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

Patricia Romero
Scientific officer – Applications Desk
OVERVIEW

- **APDESK UNIT**
  - Vision, mission and objectives

- **Services to applicants**
  - Guidance document
  - Catalogue of services
  - New dedicated support for SMEs
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**.
Applications are submitted to EFSA

EFSA / APDESK

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

VALID application

Risk assessment

Individual scientific units

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)
  - **The services**
    EFSA’s Catalogue of support initiatives during the life-cycle of applications for regulated products (updated 2019)
  - **The framework**
    Relevant regulatory framework, administrative and scientific guidance documents per regulated product area

- **2 webinars**
  - Webinar: what services does EFSA offer to regulated products’ applicants? (Dec 2016)
  - Webinar: what services does EFSA offer to Small and Medium-sized Enterprises? (May 2019)

- **1 web form**
  - Ask a question webform
ADMINISTRATIVE GUIDANCE FOR THE PROCESSING OF APPLICATIONS

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

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**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 regularly updating its guidance on applications for regulated products on a yearly basis, so far including more than 34 different EU Directives and Implementing Regulations. EFSA has also updated the list of support initiatives to applicants, which is part of the “Administrative guidance for the processing of applications for regulated products.” Various initiatives have been updated or newly created in 2019, such as initiatives to support small and medium-sized enterprises. The updated administrative guidance for the processing of applications for regulated products describes its role in a harmonised way in the general workflow of applications, the key steps of the scientific risk assessment process, the mechanisms of suspension/extension of the scientific assessment, the rapid, the conclusion of the scientific risk assessment process, and the publication of the scientific output. EFSA will continue to develop and provide support initiatives with the aim of ensuring transparency and consistency in the risk assessment process, and to ensure that a coherent, rapid, systematic and efficient process is carried out in compliance with each national legislation. The administrative guidance for the processing of applications for regulated products describes its role in a harmonised way in the general workflow of applications, the key steps of the scientific risk assessment process, the mechanisms of suspension/extension of the scientific assessment, the rapid, the conclusion of the scientific risk assessment process, and the publication of the scientific output. EFSA will continue to develop and provide support initiatives with the aim of ensuring transparency and consistency in the risk assessment process, and to ensure that a coherent, rapid, systematic and efficient process is carried out in compliance with each national legislation.
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.

Highlight:
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
Any stakeholder interested in 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

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

Submit **EFSAs:**
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, 1 hour, 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
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)

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

Administrative support
Monitoring of applications
Fast processing of queries
Official register of SMEs

Since April 2019
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**
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
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**
DEDICATED SUPPORT FOR SMEs

Official register of SMEs

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

https://ec.europa.eu/eusurvey/runner/SMEsRegister
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
- Administrative support, 36
- Fast processing of queries, 65
- Monitoring of applications, 5
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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APPLICATIONS RECEIVED FROM SE STAKEHOLDERS

- NUTRITION, 12
- FEED, 4
- PESTICIDES, 1
- GMO, 1
- FIP, 1

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

STEP 1 - Reception: Processing dossier and mandate

STEP 2 - Acknowledgement of reception of application

STEP 3 - Completeness check/ Suitability check

STEP 3.1 – Possible request of missing information

STEP 3.2 - Reception of missing information

STEP 4 - Validation of the application
SERVICES TO APPLICANTS

Jan – Sep 2019 (tot: 153)

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<td>Ad-hoc meeting with industry representatives</td>
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<tr>
<td>Applicant's hearing</td>
<td>4</td>
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<tr>
<td>Clarification teleconference during CC</td>
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<tr>
<td>Clarification teleconference during RA</td>
<td>57</td>
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<tr>
<td>Post-adoption teleconference</td>
<td>31</td>
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<td>REPRO Webinar</td>
<td>5</td>
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<td>Technical meeting</td>
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APDESK WEBFORM REQUEST

Jan 2013 – Sep 2019 (tot: 2481)

Affiliation

- Consultant: 28%
- Industry - Multinational: 20%
- Industry - SME: 23%
- Other: 10%
- Private citizen/consumer: 5%
- Public authority: 4%
- Science/academia: 9%
- NGO/consumer group: 1%

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<td>Consultant</td>
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<td>Industry - Multinational</td>
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<td><strong>Grand Total</strong></td>
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Jan 2013 – Sep 2019 (tot: 2481)