1			
■ Nutrition	1	1	9			2	17		1
■ GMO	6	2	3		1	1	25	1	2
■ Food Ingredients and Packaging	5	1	6				28	1	3
■ FEED	7	2	9		1	1	17		

WEBINAR: CATALOGUE OF SERVICES

Webinar recording:

What
services
does EFSA
offer to
regulated
products'
applicants?

1 and throughout the application lifecycle

What services does EFSA offer to regulated products' applicants...



EFSA expert **EFSA staff**

- Regulated products Department units
- Production, revision and updates of EFSA's technical and administrative documents to explain administrative or scientific requirements
- They can include: Examples or case studies; Data requirements; and of scientific evidence. Explanatory notes are supplementary documents including key principles and examples of good studies/reporting
- New guidance documents (technical or administrative) published on the EFSA website

Video EFSA **Technical Questions**

Available Downloads

Name	Size
Webinar on what services does EFSA offer to regulated products' applicants	1.0 MB
EFSA's catalogue of support initiatives during the life-cycle	958 KB

Administrative Guidance (Dec 2017)

WHY THE GUIDANCE

■ Objectives

- To describe and harmonise the processing of applications for regulated products by EFSA
- To enhance transparency, understanding and ensure systematic and efficient process

■ **Scope:** additives, enzymes, flavourings, novel foods, food contact materials, genetically modified organisms, food manufacturing processes and processing aids, health claims, decontamination substances

■ **Outside scope** (but to be included in next revision): pesticides processes, re-evaluation of food additives

■ To be read in conjunction with each sectorial legislation (applicable legal act)

SUSPENDING THE ASSESSMENT...

■ **Stop-the-clock** procedure

From request of additional information to reception of additional information



EFSA expert

Scientific
Assessment



EFSA
staff



APPLICANT

- **Groups requests** on the same application
- Clearly **formulates requests** and provides background information and justification
- Provides EFSA contact point
- Clearly specifies **deadline**
- Records justification for **extension of deadline**
- Informs all relevant actors on expected timeframe

Apply EFSA [Catalogue](#) of support initiatives

...RESTARTING THE ASSESSMENT

■ Re start-the-clock procedure:

- Upon **receipt** of the additional info or clarifications
- **All questions** have been addressed
- Notification from applicant that additional information **will not be submitted**
- **Deadline given** to submit the requested information
- **Deadline specified** in sectorial legislation



EFSA expert

Scientific
Assessment



EFSA
staff



APPLICANT

■ Once the clock is **re-started**:

- **Application is included, without delay, in agenda** of relevant WG
- EFSA does **not reiterate already formulated requests** or does not ask for the same info a second time

Apply EFSA **Catalogue** of support initiatives

SPONTANEOUS SUBMISSION OF INFORMATION

■ **Spontaneous submission** is possible but limited to:

- **Newly** produced data
- Info which was **not available** at the time of preparation of the dossier
- **Not already subject** of EFSA's previous requests



Applicant is expected to submit info as early as possible during RA

Apply EFSA [Catalogue](#) of support initiatives

PUBLICATION OF SCIENTIFIC OUTPUTS

- Adopted scientific outputs published within **28 working days** after adoption (editing)
- If **confidentiality claims are agreed** at publication day, the adopted scientific output is published in line with confidentiality agreement
- If **confidentiality claims are not agreed** at publication day, EFSA publishes a «**blackened scientific output**». Once agreement is reached, a final scientific output is published

Thank you!

- Do you want to consult the **Catalogue**? Go to the [EFSA website](#)
- Do you want to check the **administrative guidance**? Look it up on the [EFSA website](#)
- Are you looking for information on **regulated products**? Check the [Applications section](#)
- Do you **have a question** on applications? Contact EFSA via the [APDESK webform](#)
- If you wish to **follow me**: @[margheguidi](#)





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