



The EFSA catalogue of services

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INTRODUCTION TO THE CATALOGUE



The screenshot shows the EFSA Applications helpdesk page. At the top, there is the EFSA logo and navigation menus for 'About', 'News', 'Discover', 'Science', 'Publications', 'Applications', and 'Engage'. A search bar is also present. The main heading is 'Applications helpdesk'. Below this, there is a banner image with the text 'All the resources you need to assist you with the submission and the monitoring of an application for regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union.' A button labeled '> Discover our services catalogue' is highlighted with a red box. To the right, there is a 'Highlights' section with two entries: 'Webinar: what services does EFSA offer to regulated products' applicants? - Registrations open' (dated 5 December 2016) and 'New guidance adopted by the NDA Panel for the preparation and presentation of an application for authorisation of Novel Foods (EFSA-Q-2014-00216)' (dated 21 September 2016). Below the highlights, there is a section 'Application resources by food sector area' with four categories: 'Biological hazards', 'Feed additives', 'Food contact materials', and 'Food ingredients', each with a brief description and a representative image. At the bottom right, there is an 'Application toolbox' with three items: 'Track your application', 'Event calendar', and 'Ask a question'.

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**

INTRODUCTION TO THE CATALOGUE

How it is structured:

Phases

1: Pre-submission

2: Submission

3: Evaluation

3a: Completeness/
suitability check

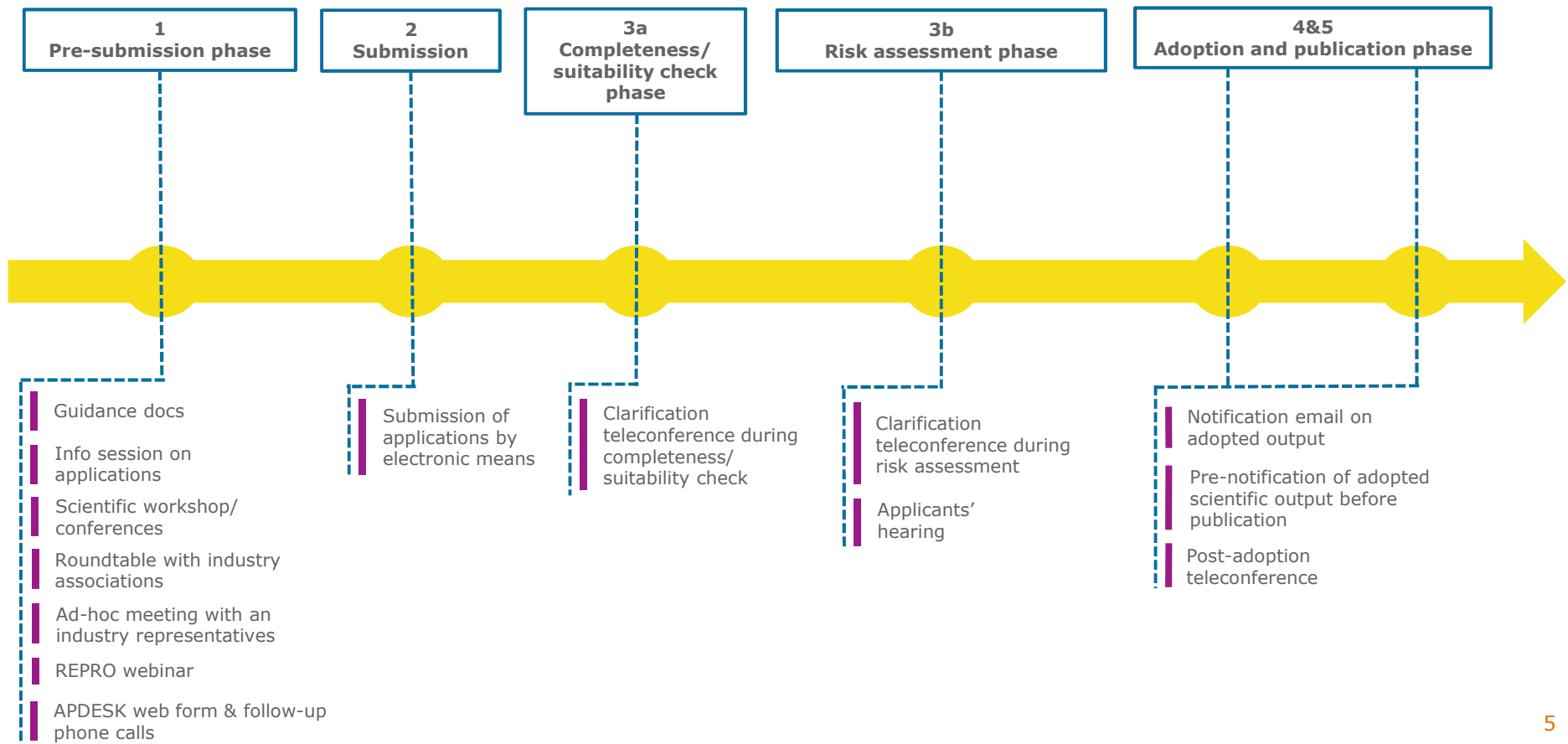
3b: Risk assessment

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



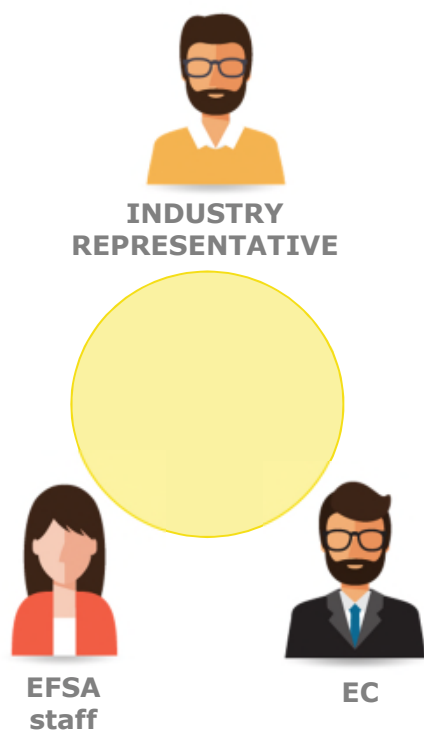
PRE-SUBMISSION PHASE (1)

1
Pre-submission phase

1 and throughout the application life-cycle

- | 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

AD-HOC MEETING WITH INDUSTRY REPRESENTATIVES



Industry representative



Exchange information and views on food and feed regulated products applications



EFSA staff, EC, industry representative



1 hour up to 4 hours (indicative timeline)



Contact the scientific unit

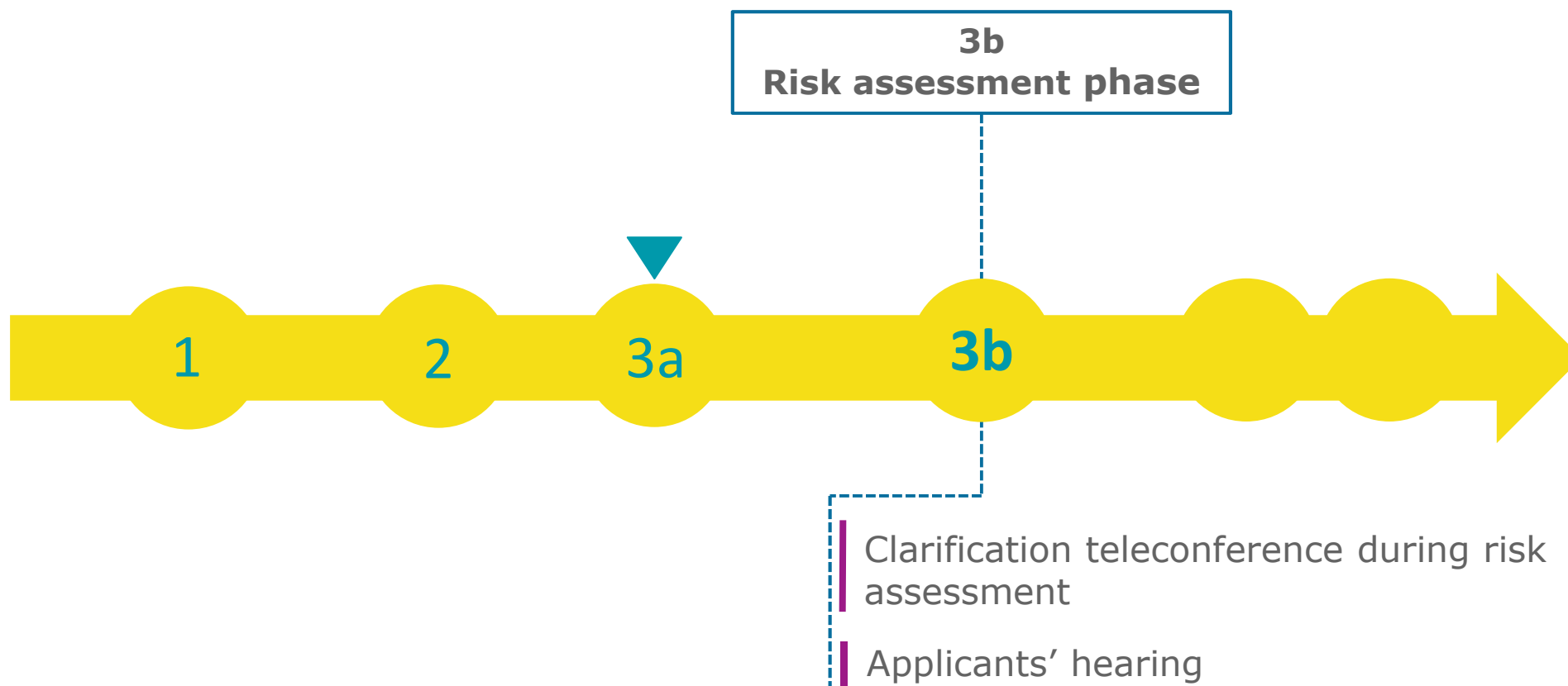


Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas



Final agenda, all presentations, list of participants

RISK ASSESSMENT PHASE (3B)



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

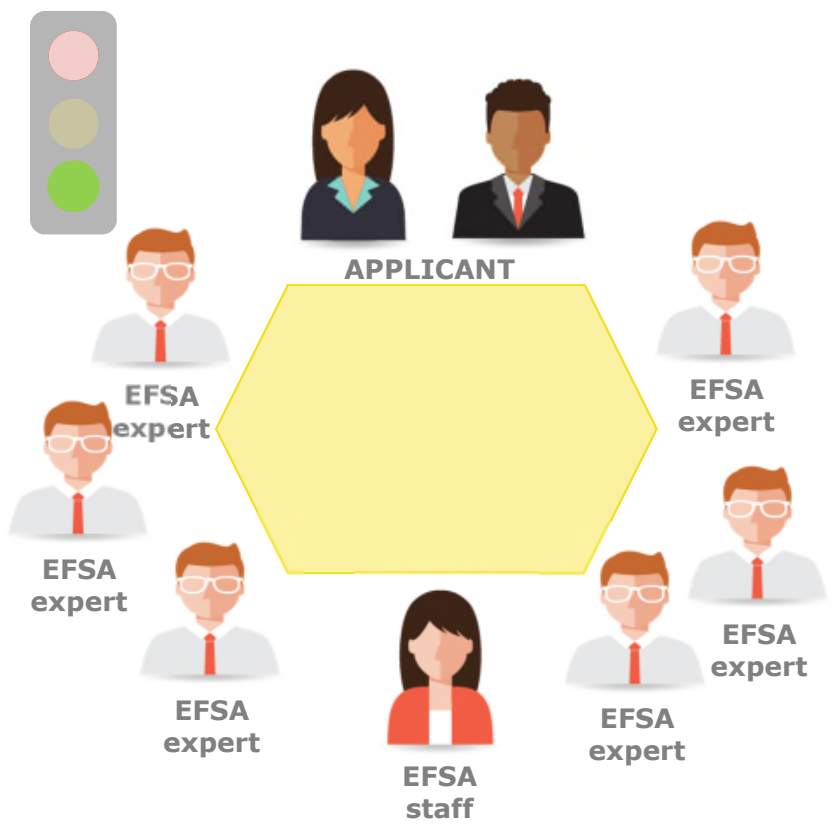









Clarify the scientific rationale of individual questions raised during RA, ensure understanding of the questions to be answered. It does not provide pre-assessment on upcoming responses



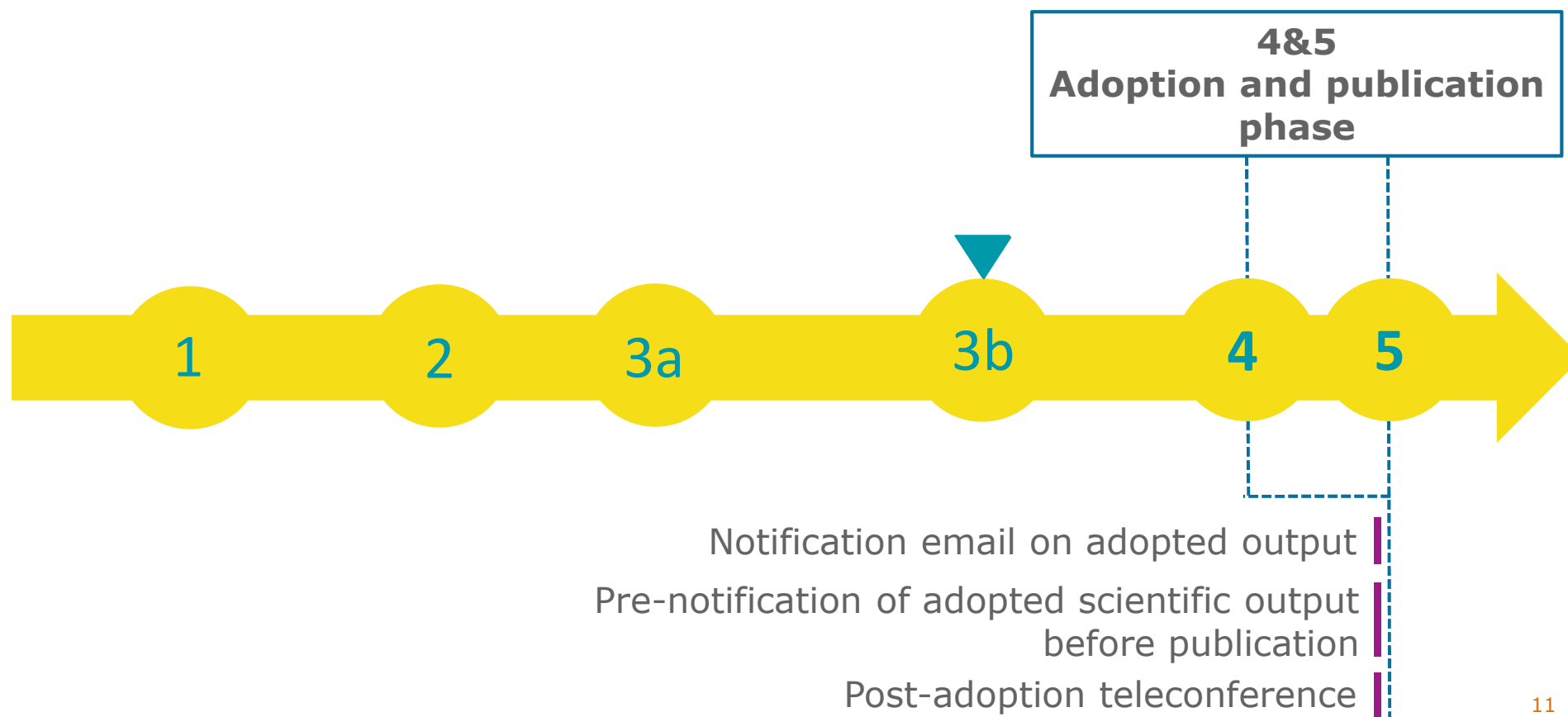
EFSA e-mail acknowledging that the teleconference took place indicating date and duration

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

ADOPTION AND PUBLICATION PHASE (4&5)



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

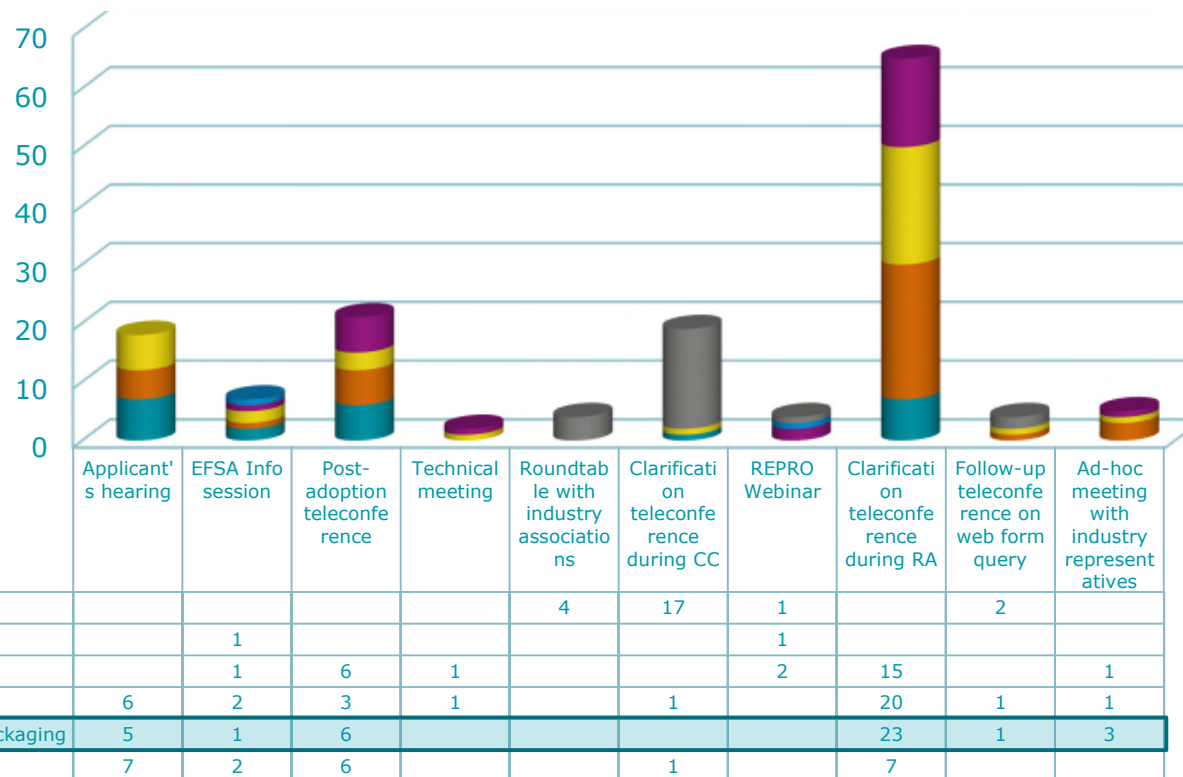


Follow-up letter including main points of discussion to keep track of what has been discussed

OVERVIEW ON SERVICES REQUESTED

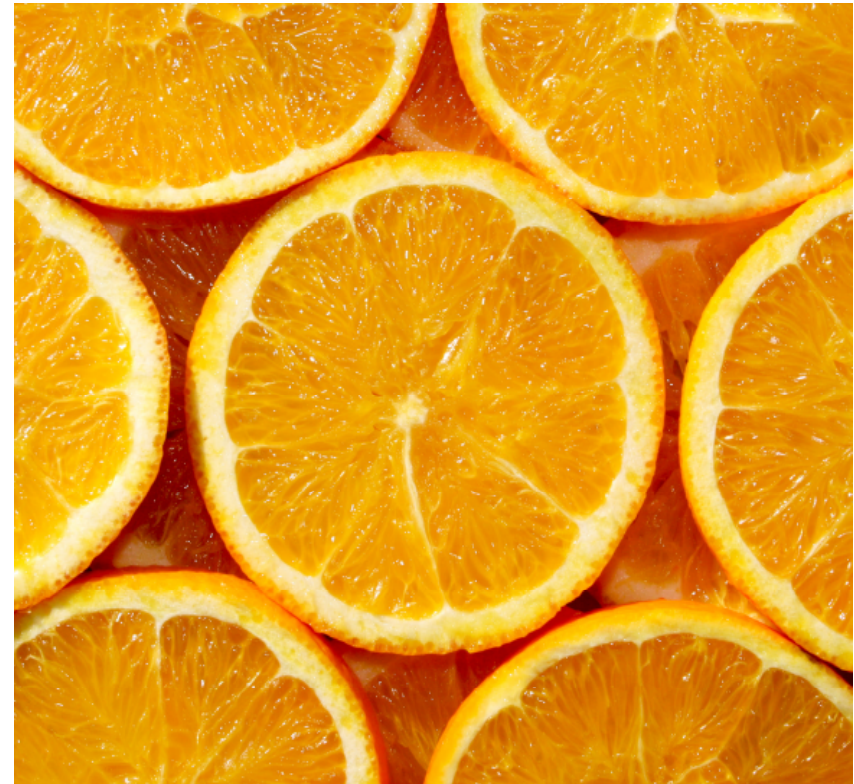
Status: March 2015 – October 2017

Total: 147



Thank you!

- Do you want to consult the Catalogue? Go to 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](#)





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