



*Stakeholder workshop on small particles
and nanoparticles in food
31 March – 1 April 2022*

EFSA's catalogue of support initiatives

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Trusted science for safe food

Applications helpdesk

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.



Discover our updated Catalogue of services

Check out our updated Administrative guidance for the processing of applications for regulated products

EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (update 2021)

Published: 3 March 2021



 [Read the article](#)
 [Access the PDF](#)

DOI: <https://doi.org/10.2903/sp.efsa.2021.EN-6472>

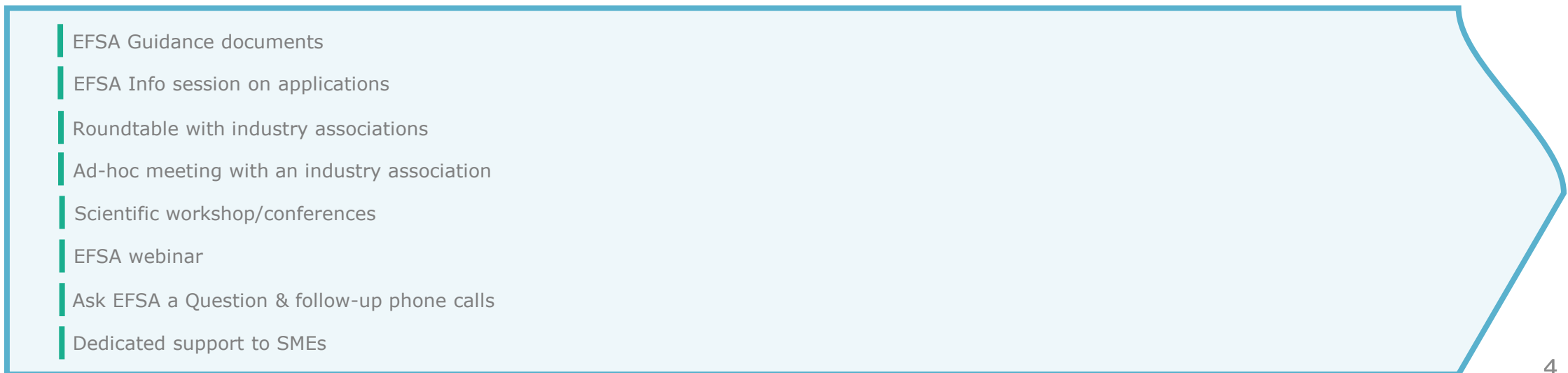
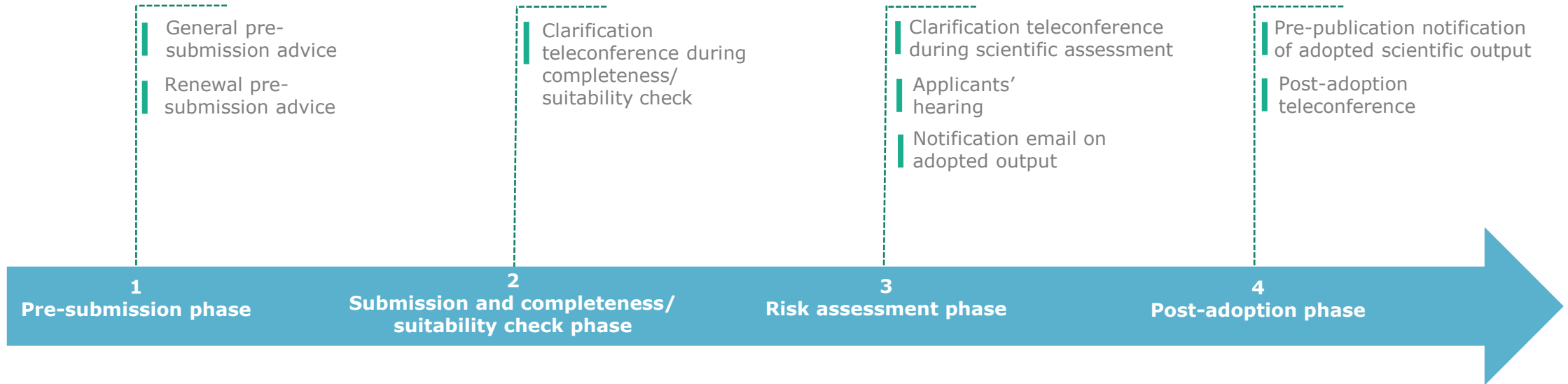
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- Metadata
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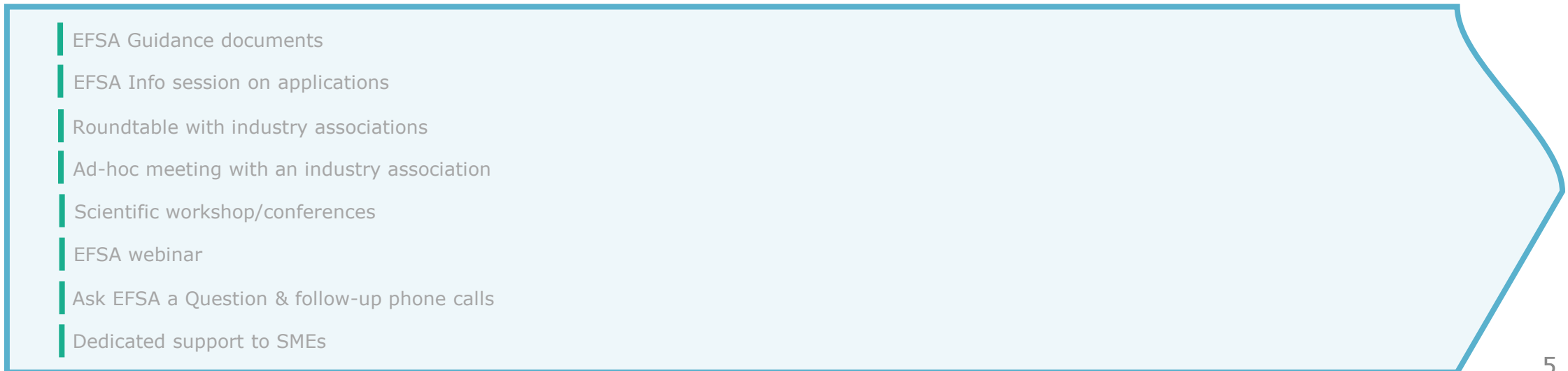
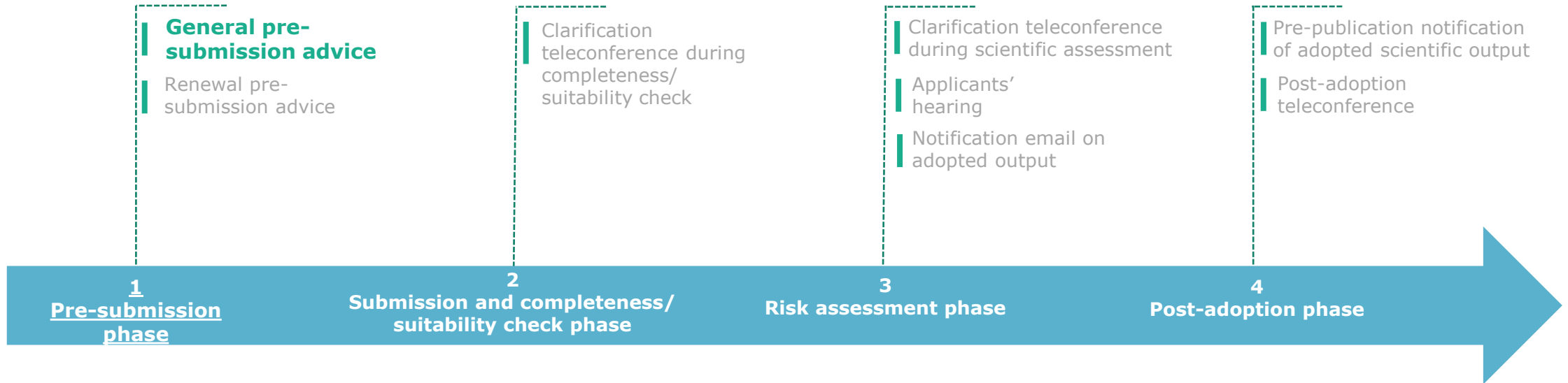
List of harmonised support initiatives targeted to applicants that are currently implemented in EFSA during the entire life-cycle of applications

- Description of each initiative
 - ✓ nature and the scope of the service
 - ✓ the phase in the life-cycle of the application
 - ✓ the format
 - ✓ the unit in charge
 - ✓ the date from which the service is in place
 - ✓ the participants involved
 - ✓ the type of outcome expected
 - ✓ who can request the service
 - ✓ when and how to access the service
- Tailored services for small and medium-sized enterprises
- New possibilities of interaction with EFSA introduced by the Transparency Regulation

Overview of the initiatives



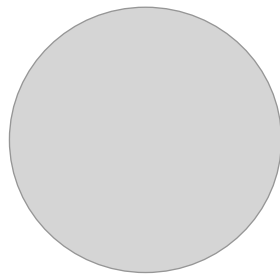
Overview of the initiatives



General pre-submission advice (GPSA)



POTENTIAL
APPLICANT



EFSA
staff

- ▶ Upon request of a potential applicant
- ✉ Filling in the dedicated 'GPSA form' in [Connect.EFSA](#), after having created a pre-application ID
- 🔍 Indication on the rules applicable to, and the content required for, the application
- 👥 Potential applicant, EFSA staff
- 🕒 Anytime, preferably at least six months before submission



Exhaustive list of questions:

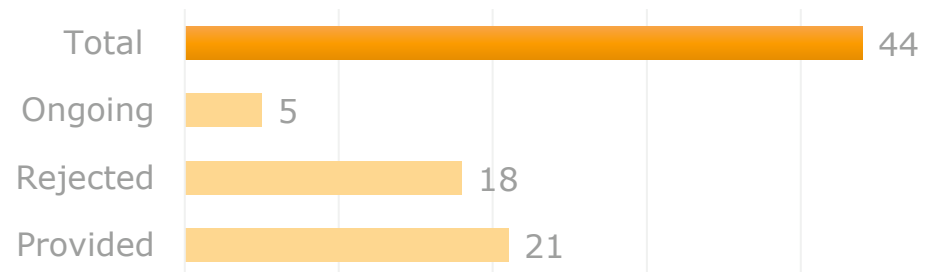
- With a **level of information** which enables EFSA to understand the concerns/doubts of the potential applicants and to advise them as constructively as possible
- questions should be formulated in a **concise and clear manner**, be numbered, and make precise reference to the rules or guidance document which they concern



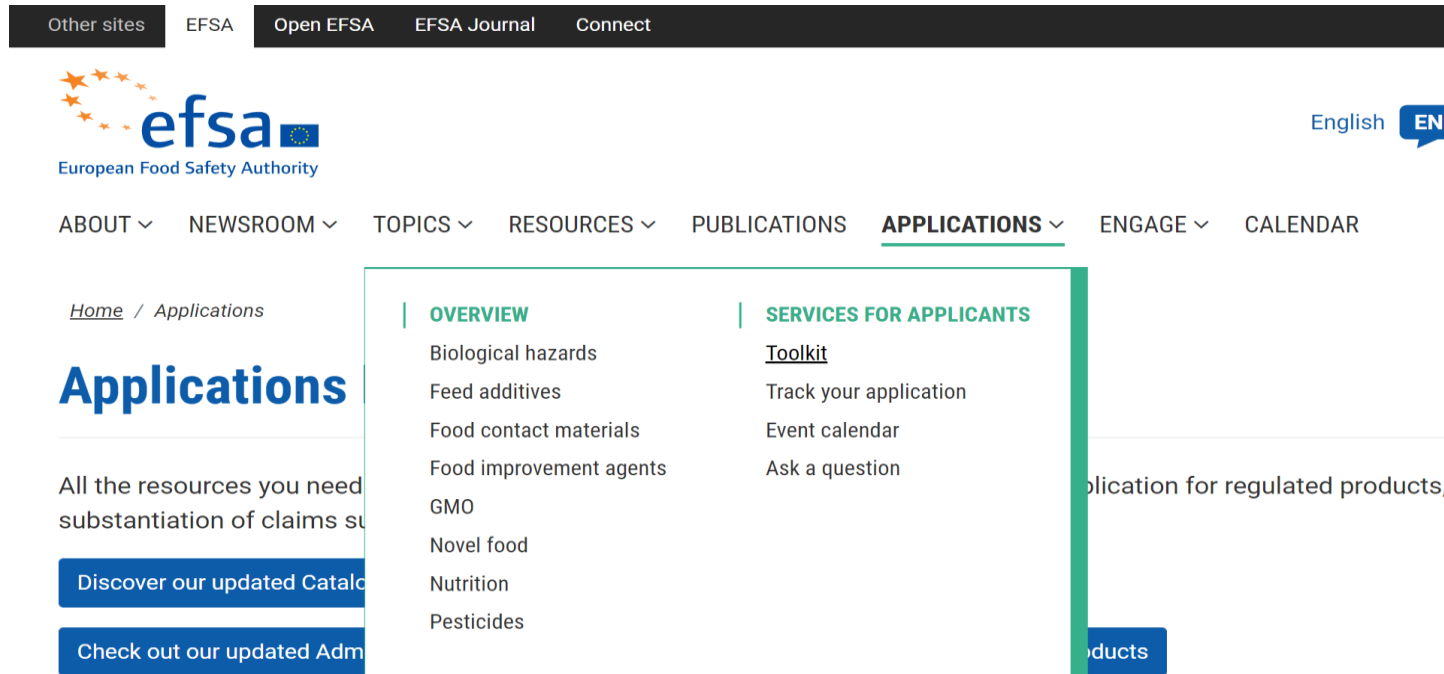
Out of scope:

- design of studies, unless addressed in EFSA guidance documents
- how to develop and manage a study, hypothesis to be tested, etc.
- the assessment of the qualification of the specific regulated product under a given regulated product area
- any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to applications

GPSA
29/03/2022



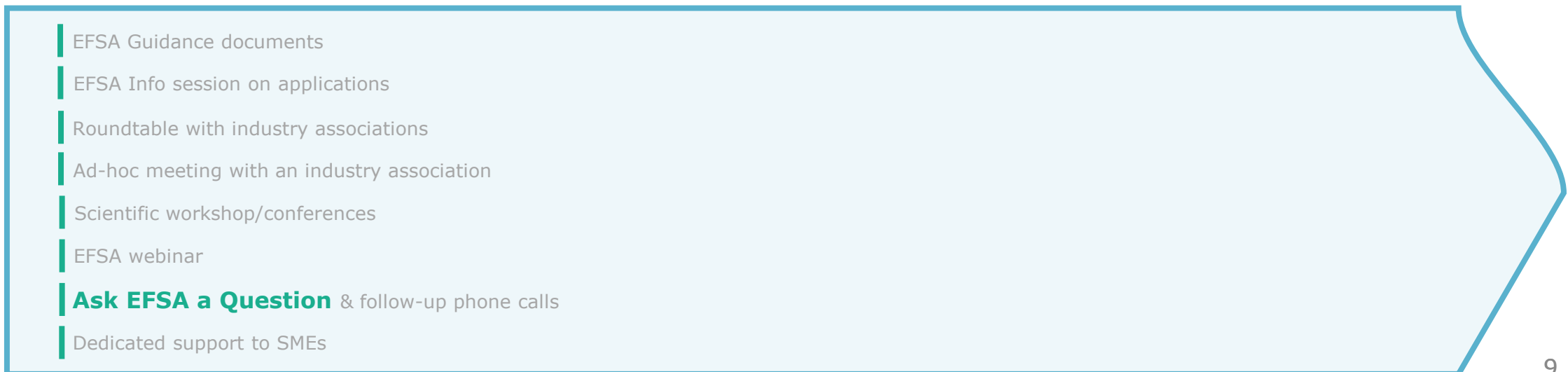
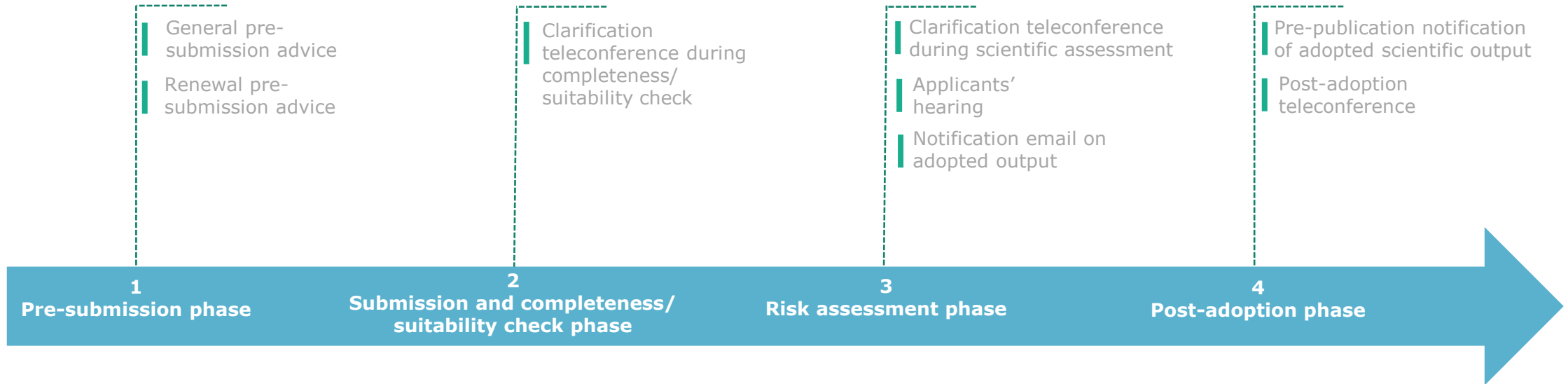
Material available on GPSA



The screenshot shows the EFSA website's 'Applications' page. At the top, there is a navigation bar with links for 'Other sites', 'EFSA', 'Open EFSA', 'EFSA Journal', and 'Connect'. Below this is the EFSA logo and the text 'European Food Safety Authority'. A language selector shows 'English' with a flag icon. The main navigation menu includes 'ABOUT', 'NEWSROOM', 'TOPICS', 'RESOURCES', 'PUBLICATIONS', 'APPLICATIONS' (which is underlined and has a dropdown arrow), 'ENGAGE', and 'CALENDAR'. The breadcrumb trail reads 'Home / Applications'. The main heading is 'Applications'. Below the heading, there is a sub-heading 'All the resources you need' followed by a partially visible sentence 'substantiation of claims su'. There are two blue buttons: 'Discover our updated Catalogue' and 'Check out our updated Administrative'. A dropdown menu is open under 'APPLICATIONS', showing two columns: 'OVERVIEW' and 'SERVICES FOR APPLICANTS'. The 'OVERVIEW' column lists: Biological hazards, Feed additives, Food contact materials, Food improvement agents, GMO, Novel food, Nutrition, and Pesticides. The 'SERVICES FOR APPLICANTS' column lists: Toolkit, Track your application, Event calendar, and Ask a question. To the right of the dropdown, there is a partially visible sentence 'Application for regulated products, s' and a blue button 'Products'.

- [User Guide](#): Pre-application ID
- [Webinar](#): Introduction on notification of studies and pre-submission advice
- [Webinar](#): Notification of studies and Pre-submission Advice

Overview of the initiatives



Ask EFSA a Question



<https://connect.efsa.europa.eu/RM/s/askefsa>

Ask EFSA a Question

EFSA welcomes feedback and we answer questions from any party interested in our work. All questions receive an **individual response**.

EFSA is at your disposal to answer questions about applications for regulated products, public access to documents, job applications, website and much more.

Ask a Question

New Request

* Full Name (max. 80 characters)


Company Name (max. 80 characters)

* Email

* Country
Afghanistan

* Subject (max. 255 characters)

* Area
Question about Scientific Application Process

Regulated product application/Output ref 

* Affiliation
Academia/Research Institute

* Type of Question
Scientific issues

* Topic
Novel Foods

* Body (max. 131.072 characters)

EU Citizen or Resident



EFSA Stakeholders.

For regulated products select as area: Question about scientific application process



Filling in the dedicated webform in [Connect.EFSA](#)



Administrative and scientific issues, the EU regulatory framework governing specific scientific areas, guidance documents requirements, 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 vs GPSA



Requester

Check [FAQ!](#)


GPSA

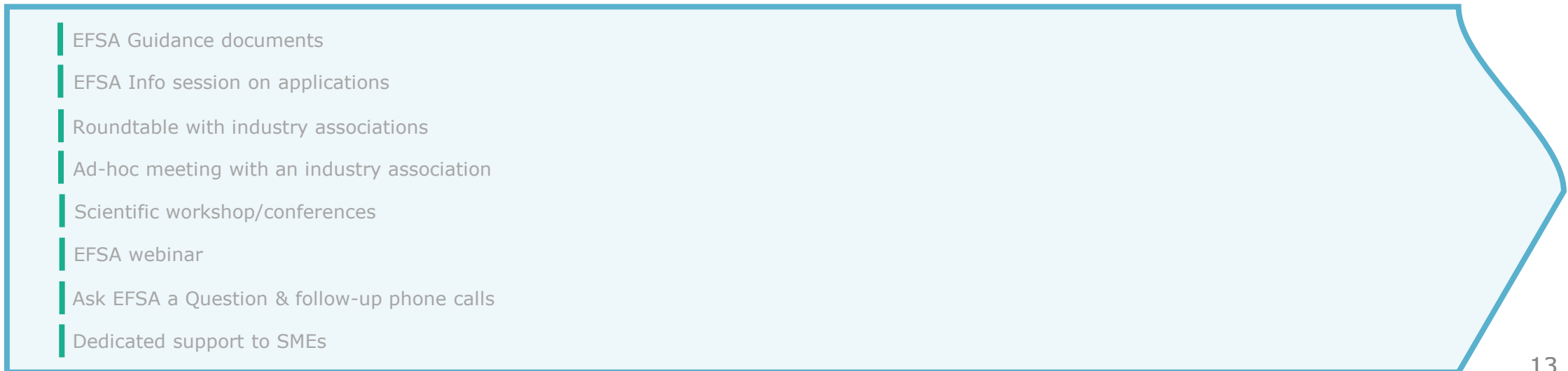
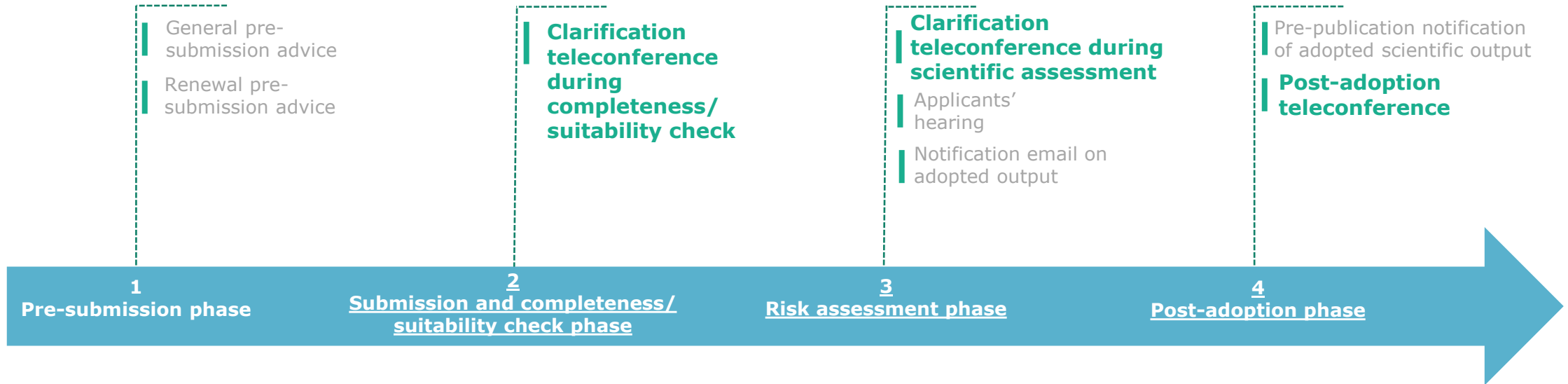
Questions from a potential applicant arising on a single application during the pre-submission phase

Ask a Question





General questions on EFSA guidance, not related to the preparation of a specific application

Requests from potential applicants falling within the scope of the GPSA will not be replied via Ask a Question, they will need to be re-submitted using the GPSA form





Overview of the initiatives







During completeness/ suitability check

-  on request by the applicant and/or by EFSA
-  Contact FDP at:
fdp@efsa.europa.eu
- 
 - i) clarify administrative and scientific rationale of individual questions;
 - ii) ensure understanding of the questions to be answered
 - iii) clarify outstanding issues
-  Upon receipt of an EFSA request for information or at any time during the completeness/suitability check phase

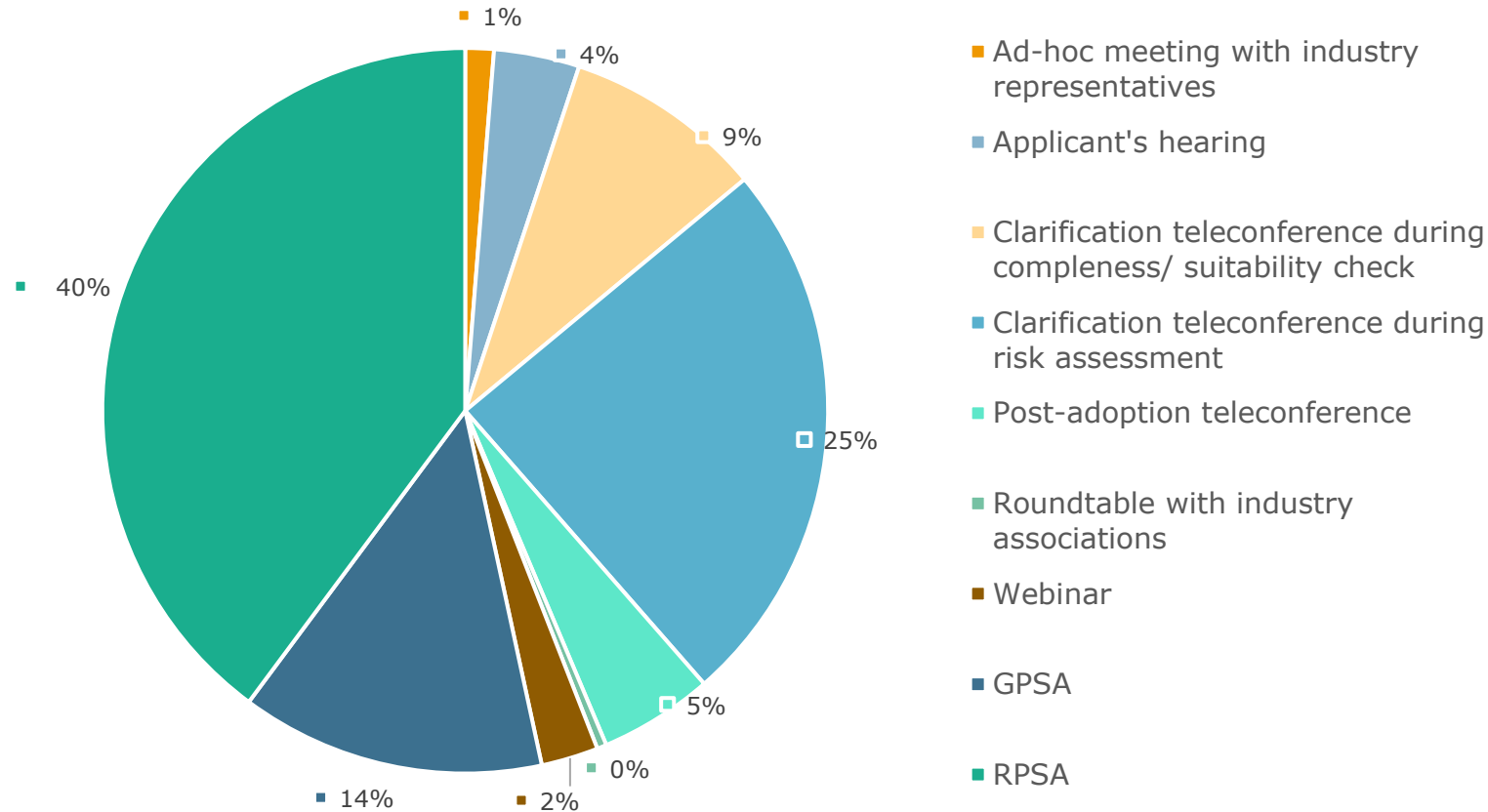
During risk assessment

-  on request by the applicant and/or by EFSA
-  Contact the responsible contact person in the scientific unit
- 
 - i) clarify the scientific rationale of individual questions raised during the risk assessment
 - ii) ensure understanding of the question to be answered by the applicant
-  Upon receipt of an EFSA request for information during the risk assessment

Post-adoption

-  on request by the applicant
-  Contact relevant EFSA Head of Unit
- 
 - i) explain the scientific rationale of the final output
 - ii) clarify the recommendations (if applicable)
 - iii) clarify the sources of evidence and the factors that influenced the outcome.
-  Following the publication of an EFSA scientific output on a regulated product

Services by category – All areas



**Ask a question
(on scientific application process)**

1480 requests

Total services

236

Webinar series to support applicants

Application procedure for food enzymes, food flavourings and food additives	Link 
Application procedure for feed additives and intended renewal applications	Link
Application procedure for novel food	Link
Application procedure for active substances in pesticides and maximum residue levels (MRLs)	Link
Application procedure for food contact materials	Link
Application procedure for smoke flavouring primary products	Link
Application procedure for Health Claims	Link
Application procedure for GMO	Link

Join our new LinkedIn group: “EFSA support to applicants”

A space where you will find:

- Information and support materials
- Updates on the developments and progress of IT tools and platforms
- Alerts on new training material and upcoming events
- Clarifications to the most frequently asked questions received by applicants
- A space for interaction with your peers.



<https://www.linkedin.com/groups/9083910/>



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