# Webinar: what services does EFSA offer to regulated products' applicants?

Karine Lheureux and Margherita Guidi

5 December 2016

11:00am-11:45am

# WEBINAR GUIDE TO ATTENDEES

## Be reminded that:

- This webinar **is being recorded!**

Please ensure that you have carefully read the EFSA Disclaimer and data protection note.

If you do not agree with the EFSA policy on webinars, please disconnect now.

- The webinar **is in English** and questions should be submitted in English.

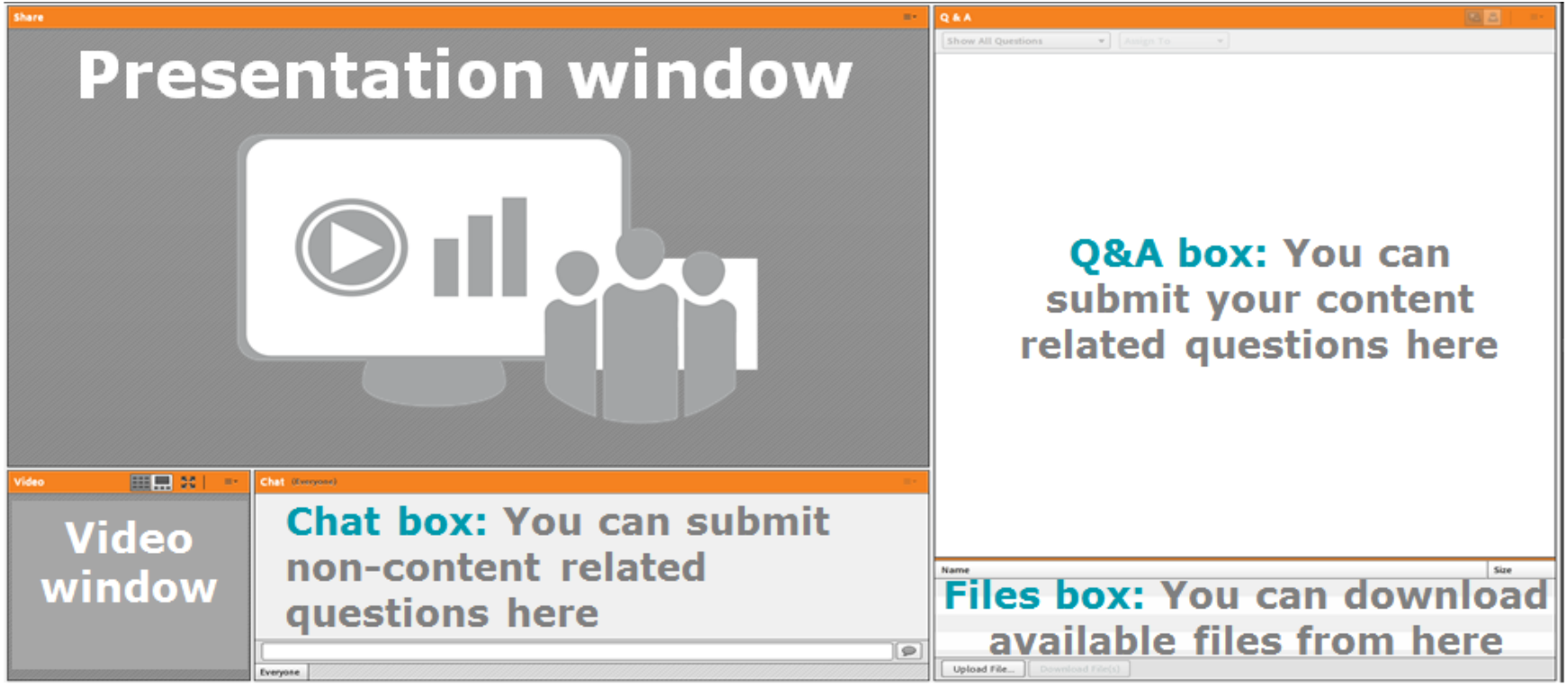
# Volume and speakers

- You are automatically connected to the audio broadcast. One-way audio (listen only mode)
- Check the audio panel to control your volume:


- Make sure you enable sound on your computer and turn on your headphones

# INTRODUCTION - GUIDE TO ATTENDEES

## Virtual Room



# Zoom in and out


Full screen
Zoom in/out

# Sending questions - Q&A box

- Questions should be **concise** and submitted **once**. Follow-up questions should be **self-explanatory**
- You can ask questions **until 11:45am**
- You will see the **answer** right below the question row once replied by EFSA
- We will address all questions as soon as possible and until **12:00 noon**
- If you do not receive an answer to your question, feel free to re-submit it through the **EFSA APDESK** web form later on:

  http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion

# Q&A contributors' Team

# Objectives of the webinar:

- Present the different support initiatives that are available at EFSA for applicants during the life cycle of application for regulated products. Focus will be on the **nature** and **scope** of the service; **who** can request the service; **when** and **how** to access it; and the expected **outcome** in the various phases of the application life-cycle.

- The webinar and Q&A **will NOT** address:
  - Advice on specific applications as well as planned or already provided support
  - Advice on particular scientific matters
  - Questions related to the legal framework and risk managers competencies

# Outcome of the webinar:

## WE WILL PUBLISH:

- Final agenda
- Presentation
- Webinar recording

## WE WILL NOT PUBLISH:

- Log of questions and answers

# What services does EFSA offer to regulated products' applicants?

Karine Lheureux and Margherita Guidi

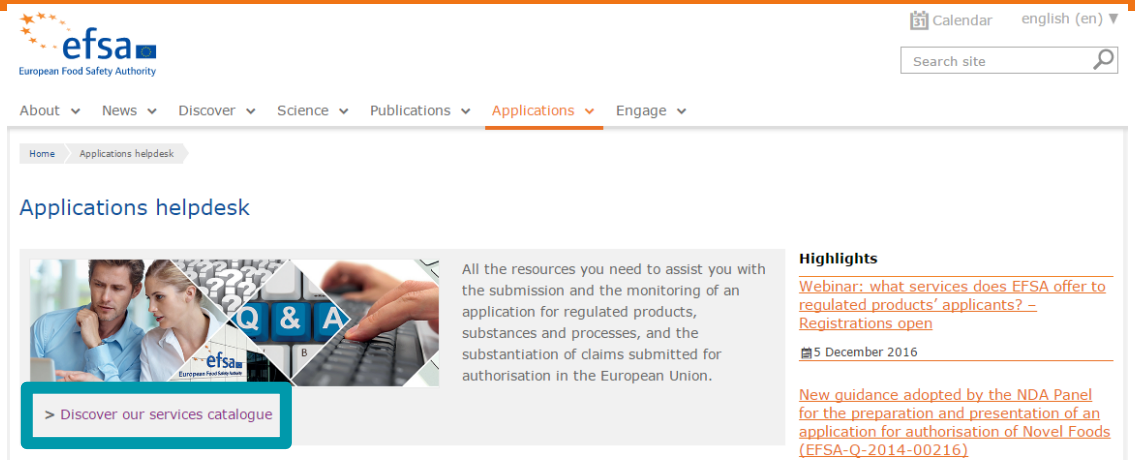
5 December 2016

11:00am-11:45am

# OUTLINE

- Introduction to the Catalogue (where to find it, purpose, structure)
- Pre-submission (phase 1)
- Submission (phase 2)
- Completeness check/suitability check (phase 3a)
- Risk assessment (phase 3b)
- Adoption and publication of a scientific output (phases 4 & 5)
- Overview on services requested
- Closure and take home messages

# INTRODUCTION TO THE CATALOGUE



# Purposes of the Catalogue

- Provide an overview of the support initiatives currently in place for applicants, Member States, universities, NGOs, etc
- Set up a global comprehensive list of all services available for regulated products 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 services

# INTRODUCTION TO THE CATALOGUE

## How it is structured:

### Phases

**1**: Pre-submission

**2**: Submission

**3**: Evaluation

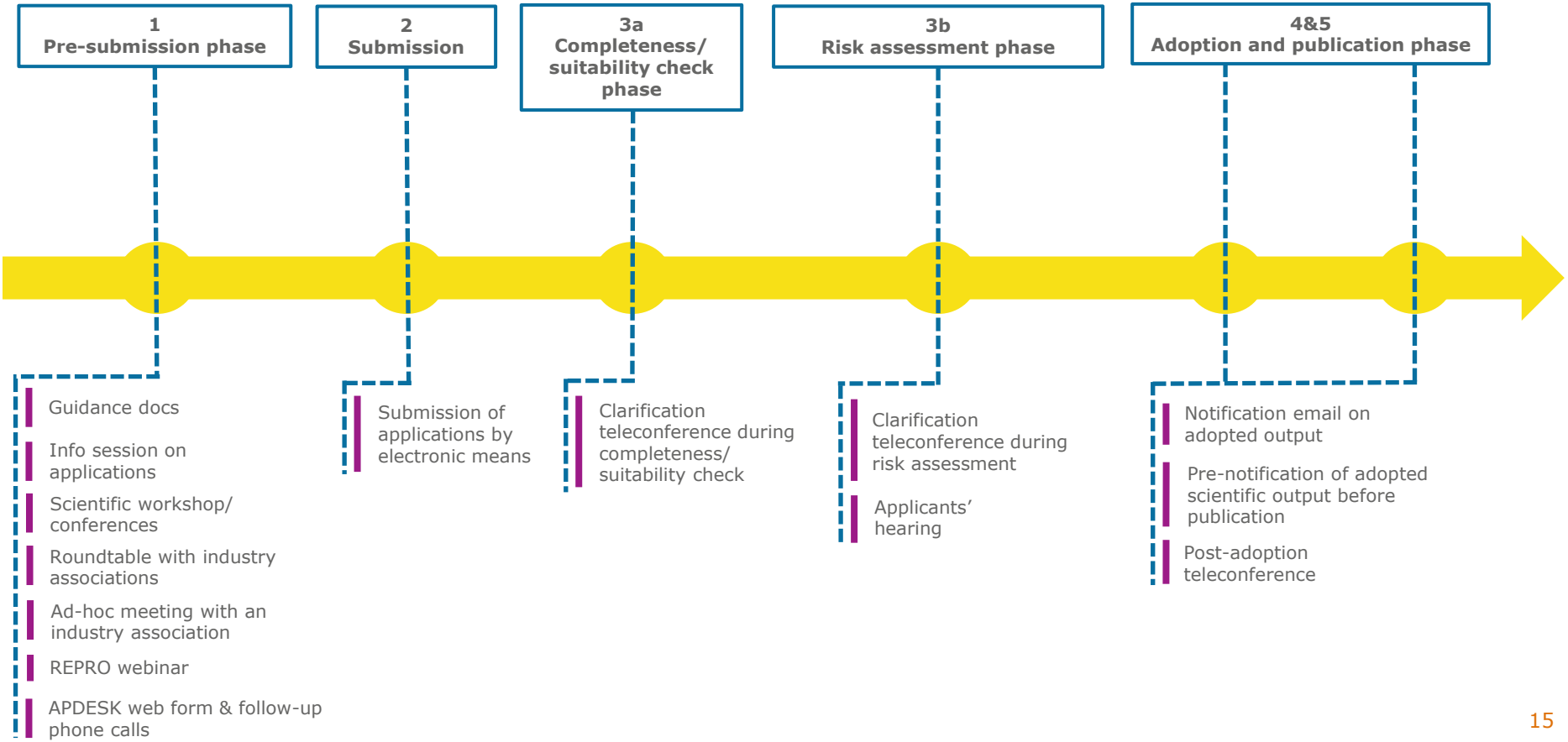
- **3a**: Completeness/ suitability check
- **3b**: Risk assessment

**4&5**: Adoption and publication of the scientific output

### Content

- Description & scope of service
- Who can request it, when and how
- Format
- Participants
- Type of outcome

# CATALOGUE OF SERVICES



# LEGEND

Who initiates the process?

Description of the initiative

Who are the participants?

How long does it last?

Who can request it?

What is the scope?

What outcome to expect?

EFSA staff

EFSA experts

European Commission representative

Applicants, industry associations, Member state competent authorities, other stakeholders

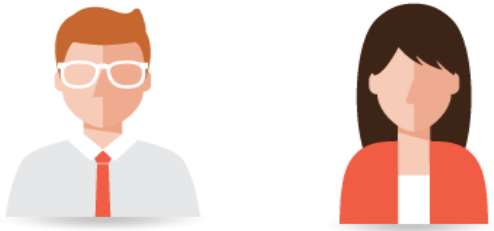
Note: **Drawings**, **icons** and **animations** are only meant to exemplify the different **roles**, **actions** and **subjects** involved in the provision and use of the Catalogue of services. The "Catalogue" remains the main reference.

# PRE-SUBMISSION PHASE (1)

**1**
**Pre-submission phase**


- Guidance docs
- Info session on applications
- Scientific workshop/ conferences
- Roundtable with industry associations
- Ad-hoc meeting with an industry association
- REPRO webinar
- APDESK web form & follow-up phone calls

# EFSA GUIDANCE DOCUMENTS

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, List 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

# INFO SESSION ON APPLICATIONS


- APDESK unit together with REPRO units
- Technical meeting that can cover administrative and scientific issues related to applications
- EFSA experts, EFSA staff, EC, online registrants
- Half a day, one day, one and a half day
- Once public registration opens on EFSA website
- Outcome of public consultations, finalised administrative and scientific guidance documents, specific scientific topics. Do not provide pre-assessment on upcoming or on-going applications
- Final agenda, all presentations, post-event summary

# ROUNDTABLE WITH INDUSTRY ASSOCIATIONS


EFSA

Annual meeting on food and feed regulated products to increase transparency and engagement

EFSA staff, EC, industry associations

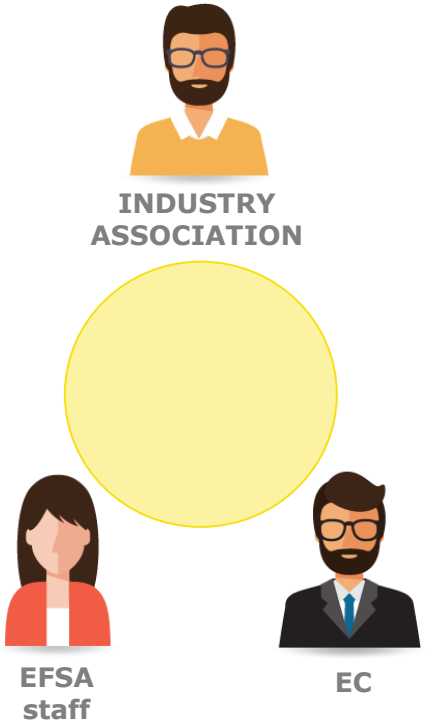
Half a day

Upon invitation by EFSA

Administrative, scientific, managerial, communication issues and challenges linked to applications for regulated products

Final agenda, all presentations
list of participants, post-event summary

# AD-HOC MEETING WITH AN INDUSTRY ASSOCIATION




Industry association

Exchange information and views on food and feed regulated products applications

EFSA staff, EC, industry association

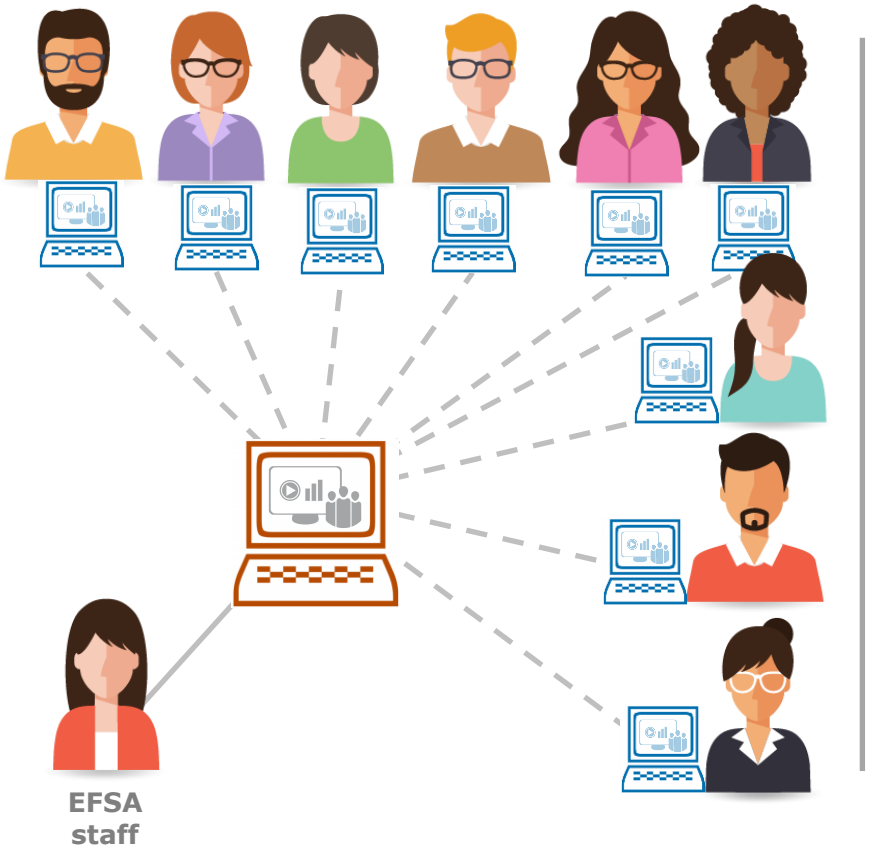
1hour up to 2 hours

Contact the scientific unit

Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas

Final agenda, all presentations, list of participants

# REPRO WEBINAR




APDESK unit together with REPRO units

Online event to exchange views and enhance an open dialogue on practical scientific and administrative issues as well as tools

EFSA experts of Working Groups/Panels, EFSA staff, EC, Online registrants

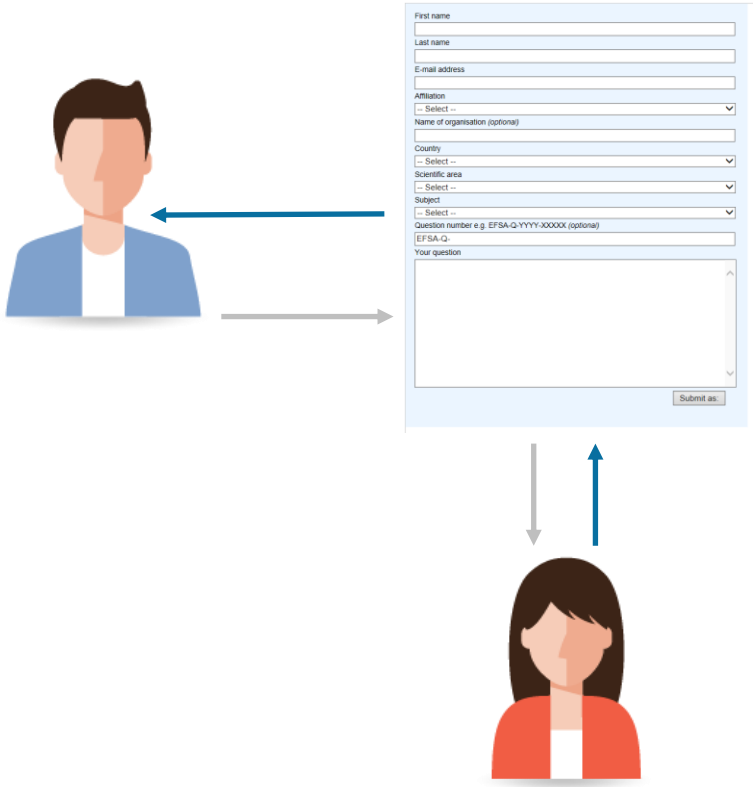
30 minutes, 1hour, 2 hours

Online registration once public registration to a webinar is opened on EFSA website

Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas

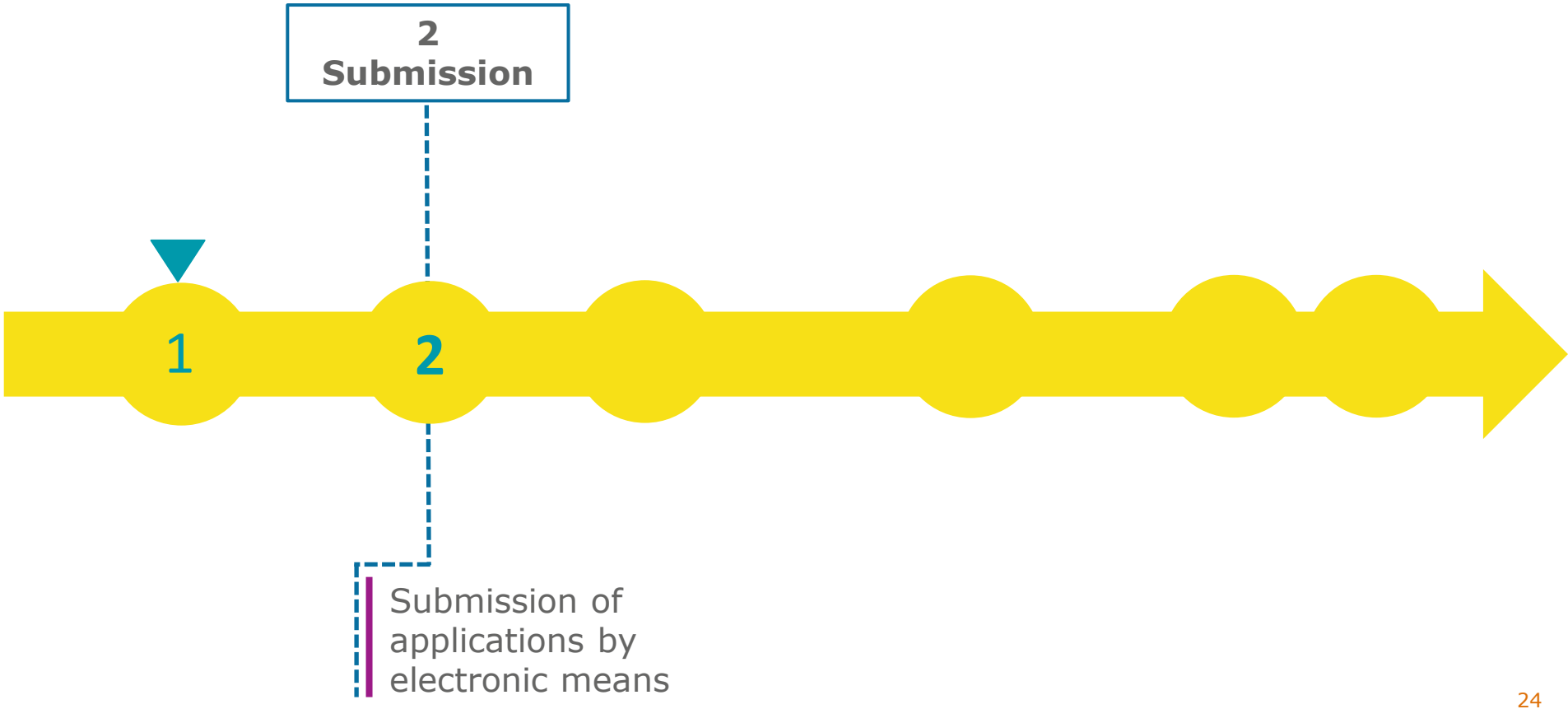
Final agenda, presentations, post-event summary, webinar recording

# APDESK WEB FORM

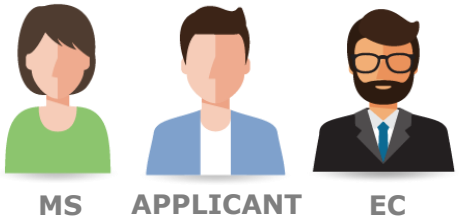



- Any stakeholder interested on regulated products
- Front office and support desk on regulated products related matters
- EFSA staff, web form requestor
- Responses to web form requests are provided within 15 working days
- Fill-in the web form available on EFSA's Applications web section
- Administrative and scientific issues, EU regulatory framework, guidance documents requirements, procedural steps, status of specific applications
- Individual answer to requests within 15 working days from receipt

# SUBMISSION PHASE (2)



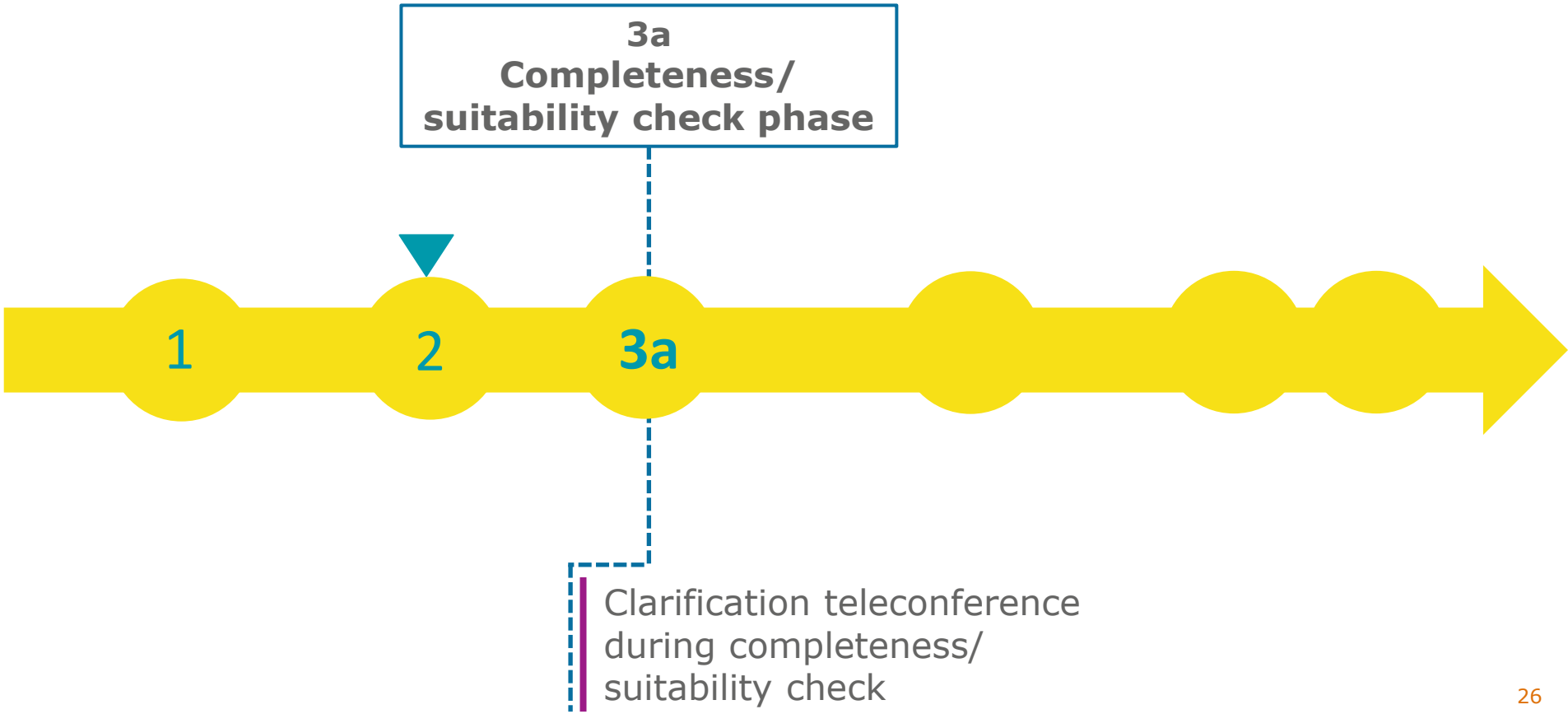
# SUBMISSION BY ELECTRONIC MEANS





- An applicant, Member State, EC
- Submit an application, updates, missing/additional information to EFSA via CD ROMS, DVDs or USB keys
- Applicants, Member States, European Commission
- Send applications and related documents via electronic means + original signed cover letter listing all annexes, tables of content and mandate
- Minimise the administrative burden for applicants and streamline the submission of applications
- EFSA letter/e-mail of acknowledgement of receipt, including EFSA contact person details and format of submission

# COMPLETENESS/SUITABILITY CHECK PHASE (3A)



# CLARIFICATION TELECONFERENCE DURING CC


Applicant

Telephone conference to clarify any outstanding issues during the completeness/suitability check (CC) phase

EFSA APDESK staff, applicant

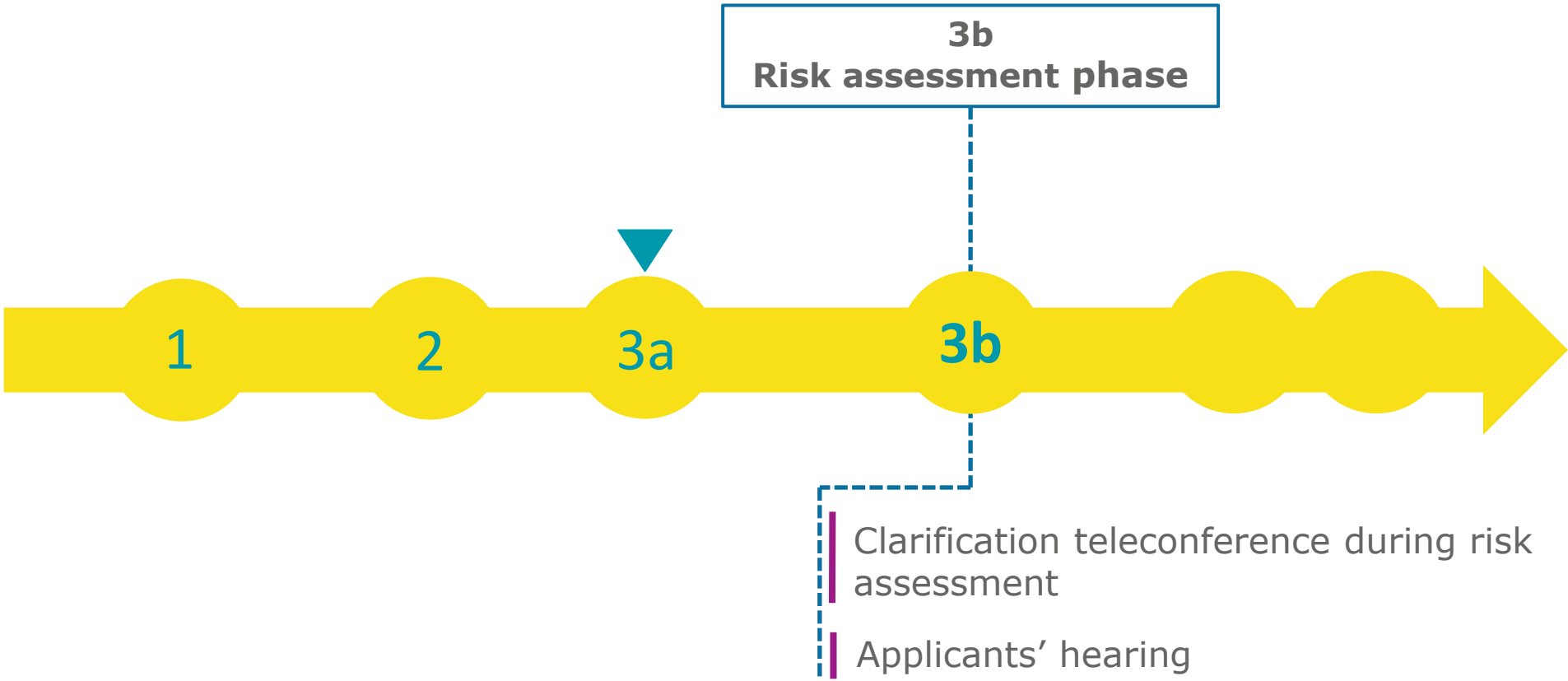
30 minutes

An applicant upon reception of an EFSA letter requesting missing information or at any time during the CC phase

Clarify administrative and scientific rationale of individual questions during CC, ensure understanding of the questions to be answered by the applicant, clarify outstanding issues

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

# COMPLETENESS/SUITABILITY CHECK PHASE (3B)



# CLARIFICATION TELECONFERENCE DURING RA


Applicant

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

EFSA REPRO units staff, applicant

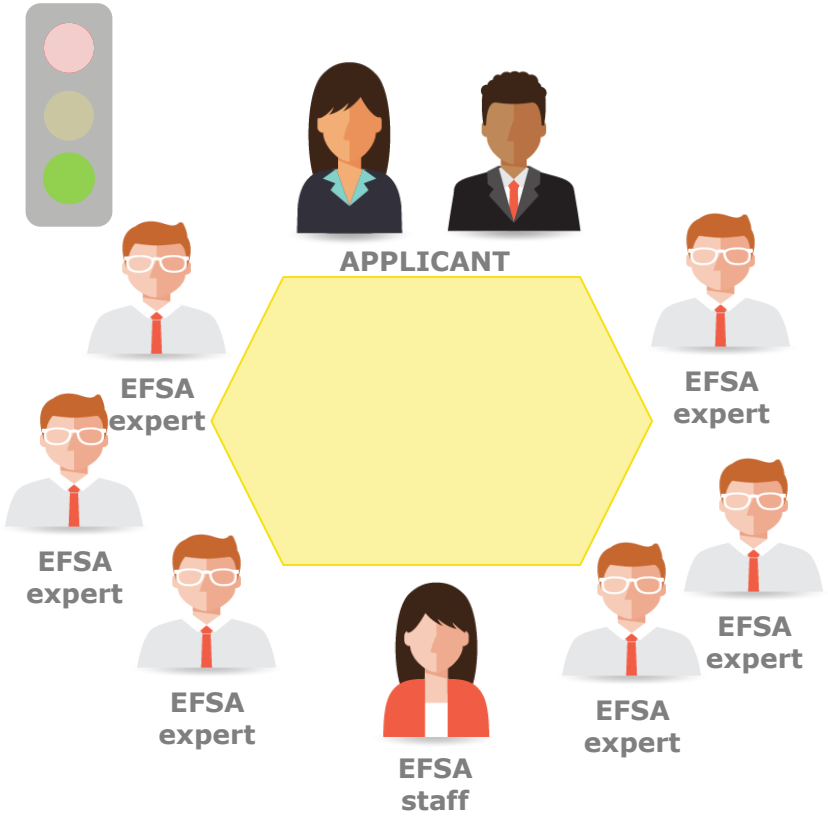
1 hour

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 request

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 Panels 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

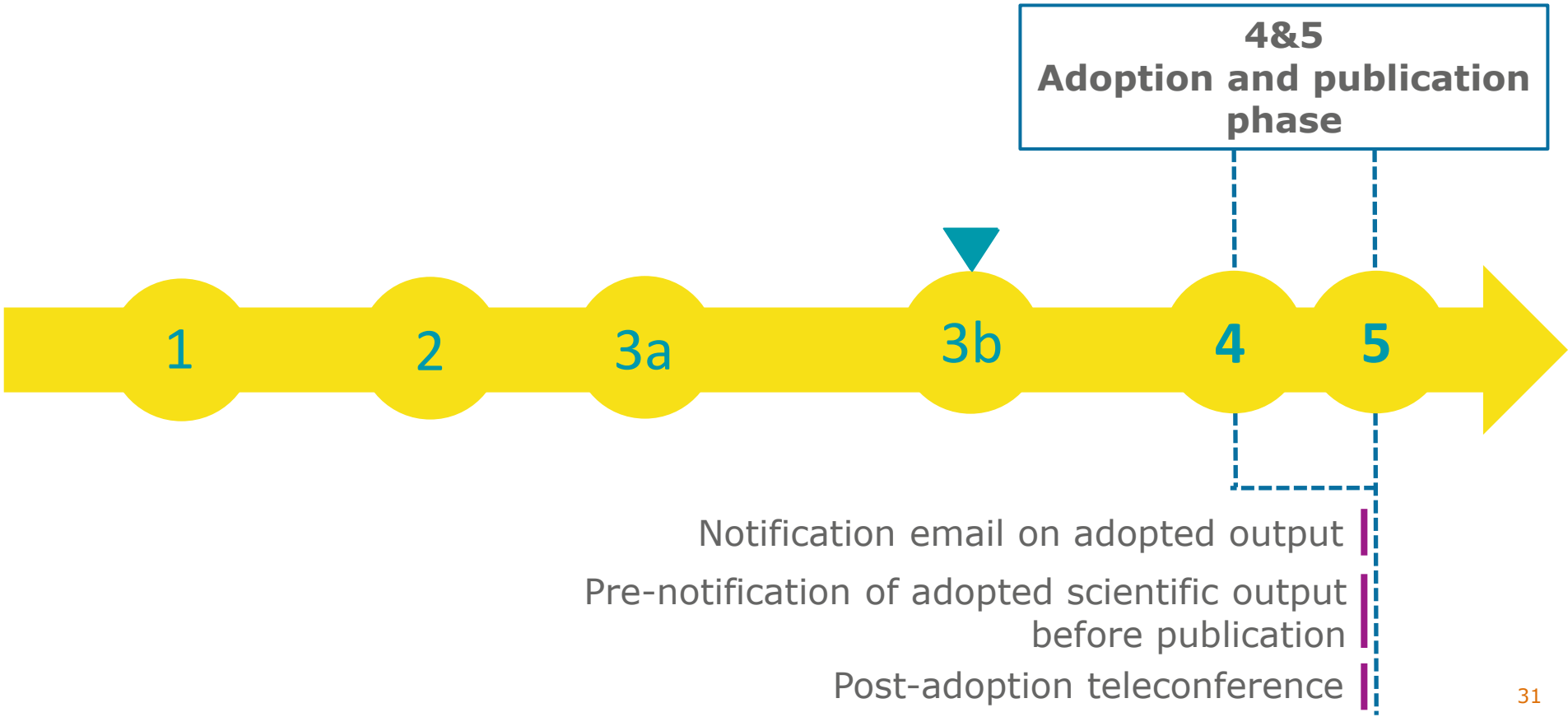
2 hours maximum

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

# ADOPTION AND PUBLICATION PHASE (4&5)



# NOTIFICATION EMAIL ON ADOPTION OF OUTPUT


EFSA

A notification email is addressed to the applicant informing on the adoption of the scientific output by the EFSA Scientific Panel

EFSA staff in the scientific units

Within one working day from the adoption

An applicant who has filed an application at EFSA

E-mail sent by the EFSA scientific unit to applicants informing on the adoption of the scientific output by the EFSA scientific Panel

# POST-ADOPTION TELECONFERENCE


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

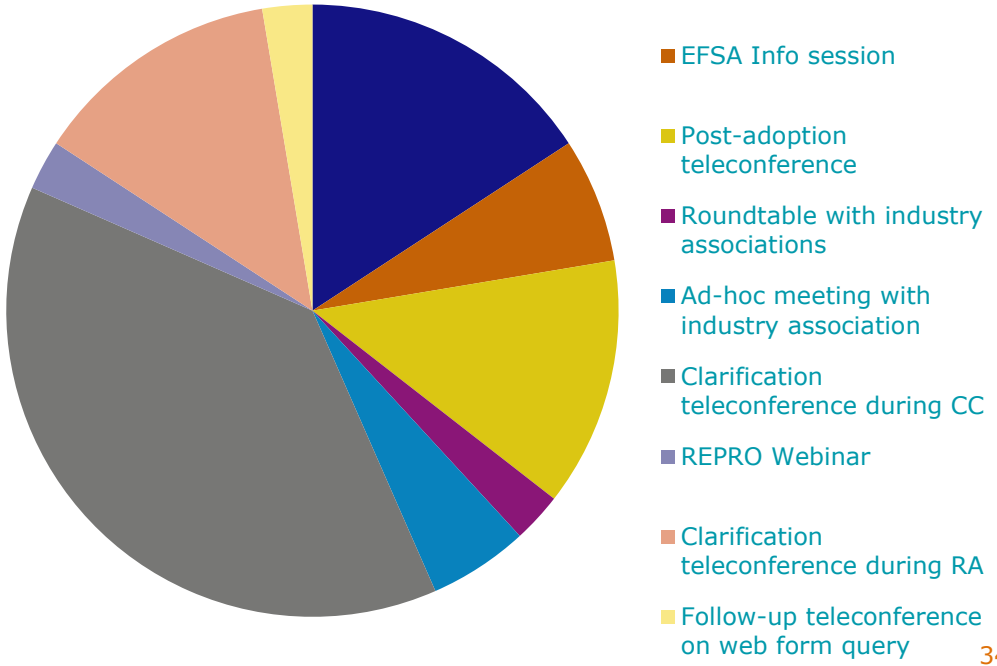
Explain the scientific rationale of the final output from the Panel and/or EFSA, clarify recommendations, clarify the sources of evidence and factors that influenced the outcome. Such teleconference do not provide any scientific advice for future submissions

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

# OVERVIEW ON SERVICES REQUESTED

## Status: March 2015 – November 2016

| Service type | Total |
|---|---|
| Applicant's hearing | 12 |
| EFSA Info session | 5 |
| Post-adoption teleconference | 10 |
| Roundtable with industry associations | 2 |
| Ad-hoc meeting with industry association | 4 |
| Clarification teleconference during CC | 29 |
| REPRO Webinar | 2 |
| Clarification teleconference during RA | 10 |
| Follow-up teleconference on web form query | 2 |
| **Grand Total** | **76** |



# CLOSURE AND TAKE HOME MESSAGES

- Make use of the catalogue
- It is updated regularly (once per year), search for the most up to date version
- Some initiatives are currently under consideration
- No recordings or transcript is allowed for teleconference and meetings  included in the Catalogue
- In case of doubt or feedback please contact the: apdesk.applications@efsa.europa.eu

# Thank you for attending our webinar!


Please take 5 more minutes to fill out our evaluation form, your feedback will help us improve our service

EUSurvey