



**Delegation from Region Västerbotten
EFSA, Parma, 16 October 2019**

EFSA's Applications desk work in supporting applicants in the area of regulated products

Patricia Romero

Scientific officer – Applications Desk

Trusted science for safe food

OVERVIEW

- **APDESK UNIT**
 - Vision, mission and objectives
- **Services to applicants**
 - Guidance document
 - Catalogue of services
 - New dedicated support for SMEs



APPLICATIONS DESK UNIT

Vision

to facilitate **high quality applications** for regulated products

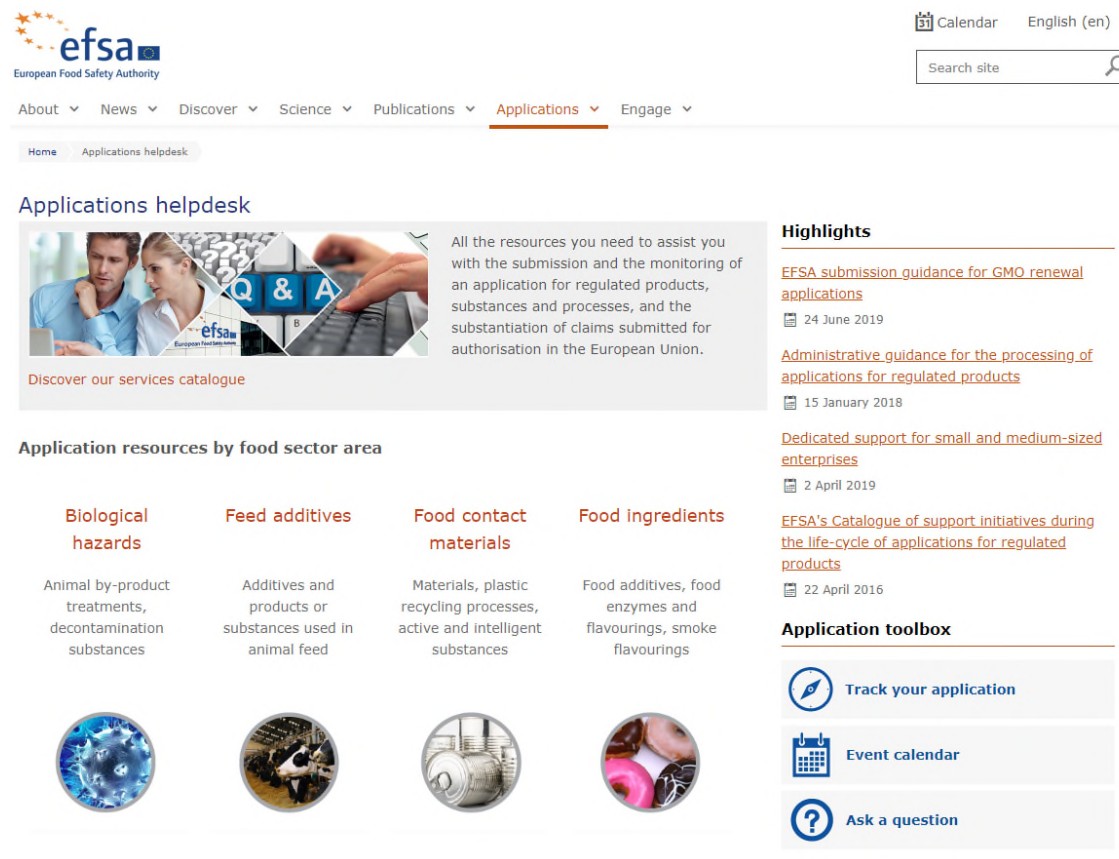
Mission

to be the **front office** and **support desk** on regulated products applications:

- **registration** and **completeness check** of dossiers
- **support desk** for applicants (front office)
- **engagement** and **dialogue** with applicants
- **internal coordination** (back office)

Objectives

- **Stakeholders support** (develop new services for applicants during the life-cycle of applications for regulated products);
- **Engagement** with applicants on EFSA's work (EFSA engagement strategy);
- **Support to scientific REPRO units.**



The screenshot shows the EFSA Applications helpdesk website. At the top, there is the EFSA logo and a navigation menu with options: About, News, Discover, Science, Publications, Applications (highlighted), and Engage. Below the menu, there is a search bar and a calendar icon. The main content area is titled "Applications helpdesk" and features a large image of two people looking at a document with "Q & A" written on it. Below the image is a link to "Discover our services catalogue". To the right of the image is a text block: "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." Below this text is a section titled "Application resources by food sector area" with four columns: "Biological hazards" (Animal by-product treatments, decontamination substances), "Feed additives" (Additives and products or substances used in animal feed), "Food contact materials" (Materials, plastic recycling processes, active and intelligent substances), and "Food ingredients" (Food additives, food enzymes and flavourings, smoke flavourings). Each column has a corresponding circular icon. On the right side of the page, there is a "Highlights" section with three items: "EFSA submission guidance for GMO renewal applications" (24 June 2019), "Administrative guidance for the processing of applications for regulated products" (15 January 2018), and "Dedicated support for small and medium-sized enterprises" (2 April 2019). Below the highlights is a link to "EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products" (22 April 2016). At the bottom right, there is an "Application toolbox" with three items: "Track your application" (with a magnifying glass icon), "Event calendar" (with a calendar icon), and "Ask a question" (with a question mark icon).

CENTRALIZATION OF APPLICATIONS

Applications are submitted to EFSA

Individual scientific units



EFSA / APDESK

- ✓ Reception
- ✓ Acknowledgement
- ✓ Administrative issues
- ✓ Completeness check
- ✓ ...

VALID application

Risk assessment

FIP Unit

FEED Unit

GMO Unit

NUTRITION Unit

PRES Unit

PREV Unit

BIOHAZ Unit

SERVICES TO APPLICANTS



■ 3 documents

The process

Administrative guidance for the processing of applications for regulated products (updated 2019)

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1362>

The services

EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (updated 2019)

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1025>

The framework

Relevant regulatory framework, administrative and scientific guidance documents per regulated product area

<http://www.efsa.europa.eu/sites/default/files/applications/apdeskhov.pdf>



■ 2 webinars

Webinar: what services does EFSA offer to regulated products' applicants? (Dec 2016)

<http://www.efsa.europa.eu/en/events/event/161205>

Webinar: what services does EFSA offer to Small and Medium-sized Enterprises? (May 2019)

<http://www.efsa.europa.eu/en/events/event>



■ 1 web form

Ask a question webform

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



ADMINISTRATIVE GUIDANCE FOR THE PROCESSING OF APPLICATIONS

Applications helpdesk



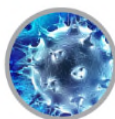
All the resources you need to assist you with the submission and the monitoring of an application for regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union.

[Discover our services catalogue](#)

Application resources by food sector area

Biological hazards

Animal by-product treatments, decontamination substances



Feed additives

Additives and products or substances used in animal feed



Food contact materials

Materials, plastic recycling processes, active and intelligent substances



Food ingredients

Food additives, food enzymes and flavourings, smoke flavourings



Highlights

[EFSA submission guidance for GMO renewal applications](#)

24 June 2019

[Administrative guidance for the processing of applications for regulated products](#)

15 January 2018


[Dedicated support for small and medium-sized enterprises](#)


2 April 2019


[EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)

22 April 2016

Application toolbox

 [Track your application](#)

 [Event calendar](#)

 [Ask a question](#)

TECHNICAL REPORT

APPROVED: 15 December 2017
LAST UPDATE: 17 June 2019
doi:10.2903/ap.efsa.2018.EN-1362

Administrative guidance for the processing of applications for regulated products (update 2019)

European Food Safety Authority

Abstract

EFSA is continuously striving to enhance its support initiatives in the area of regulated products, enhancing a customer-oriented approach, supporting applicants during the whole life-cycle of the applications for regulated products. EFSA is registering around 500 mandates on applications for regulated products on a yearly basis governed by more than 34 different EU Directives and Regulations and following 39 workflows. In this context, EFSA developed this administrative guidance on the principles followed to process applications for regulated products in order to enhance transparency and understanding, and to ensure that a coherent, sound, systematic and efficient process is carried out, in compliance with each sectorial legislation. This administrative guidance for the processing of applications for regulated products describes in a harmonised way: the general workflow of applications, the key steps of the scientific risk assessment process, the mechanism of suspension/extension of the scientific assessment, its restart, the conclusion of the scientific risk assessment process, the publication of the scientific output, EFSA inconclusive opinion and processing of confidentiality claims by EFSA. This update of the administrative guidance does not apply to pesticides processes and to the re-evaluation of food additives which will be integrated in the document in a next version. This update includes an Annex listing the indicative timelines for submitting additional/supplementary information to EFSA during the risk assessment which is applicable to all areas of regulated products, including for requesting additional studies on endocrine properties in the area of Pesticides. EFSA will update the administrative guidance for the processing of applications for regulated products, when needed, in line with amendments to the legal acts, the evolving case-law of the Union Courts, relevant changes to guidance documents and/or approaches, and according to the experience gained in handling and assessing applications. Applicants are advised to always consult the latest published version of this document available on the EFSA website. The current Administrative Guidance (version 2019) supersedes the previous version (version 2017) and will be further updated by 2021 in light of the upcoming new rules on the transparency and sustainability of the EU risk assessment in the food chain.

© European Food Safety Authority, 2019

Key words: APDESK Unit, applicants, applications, mandates, regulated products, REPRO Department, sectorial legislation, scientific assessment, scientific outputs, workflows

Question number: EFSA-Q-2015-00504

Requestor: European Food Safety Authority

Question number: EFSA-Q-2015-00504

Correspondence: apdesk.applications@efsa.europa.eu

CATALOGUE OF SERVICES

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 services catalogue](#)

Application resources by food sector area

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2 April 2019


[EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)

22 April 2016

Application toolbox

 Track your application

 Event calendar

 Ask a question

TECHNICAL REPORT

APPROVED: 22 April 2016

UPDATED: 01 August 2019

doi:10.2903/sp.efsa.2016.EN-1025

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

European Food Safety Authority (EFSA)

Abstract

As part of EFSA's ongoing commitment to engage with its stakeholders and to increase understanding of its scientific risk assessment work, EFSA's Scientific Evaluation of Regulated Products (REPRO) Department has developed a customer-oriented approach to stakeholders in the area of applications for regulated products with the aim of establishing an interactive and responsive evaluation process. The current EFSA Catalogue provides a list of harmonised support initiatives targeted to applicants that are currently implemented in EFSA during the entire life-cycle of applications for regulated products. The description of each initiative includes the 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, and the staff member/s in charge. By describing the details of each support initiative, EFSA wishes to increase awareness of the initiative and especially encourage an active accessibility to the different services in place for applicants. The current Catalogue (version 2019) supersedes the previous version (version 2017) and will be further updated by 2021 in light of the upcoming new rules on the transparency and sustainability of the EU risk assessment in the food chain.

© European Food Safety Authority, 2016

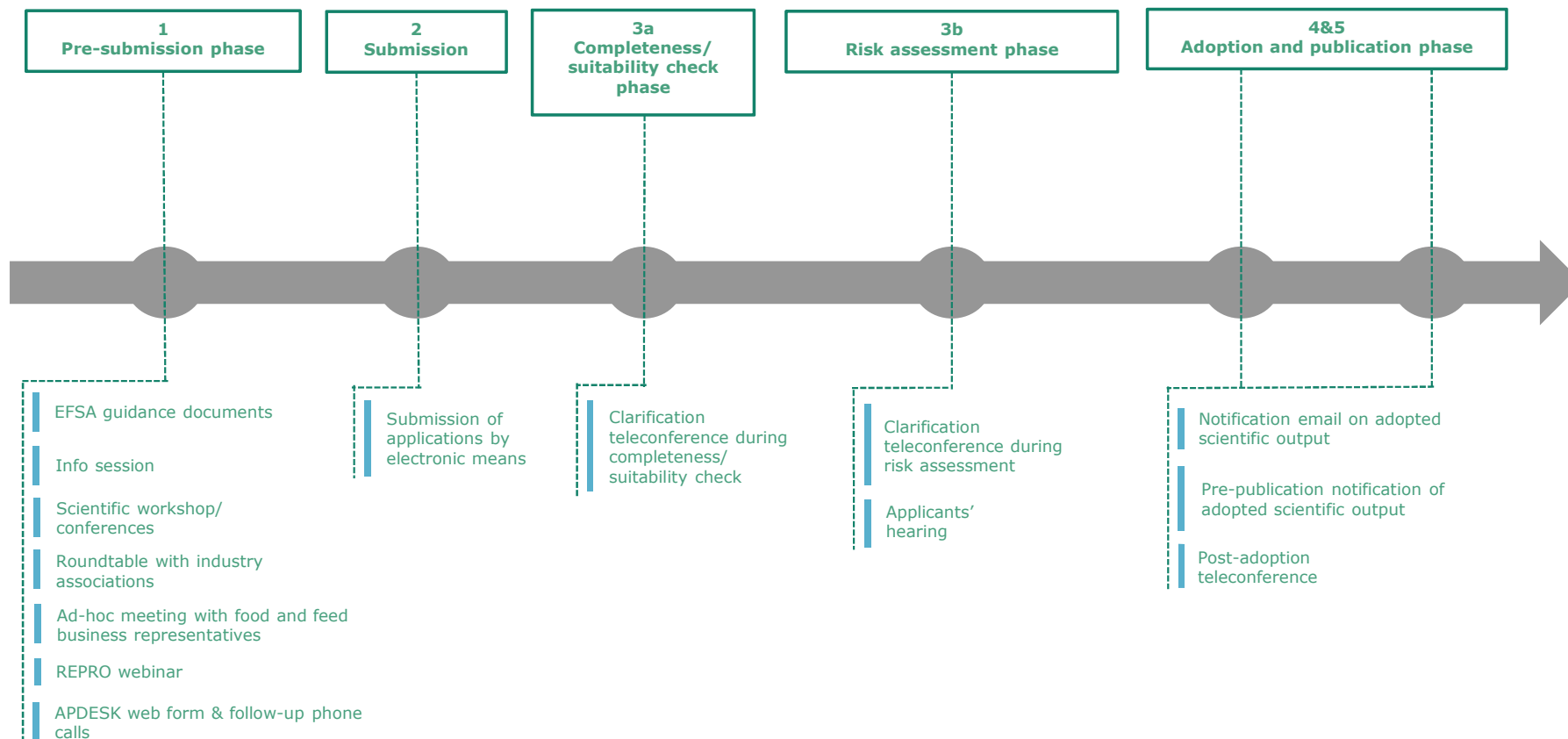
Key words: applicants, stakeholders, applications, support initiatives, regulated products, APDESK Unit, REPRO Department

Requestor: EFSA

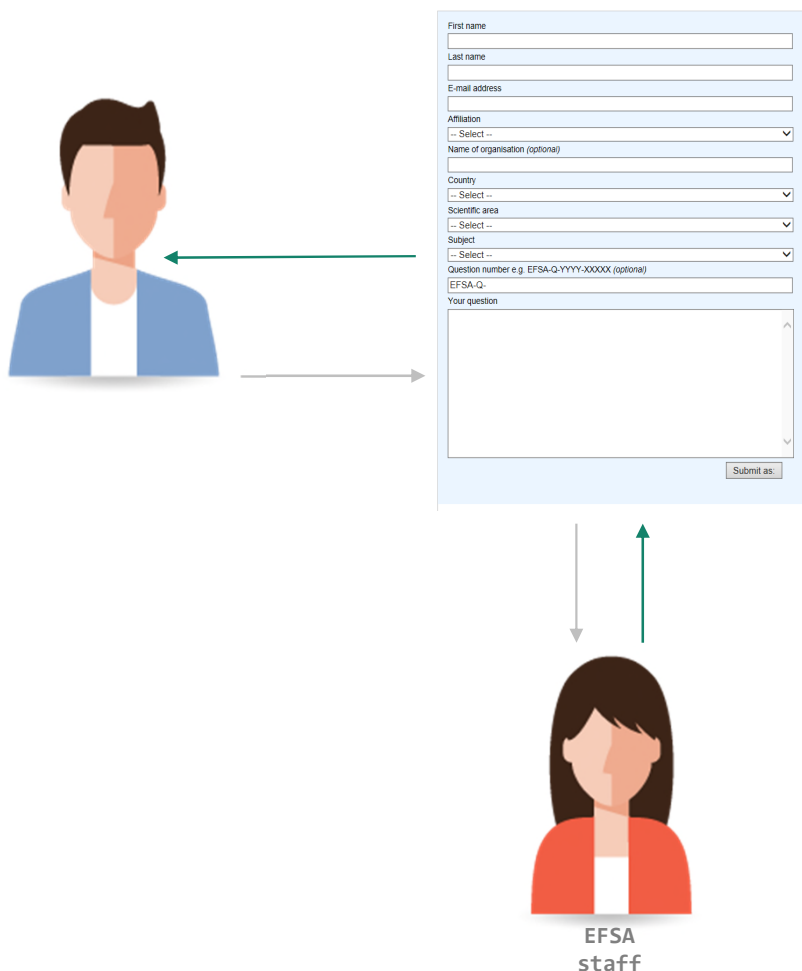
Question number: EFSA-Q-2016-00282

Correspondence: APDESK.applications@efsa.europa.eu

CATALOGUE OF SERVICES AT A GLANCE



APDESK WEB FORM REQUEST



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

APDESK WEB FORM REQUEST

- Biological hazard
- Feed additives
- Food contact materials
- Food ingredients
- GMO
- Nutrition
- Pesticides

About Applications helpdesk

- Submitting an application
- Services for applicants
- Ask a question**

Ask a question

You can check the answer to your question about applications for regulated products in the FAQ on the relevant food sector area:

- [Biological hazards](#)
- [Feed additives](#)
- [Food contact materials](#)
- [Food ingredients](#)
- [Genetic modification](#)
- [Nutrition](#)
- [Pesticides](#)

I have read the FAQ but I can not find answer to my question

First name

Last name

E-mail address

Affiliation

-- Select --

Name of organisation (optional)

Country

-- Select --

Scientific area

-- Select --

Subject

-- Select --

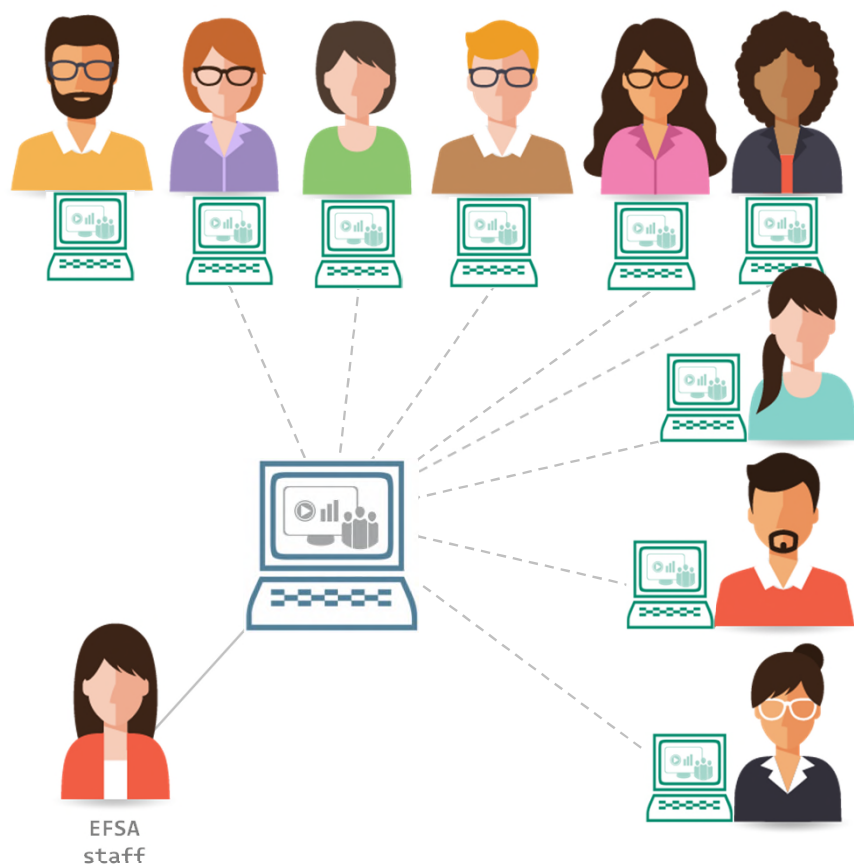
Question number e.g. EFSA-Q-YYYY-XXXXX (optional)

EFSA-Q-

Your question

Submit as:

EFSA WEBINARS



EFSA 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

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

CLARIFICATION TELECONFERENCE (CC/SC PHASE)



EFSA
staff



APPLICANT



Applicant / APDESK



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



EFSA APDESK staff, applicant



30 minutes



Applicant upon reception of an EFSA letter requesting missing information or EFSA 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

DEDICATED SUPPORT FOR SMEs



Calendar English (en)

Search site

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Home Applications helpdesk

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 services catalogue](#)

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22 April 2016

Application toolbox

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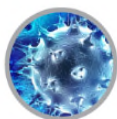
[Event calendar](#)

[Ask a question](#)

Application resources by food sector area

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Administrative support



Monitoring of applications



Fast processing of queries



Official register of SMEs

Since April 2019



Administrative support

- Direct assistance provided by APDESK staff on any **administrative aspects** related to the preparation of an application of a regulated product
- Support on applicable EFSA guidance documents, workflows, procedures, information needed etc.
- Scientific and regulatory advice are out of the scope of this activity
- Dedicated email: SMEoffice@EFSA.europa.eu



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staff



APPLICANT



Monitoring of applications

- Follow-up of applications submitted by SMEs
- Reminder emails
- Workflow with the current status of the application
- Clarification phone call if needed

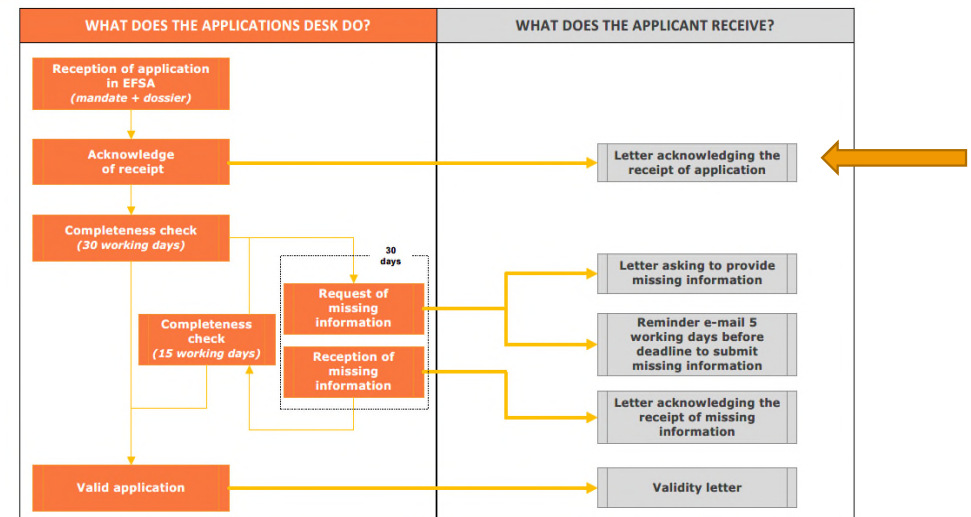


EFSA staff



APPLICANT

Applications FEED additives



DEDICATED SUPPORT FOR SMEs



Fast processing of queries

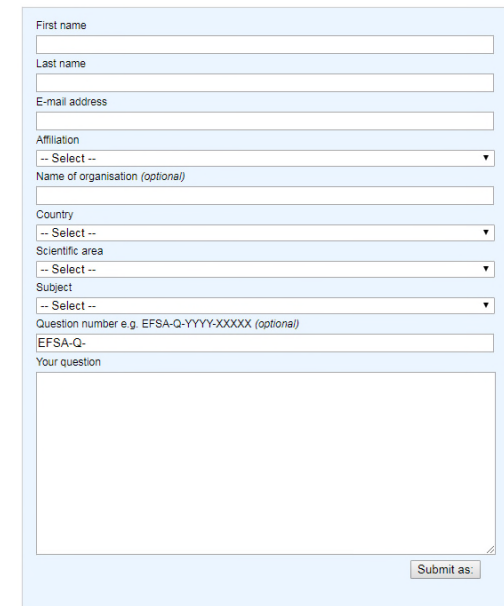
- **Responses** to request through APDESK Web form **in max 7 working days**
- **Phone call** for clarification **if needed**



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APPLICANT



First name

Last name

E-mail address

Affiliation
-- Select --

Name of organisation (optional)

Country
-- Select --

Scientific area
-- Select --

Subject
-- Select --

Question number e.g. EFSA-Q-YYYY-XXXXX (optional)

EFSA-Q-

Your question

Submit as:



Official register of SMEs

- Establish an **internal EFSA register** of SMEs made of companies that are interested on EFSA's work and activities
- List of **contacts** for the development of **future initiatives**

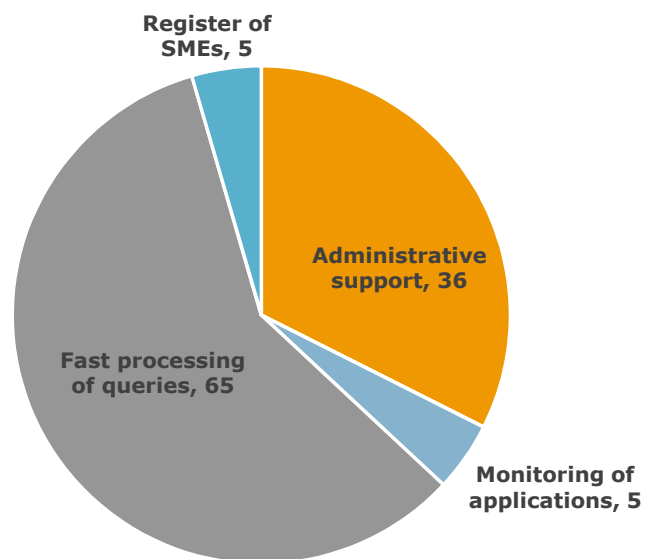


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SERVICES PROVIDED TO SMEs

Total number of services (111)
(UPDATED 14/10/19)



Register of SMEs (5)
FEED 3
NOVEL FOODS 2

Monitoring of applications (5)
BIOHAZ 1
FEED 1
NOVEL FOODS 3

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 want to check the dedicated
support for SMEs? Find it in the
[Applications section](#)
- Do you **have a question** on
applications? Contact EFSA via the
[APDESK webform](#)



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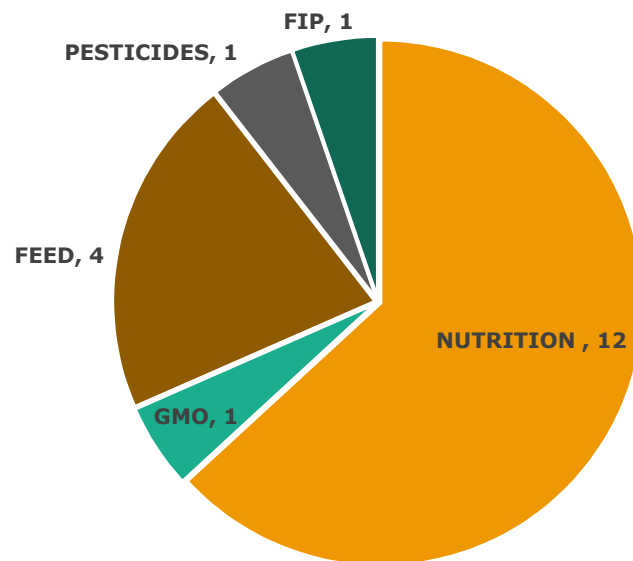


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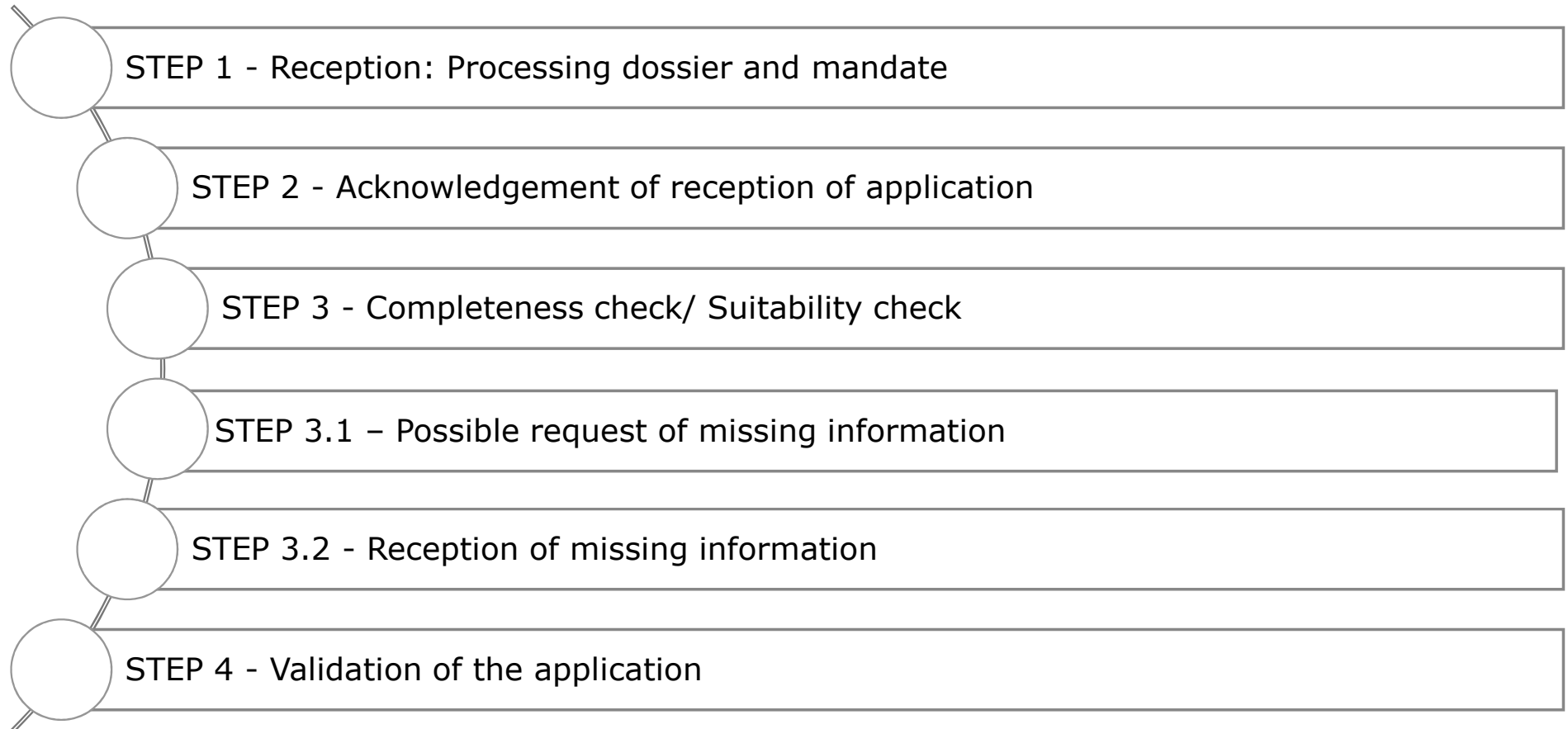
APPLICATIONS RECEIVED FROM SE

■ APPLICATIONS RECEIVED FROM SE STAKEHOLDERS



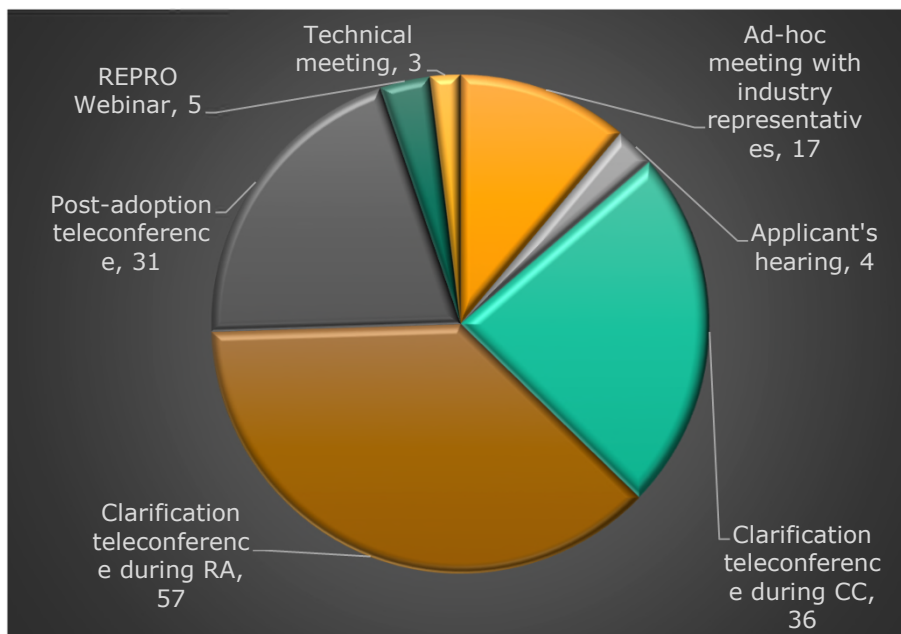
Data since 2003
FEED – Feed Additives
FIP – Food Ingredients and packaging
GMO – Genetically modified organisms
NUTRITION - Novel foods, health claims and food allergens

APPLICATIONS PROCESS: FROM RECEPTION TO VALIDATION



SERVICES TO APPLICANTS

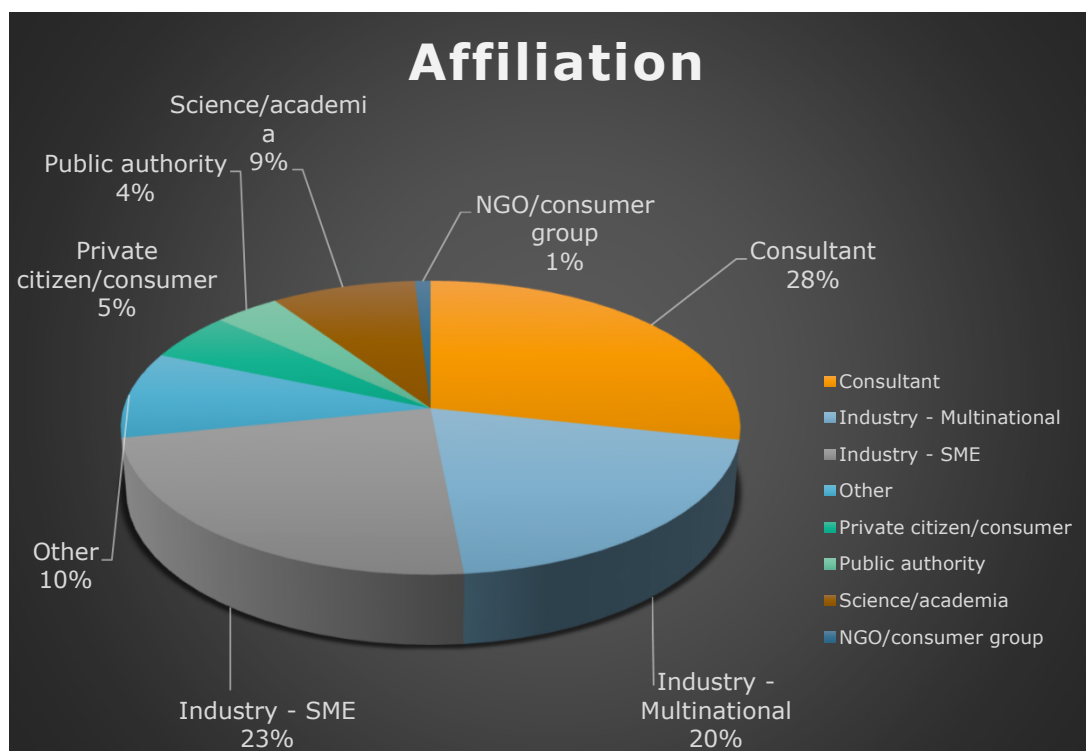
Jan – Sep 2019 (tot: 153)



Service	Count
Ad-hoc meeting with industry representatives	17
Applicant's hearing	4
Clarification teleconference during CC	36
Clarification teleconference during RA	57
Post-adoption teleconference	31
REPRO Webinar	5
Technical meeting	3

APDESK WEBFORM REQUEST

Jan 2013 – Sep 2019 (tot: 2481)



Affiliation	Total
Consultant	705
Industry - Multinational	498
Industry - SME	578
Other	236
Private citizen/consumer	131
Public authority	97
Science/academia	213
NGO/consumer group	23
Grand Total	2481