TECHNICAL REPORT

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

European Food Safety Authority

Abstract

As part of EFSA's effort on-going commitment to engage with all its stakeholders and to increase understanding of its scientific risk assessment work, the Scientific Evaluation of Regulated Products (REPRO) Department has developed an EFSA customer oriented approach towards all stakeholders in the area of applications for regulated products with the aim to establish an evaluation process that is more interactive and responsive. The current EFSA Catalogue provides the list of harmonized support initiatives 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, when it is applicable, 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 for each support initiative, EFSA wishes to increase awareness on the matter and especially encourage an active accessibility to the different services in place for applicants and other interested parties when possible and needed. The proposed support initiatives currently harmonised and presented with the EFSA Catalogue will be updated and completed with newly developed ones in the upcoming years, in view of arising needs and resource availability in EFSA.

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

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Correspondence: APDESK.applications@efsa.europa.eu

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Summary

EFSA and its Scientific Evaluation of Regulated Products (REPRO) Department are developing an EFSA customer oriented approach towards all stakeholders in the area of applications for regulated products with the aim to enhance dialogue with applicants, Member States and other interested parties (e.g. universities, research organisations, Non-Governmental Organisations, consumer groups, citizens). In order to achieve this objective, the Applications Desk Unit has developed a multi-annual project aiming at establishing an evaluation process that is more interactive and responsive. On one hand, by promoting a set of coordinated activities supporting EFSA stakeholders on regulated products and, on the other hand, regularly monitoring the satisfaction level of interested parties. It is part of EFSA's effort and on-going commitment[1] to engage with all its stakeholders and to increase understanding of its scientific risk assessment work. The current "Catalogue of support initiatives during the life-cycle of applications for regulated products" (hereafter referred to as the "Catalogue") is one of many initiatives undertaken by EFSA in this area.

The current EFSA Catalogue provides the list of harmonized support initiatives that are currently implemented in EFSA for applicants, Member States and other interested parties (e.g. universities, research organisations, Non-Governmental Organisations, consumer groups, citizens) during the entire life-cycle of applications for regulated products (pre-submission, completeness/suitability check, risk assessment, adoption and publication of the scientific output). It is not an exhaustive list of all supports provided by EFSA in the area of Regulated Products and specified in each vertical legislation.

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 (e.g. physical meeting, telephone conference, etc), the unit in charge, the date from which the service is in place, when it is applicable, 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.

The range of support initiatives harmonised and presented in the Catalogue are shown below:

- **Pre-submission phase and/or during the entire life-cycle of the application**
  - EFSA guidance document: Production, revision and update of EFSA guidance documents (including explanatory notes)
  - EFSA Info Session on Applications: EFSA Info Session on Applications on administrative and scientific issues to improve the understanding of the application process
  - Scientific workshop/conference on scientific issues as a forum for dialogue on scientific issues of interest to the scientific community
  - EFSA APDESK web form to increase understanding on: EU regulatory framework, procedural steps, status of applications, etc; follow up of EFSA APDESK web form queries to clarify administrative and scientific requirements

- **Submission**
  - Submission and update of applications and related documents for regulated products to EFSA by electronic means only (CD ROMs, DVDs or USB key)

[1] A REPRO Task Force on Customer oriented approach has been created in EFSA since May 2013. It is composed by all the Heads of Units of the REPRO Department, representatives of the Communications and External Relations Department and Legal & Regulatory Affairs Unit. The Task Force discusses the current support provided to all stakeholders during the whole life-cycle of the application and the support provided to applicants specifically (EFSA-M-2014-0106).

- **Completeness/suitability check phase**
  - Clarification teleconference when the request for missing information by EFSA is not clear to the applicant

- **Risk assessment phase**
  - Clarification teleconference when the request for additional information by EFSA during the scientific assessment is not clear to the applicant
  - Applicants' hearing provides the applicant with the possibility to clarify the additional data submitted by attending, as hearing expert, an agenda point of the EFSA Working Group or Panel meetings

- **Adoption and publication of a scientific output**
  - Notification email to the applicant on the adoption of the scientific output
  - Pre-notification of adopted scientific output before publication on the EFSA website
  - Post-adoption teleconference to clarify the scientific rationale of the final EFSA output

The Catalogue intends to make applicants and other interested parties aware of the range of support initiatives which are currently in place in EFSA to support them in the understanding of the regulated products topics and processes. At the same time the EFSA Catalogue describes the different stages of the application life-cycle in which such services could be accessed by the different stakeholders. By describing the details for each support initiative, EFSA wishes to increase awareness on the matter and especially encourage an active accessibility to the different services in place for applicants and other interested parties when possible and needed.

The proposed support initiatives currently harmonised and presented within the EFSA Catalogue will be updated and completed with newly developed ones in the upcoming years, in view of arising needs and resource availability in EFSA.

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1. Introduction

1.1. Background

In the framework of supporting innovation in the European Union, customer satisfaction of interested parties becomes a key indicator for the European Food Safety Authority (EFSA) to respond to stakeholders' needs and interests. In order to achieve its overall objective to reinforce confidence and trust in the EU food safety system and enhance its interaction with stakeholders, EFSA has created the Applications Desk (APDESK) Unit to facilitate dialogue and to provide additional support to stakeholders. The APDESK Unit is providing a front office and support desk in the area of regulated products, including a streamlined and consistent communication to applicants, Member States and other interested parties (e.g. universities, research organisations, Non-Governmental Organisations, consumer groups and citizens).

EFSA has developed a multi-annual project on "*Interactions with Stakeholders – Development of a customer oriented approach for applications for regulated products*"[2] comprising a set of coordinated activities supporting EFSA' stakeholders in the area of applications for regulated products. This project has four-year duration and aims at establishing an evaluation process that is more interactive and responsive by promoting and supporting high quality submission of applications and by regularly monitoring and measuring the satisfaction level of interested parties.

During 2012 and 2013, the following activities were set up by EFSA and its APDESK Unit in the framework of the customer oriented approach:

- In 2012, a call for tender on "*EFSA APDESK Questionnaire on Stakeholder's needs – special focus on Small and Medium-sized enterprises (SMEs) (CFT/EFSA/APDESK/2012/01)*" was launched. Stakeholders consulted were applicants, Member States and other interested parties (e.g. universities, research organisations, Non-Governmental Organisations, consumer groups, citizens). A total of 390 feedback were collected from various stakeholders and a list of the most expected services that interested parties would like to see rolled out in the future by EFSA APDESK Service was drawn. The outcome of the study was published on the EFSA website on 16 September 2013[3].
- In May 2013, an internal REPRO Task Force on Customer oriented approach was created and composed by all the Heads of Units of the REPRO Department, representatives of the Communications Department, Legal Unit and the Stakeholder Office. The Task Force discussed the current support provided to all stakeholders during the whole life-cycle of the applications and the support provided to applicants specifically. This exercise was an opportunity to share best experiences between REPRO Department units, review the impact of newly implemented initiatives and discuss the outcome of the EFSA stakeholder surveys as a way to ensure continuous service enhancement within EFSA. The activities allowed EFSA to propose the current Catalogue of support initiatives during the life-cycle of the applications for regulated products.
- In June 2013, as a follow up to the survey on stakeholders' needs, a call for tender on "*EFSA APDESK survey on stakeholders' satisfaction on provided services*" was launched. The target audience of the survey was EFSA's interested parties in the area of regulated products. The study aimed at reaching a broad range of stakeholders which are involved in the application process or are interested in the regulated products areas. The research is the first step towards a wider plan to monitor the satisfaction level on EFSA initiatives to support applicants and stakeholders and is aiming at establishing a benchmark for measuring the impact of continuous service enhancement. The outcome of the study was published on the EFSA website on 18 December 2014[4].

[2] Mandate EFSA-M-2014-0106

[3] ICF GHK, 2013. EFSA APDESK questionnaire on stakeholder needs. EFSA supporting publication 2013:EN-483, 33 pp.

[4] Valdani Vicari & Associati, 2014. EFSA APDESK survey on stakeholders' satisfaction on provided services. EFSA supporting publication 2014:EN-722, 25 pp.

1.2. Purpose

The current **EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products** (hereafter referred to as the **"Catalogue"**) provides an overview of the support initiatives that are currently implemented in EFSA for applicants, Member States and other interested parties (e.g. universities, research organisations, Non-Governmental Organisations, consumer groups, citizens) during the entire life-cycle of applications for regulated products. The Catalogue aims, on one hand to actively inform all stakeholders on the overview of support initiatives currently in place in EFSA on regulated products. On the other hand, it aims to create awareness and mutual understanding around the various opportunities for interaction and dialogue among all parties involved in regulated products applications. The Catalogue presents support initiatives which in some cases are specific for applicants, and in other cases, are addressed to all interested parties.

1.3. Structure

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 (e.g. physical meeting, telephone conference, etc), the unit in charge, the date from which the service is in place, when it is applicable, the participants, the type of outcome, who can access the service, when and how to access the service, the staff member/s in charge.

To the aim of presenting the range of support initiatives available within EFSA on regulated products, the life-cycle of an application has been divided into 5 phases:

- Phase 1: Pre-submission
- Phase 2: Submission
- Phase 3: Evaluation
    - 3a: Completeness/suitability check
    - 3b: Risk assessment
- Phases 4&5: Adoption and publication of the scientific output

Figure 1: Overview of EFSA support initiatives available during the life-cycle of an application for food and feed regulated products, except Pesticides

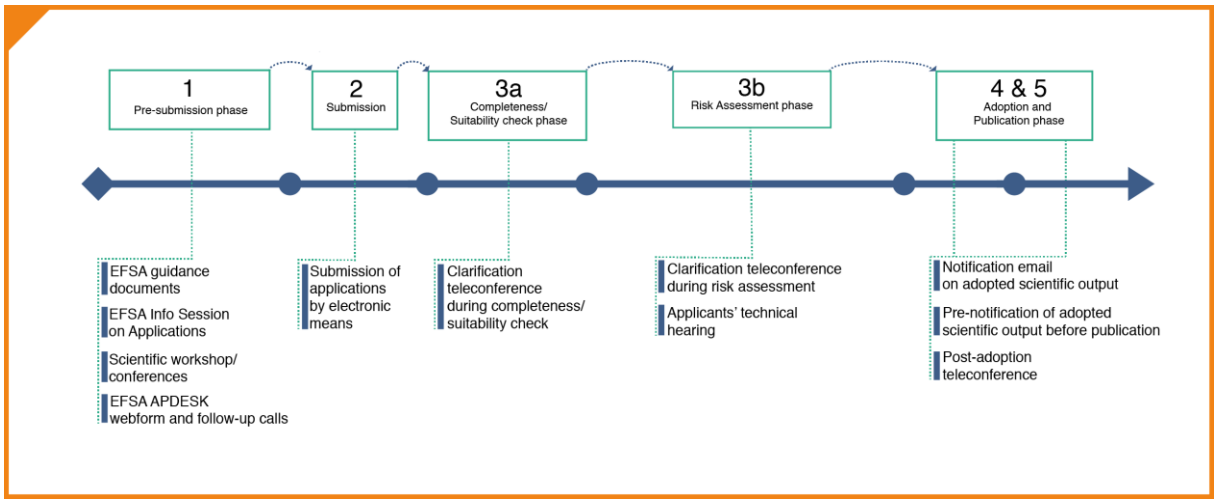
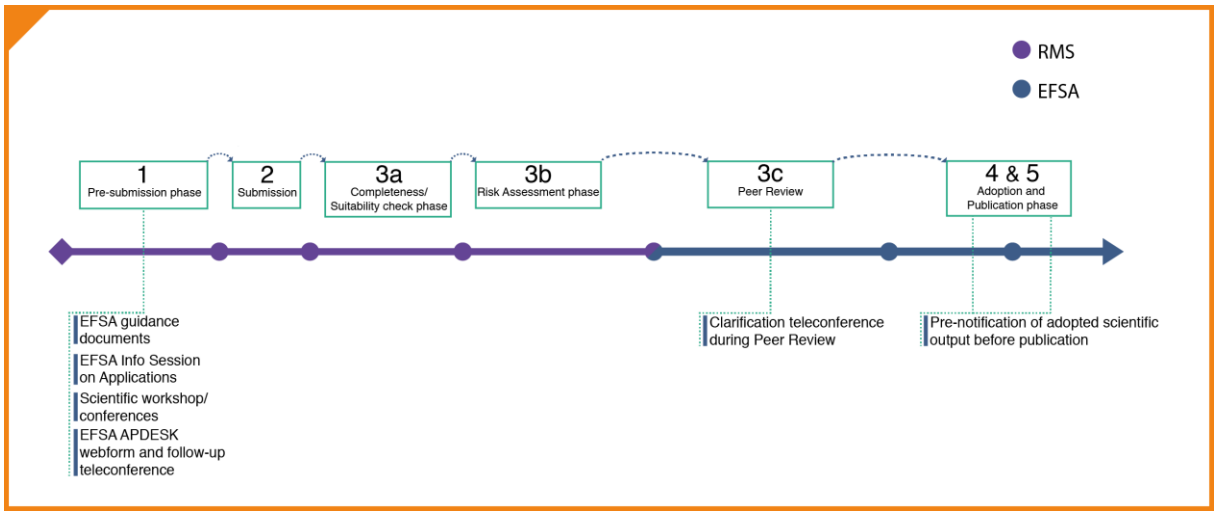


Figure 2: Overview of EFSA support initiatives available during the life-cycle of an application for Pesticides



2. The Catalogue

2.1. PHASE 1 – PRE-SUBMISSION

Please note that all the initiatives listed under this chapter are also applicable throughout the entire life-cycle of the application.

2.1.1. EFSA guidance document

Service name	EFSA guidance document
Unit in charge	Units of the REPRO Department
Service available from	2003
Description	The production, revisions and updates of EFSA guidance documents are performed regularly, on an *ad hoc* basis, by the EFSA scientific Panels of the REPRO Department depending on the need to explain certain administrative or scientific requirements. Two types of guidance documents are produced: technical guidance document and administrative guidance document. The production of new guidance documents depends on an identified need or a new topic. The update of an existing EFSA guidance document can include: i) more examples or case studies; ii) detailed data requirements (e.g. checklists); iii) list of scientific evidence to be submitted; etc. The development of explanatory note documents to an existing EFSA guidance are supplementary documents including detailed explanation of key principles and examples of good studies/reporting that could be helpful to better understand the data requirements specified in the guidance documents.
Participants	NA
Scope	The production and revision of guidance documents aims at explaining the administrative and scientific requirements for the submission of an application for regulated products in a specific thematic area, by providing more detailed information on administrative, scientific and technical topics.
Duration	NA
Outcome	New guidance documents, updated ones and explanatory notes are published on the EFSA website/Panel & Units section/under Guidance for applicants and are incorporated on the table on the 'Overview of regulatory framework and guidance documents' under the Applications Helpdesk section.
Who can request the service	NA
When to request the service	NA
How to request the service	NA
Staff in charge	NA

2.1.2. EFSA scientific opinions and guidance document for Pesticides

Service name	EFSA scientific opinions and guidance document for Pesticides
Unit in charge	Pesticides Unit
Service available from	2003
Description	The production, revisions and updates of guidance documents issued by the Panel on Plant Protection Products and their Residues (PPR Panel) and by EFSA guidance documents are performed regularly, on an *ad hoc* basis, according to the priorities established at the Pesticide Steering Network, the PPR Panel self-mandates for updating the scientific assessments and the mandates received from the European Commission. Two types of documents are produced: • specific guidance documents issued by the PPR Panel or by EFSA. The guidance documents after being adopted by EFSA are submitted for discussion and possible comments to the PAFF Standing Committee, who decides on the regulatory implementation of the guidance document • scientific opinions covering the current state of the art. They are usually the starting point for a guidance development but they are not part of the formal regulatory implementation. Nevertheless they offer EFSA's recommendations for the scientific assessment of pesticides
Participants	NA
Scope	The guidance documents aim at explaining the risk assessment process to be followed by the applicant, the rapporteur Member State and EFSA.
Duration	NA
Outcome	The guidance documents formally adopted in the regulatory context and available from the European Commission web site. The scientific opinions and new or updated guidance documents are published on the EFSA Journal and are available from the EFSA website/Pesticides section/Guidance for applicants.
Who can request the service	NA
When to request the service	NA
How to request the service	NA
Staff in charge	NA

2.1.3. EFSA Info Session on Applications

Service name	EFSA Info Session on Applications
Unit in charge	Applications Desk Unit together with REPRO Scientific Units
Service available from	November 2012
Description	EFSA Info Sessions on Applications are technical meetings organised by the APDESK Unit together with the Scientific Units in REPRO and addressed to applicants, Member States and any other interested parties. The technical meetings can cover administrative and scientific issues related to the preparation and presentation of applications for regulated products. They represent a forum to discuss: i) the outcome of public consultations; ii) finalised administrative and scientific guidance documents; iii) specific scientific topics of relevance for the REPRO Department.
Scope	The technical meetings aim at setting up a dialogue between EFSA and various stakeholders involved with regulated products by improving the understanding and the communication on the applications process. They provide applicants and interested parties with an opportunity to exchange views and enhance an open dialogue on specific scientific issues related to applications for regulated products. These technical meetings do not provide pre-assessment on upcoming or on-going applications.
Participants	• EFSA experts of Working Groups/Panels members • EFSA staff • European Commission representatives (on an *ad hoc* basis) • Online registrants[5]
Duration	Possible options: Half a day, one day, one and a half day
Outcome	Publication on EFSA website Events section of: • the final agenda of the technical meeting • all presentations • a short post-event summary with the main points of discussion
Who can participate	Everybody[5]
When to request participation	Once public registration to an Info Session is opened on EFSA website
How to request participation	Online registration on EFSA website
Staff in charge	APDESK staff: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK Unit staff members (EFSA directory)

[5] In case the maximum number of participants is reached for a dedicated event, EFSA reserves the rights to select participants in order to ensure a thorough discussion to the meeting.

2.1.4. Scientific workshop/conference on scientific issues

Service name	Scientific workshop/conference
Unit in charge	EFSA Units
Service available from	2003
Description	Scientific workshops and conferences provide a forum for dialogue, exchange of information and views on scientific food and feed safety issues of interest to the scientific community. The scientific topics are not strictly related to applications for regulated products and can cover various topics linked to the scientific assessment of all risks associated with the food chain (methodology, design of study, reporting activity, presentation of a document for public consultation).
Scope	These conferences and workshops aim at setting up direct communication and an open dialogue with interested parties on specific and tailored scientific topics. EFSA aims to create a forum for discussion among various experts to increase awareness on specific scientific issues in order to allow exchange of views on topics of interest to the scientific community and to the consumers.
Participants	• EFSA experts of Working Groups/Panels members • EFSA staff • European Commission representatives (on an *ad hoc* basis) • Online registrants[6]
Duration	NA
Outcome	Publication on EFSA website/Events section of: • the final agenda of the workshop/conference • all presentations • the list of participants • the event report
Who can participate	Everybody[6]
When to request participation	Once public registration to a workshop/conference is opened on EFSA website
How to request participation	Online registration on EFSA website
Staff in charge	NA

[6] In case the maximum number of participants is reached for a dedicated event, EFSA reserves the rights to select participants in order to ensure a thorough discussion to the meeting.

2.1.5. EFSA APDESK web form

Service name	EFSA APDESK web form on regulated products
Unit in charge	Applications Desk Unit
Service available from	November 2011
Description	Front office and support desk activity promoting a direct communication channel and managed by the Applications Helpdesk, through which requestors can submit queries to EFSA related to regulated products matters (including administrative and scientific issues, EU regulatory framework, guidance documents requirements, procedural steps, status of specific applications, etc.). The Application Helpdesk service, in consultation with the scientific units, provides answers to all requestors within a maximum of 15 working days.
Scope	The web form aims at boosting dialogue with stakeholders and audience interactivity improving two-way communication between EFSA and its stakeholders and providing a direct communication channel. It seeks to increase understanding of regulated products regulatory framework, EFSA's scientific and administrative requirements for the submission of applications on regulated products. It also aims at providing timely responses to requestors on the status of specific applications and clarifications on further steps of the assessment procedure.
Participants	NA
Duration	Responses to web form requests are provided within 15 working days
Outcome	The Application Helpdesk service provides answers to all requestors within 15 working days from receipt.
Who can submit a request	Any stakeholder interested in the work of EFSA on regulated products
When to submit a request	Anytime, throughout the entire application life-cycle
How to submit a request	Fill in the web form available on EFSA's Applications Helpdesk web section
Staff in charge	NA

2.1.6. Follow up on EFSA APDESK web form queries

Service name	Teleconference following an EFSA APDESK web form query
Unit in charge	Applications Desk Unit
Service available from	July 2014
Description	As a follow-up to complex requests on applications received through the web form, APDESK might decide to set up *ad hoc* telephone conferences with the requestor to further clarify the issue raised in the web form queries.
Scope	This teleconference, organised by EFSA, aims at enhancing dialogue with stakeholders and interactivity, improving understanding of scientific and administrative requirements for the submission of applications in the area of regulated products. Such telephone conferences do not provide pre-assessment on possible data submission by the applicant on a specific application.
Participants	• EFSA APDESK staff • Web form requestor
Duration	On a case-by-case basis
Outcome	APDESK staff sends an e-mail to the requestor certifying that the teleconference took place including the date and the time of the phone call
To whom the service is provided	Everybody[7] who has sent queries via the web form
When the service is provided	Upon EFSA's decision and following several exchanges via the EFSA APDESK web form to clarify administrative and scientific issues on regulated products
How to request the service	Fill in the web form available on EFSA's Applications Helpdesk web section
Staff in charge	APDESK staff: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK Unit staff members (EFSA directory)

[7] Depending on the subject of concern, the organisation of the teleconference is subject to EFSA' staff decision

2.2. PHASES 2 – SUBMISSION

2.2.1. Submission by electronic means

Service name	Submission of applications and related documents by electronic means
Unit in charge	Applications Desk Unit
Service available from	September 2014
Description	The applications for regulated products and related documents are submitted to EFSA by electronic means such as CD ROMs, DVDs or USB keys. The updates to applications, response to requests for missing/additional information from EFSA are also submitted by electronic means. All applications and related documents submitted to EFSA (either by an applicant, a Member State or the European Commission) shall include the original of a signed cover letter listing all annexes, their tables of content and the mandate.
Participants	Applicants, Member States, European Commission
Scope	The submission by electronic means aims at minimising the administrative burden for applicants and deliver efficiency gains by streamlining the submission of applications and related documents for regulated products in view of the development of a comprehensive IT tool for the electronic management of applications. The submission by electronic means only applies to the submission of applications and related documents addressed to EFSA as per legal requirements. This is without prejudice to the legal requirements imposed on applicants with regards to other institutions or bodies involved in the procedure.
Duration	NA
Outcome	EFSA letter/e-mail of acknowledgement of receipt, including contact person details and format of submission.
To whom the service is provided	An applicant submitting an application, an update, missing/additional information of an application for regulated products to EFSA
When the service is provided	Throughout the application life-cycle
How to request information on the service	During initial submission and completeness/suitability check, contact the APDESK Unit: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK person responsible of the application. The contact name and details are specified in the EFSA letter to applicant During the risk assessment phase, contact the REPRO scientific units: • Contact details: EFSA directory
Staff in charge	During initial submission and completeness/suitability check, APDESK staff: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK Unit staff members (EFSA directory) During the risk assessment phase, REPRO scientific units: • Contact details: EFSA directory

2.3. PHASE 3a –COMPLETENESS CHECK/SUITABILITY CHECK

2.3.1. Clarification teleconference during completeness/suitability check

Service name	Clarification teleconference during completeness/suitability check[8]
Unit in charge	Applications Desk Unit
Service available from	July 2014
Description	A clarification teleconference is a telephone conference organised between EFSA APDESK staff and the applicant, following a letter from EFSA requesting missing information to the applicant during the completeness/suitability check (CC) phase (Figure 1 - phase 3a). It is organised upon request by the applicant and/or by EFSA in case of several attempts of submission of incorrect missing information. In exceptional circumstances, the clarification teleconference might be organised in the form of a physical meeting.
Scope	The clarification teleconference is organised in case a request for missing information by EFSA is not clear to the applicant. This teleconference can be requested to: i) clarify administrative and scientific rationale of individual questions raised during the completeness/suitability check; ii) ensure understanding of the question to be answered by the applicant.
Participants	• EFSA APDESK staff • Applicant
Duration	1 hour (indicative timeline)
Outcome	EFSA APDESK staff sends an e-mail acknowledging that the teleconference took place indicating the date and duration of the teleconference.
Who can request the service	An applicant who has an application filed within EFSA
When to request the service	Upon reception of an EFSA letter requesting missing information during the completeness /suitability check of an application (Figure 1 - phase 3a)
How to request the service	Contact the APDESK Unit via: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK person responsible of the application. The contact name and details are specified in the EFSA letter to applicant (i.e. missing information letter)
Staff in charge:	APDESK staff: • E-mail: APDESK.applications@efsa.europa.eu • Phone: APDESK Unit staff members (EFSA directory)

[8] This service is not applicable for applications for PESTICIDES (i.e. Peer Review, MRL) as, according to the applicable Regulations, the first phase of the risk assessment of the application is performed by the Rapporteur/evaluating Member State (see Figure 2).

2.4. PHASE 3b – RISK ASSESSMENT

2.4.1. Clarification teleconference during risk assessment

Service name	Clarification teleconference during risk assessment
Unit in charge	Scientific Units of the REPRO Department
Service available from	July 2014
Description	A clarification teleconference is a telephone conference organised between EFSA staff of the scientific REPRO Units and the applicant, following a letter from EFSA requesting additional information to the applicant during the risk assessment (RA) phase (Figure 1 - phase 3b). It is organised upon request by the applicant. In exceptional circumstances, the clarification teleconference might be organised in the form of a physical meeting and on an *ad-hoc* basis participation of EFSA's experts might be considered by EFSA.
Scope	The clarification teleconference is organised in case a request for additional information by EFSA is not clear to the applicant. This teleconference can be requested to: 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. This meeting does not provide pre-assessment on upcoming responses to be submitted by the applicant.
Participants	• EFSA staff • Applicant
Duration	1 hour (indicative timeline)
Outcome	EFSA staff from the scientific unit sends an e-mail to all participants acknowledging that the teleconference took place indicating the date, duration of the teleconference.
Who can request the service	An applicant who has an application filed within EFSA
When to request the service	Upon reception of an EFSA letter requesting additional information during the risk assessment of an application (Figure 1 - phase 3b)
How to request the service	E-mail or phone call the contact person responsible of the application in the Scientific Unit (EFSA directory). Contact details are specified in the EFSA letter to applicant – request for additional information.
Staff in charge	REPRO scientific units' staff: • Contact details: EFSA directory

2.4.2. Clarification teleconference during Peer Review for Pesticides

Service name	Clarification teleconference during Peer Review
Unit in charge	Pesticides Unit of the REPRO Department
Service available from	July 2014
Description	A clarification teleconference is a telephone conference organised between EFSA staff of the Pesticides Unit and the applicant, following a letter from EFSA requesting additional information to the applicant during the peer review phase (Figure 2 - Phase 3c). It is organised upon request from the applicant. In exceptional circumstances, the clarification teleconference might be organised in the form of a physical meeting.
Scope	The clarification teleconference is organised to clarify scientific rationale of individual questions raised during the peer review process and when the additional information requested by EFSA is not clear to the applicant. This teleconference can be requested to: i) clarify scientific rationale of individual questions raised during the peer review; ii) ensure understanding of the answers to be provided by the applicant. This meeting does not provide pre-assessment on upcoming responses to be submitted by the applicant.
Participants	• EFSA staff • Applicant • Rapporteur / evaluating Member States (on an *ad-hoc* basis)
Duration	1 hour (indicative timeline)
Outcome	EFSA sends an e-mail to all participants certifying that the teleconference took place indicating the date, duration of the teleconference.
Who can request the service	An applicant who has an application submitted in the Member States and for which a peer review has been requested to EFSA
When to request the service	Upon reception of an EFSA letter requesting additional information during the peer review phase (Figure 2 - phase 3c)
How to request the service	E-mail or phone call the contact person responsible of the peer review in the Pesticides Unit (EFSA directory). Contact details are specified in the EFSA letter requesting additional information.
Staff in charge	REPRO scientific units' staff: • Contact details: EFSA directory

2.4.3. Applicants' hearing

Service name	Applicants' hearing at Working group and Panel's plenary meetings during risk assessment[9] (upon request from EFSA only)
Unit in charge	Scientific Unit of the REPRO Department
Service available from	July 2014
Description	Upon request from EFSA, an applicant is invited, as hearing expert, to attend a specific agenda item of the Authority's Working Groups or Panels meetings - either in person or via teleconference - to answer questions and to clarify outstanding issues about the submitted data.
Scope	The participation of an applicant to a technical hearing in front of Working Group and/or Panel Plenary meetings is organised after examining the written response from the applicant to the Authority's request for additional information. It aims at clarifying the additional data or supplementary information provided by the applicant during the risk assessment phase, when considered not appropriate or unclear by the members of Working Groups and/or Panels and/or EFSA staff.
Participants	• Experts of Working Groups/Panels participants • EFSA staff • Applicant
Duration	2 hours (as a maximum)
Outcome	The participation of an applicant to as hearing expert is reported in the Working Group/Panel meeting minutes, published on EFSA's website. After the teleconference/meeting, EFSA staff sends a follow-up letter to the applicant clarifying the main points discussed and the outcome of the discussion to ensure mutual understanding.
Who can request the service	EFSA's Working Groups, EFSA's Panels members
When to request the service	EFSA Working Groups and/or Panel members decide if it is necessary to hear the applicants' after examining the written response from the applicant to the Authority's initial request for additional or supplementary information
How to participate	EFSA invites applicants to attend specific agenda items of the meetings of the Authority's Working Groups or Scientific Panels as hearing experts
Staff in charge	REPRO scientific units' staff: • Contact details: EFSA directory

[9] This service is not applicable for Pesticides (i.e. Peer Review, MRL) as, according to the applicable Regulations, the risk assessment of the additional information is performed by the Rapporteur / evaluating Member State.

2.5. PHASES 4 & 5 – ADOPTION AND PUBLICATION OF A SCIENTIFIC OUTPUT

2.5.1. Notification email on adoption of scientific output

Service name	Notification email on adoption of scientific output[10]
Unit in charge	Scientific Unit of the REPRO Department
Service available from	July 2014
Description	Within one working day after adoption of a scientific output on applications, EFSA's staff sends a notification email to the applicant informing on the adoption of the scientific output by the EFSA scientific Panel. EFSA aims at publishing all its adopted outputs within 15 working days after their adoption by the relevant EFSA Scientific Panels.
Scope	Inform the applicant on a timely manner that the output related to his/her application has been adopted by the Panel.
Participants	EFSA staff of the respective Scientific Unit of the REPRO Department
Duration	NA
Outcome	Email sent by EFSA staff to applicants informing on the adoption of the scientific output by the EFSA scientific Panel.
To whom the service can be provided	An applicant who has filed an application at EFSA
When to request the service	NA
How to request the service	NA (not to be requested as it is a standard EFSA's practice)
Staff in charge	REPRO scientific units' staff: • Contact details: EFSA directory

[10] This service is not applicable for Pesticides (i.e. Peer Review, MRL) as, according to the applicable Regulations, the process of adoption and publication of scientific outputs follows a different workflow (see Figure 2) and it is covered by the service "pre-notification of adopted scientific output before publication".

2.5.2. Pre-notification of adopted scientific output before publication

Service name	Pre-notification of adopted scientific output before publication
Unit in charge	Scientific Unit of the REPRO Department
Service available from	2008
Description	EFSA staff informs, under embargo, the applicant and selected recipients of the upcoming publication of the scientific output already adopted by EFSA. At least 24 hours prior to publication, a copy of the adopted scientific output on applications is shared with selected recipients including the applicant. EFSA website remains the official reference site where to seek confirmation of the final adopted output.
Scope	Inform in a timely manner the applicant, the European Commission and other stakeholders of the publication of the adopted scientific output on the EFSA website
Participants	Scientific Unit of the REPRO Department
Duration	NA
Outcome	E-mail sent, under embargo, by EFSA with the adopted scientific output on applications in attachment (pdf format)
Who can request the service	NA
When to request the service	NA
How to request the service	NA (not to be requested as it is a standard EFSA's practice)
Staff in charge	REPRO scientific units' staff: • Contact details: EFSA directory

2.5.3. Post-adoption teleconference

Service name	Post-adoption teleconference with individual applicants[11]
Unit in charge	Scientific Unit of the REPRO Department
Service available from	March 2015
Description	Post-adoption teleconference between the applicant and EFSA staff organised following the publication of an EFSA scientific output on a regulated product. Please note that, for the time being, due to resource and budget constraints, the service will be granted in the case of negative and/or inconclusive scientific output.
Scope	This telephone conference aims at establishing a dialogue between applicants and EFSA to i) explain the scientific rationale of the final output from the Panel and/or EFSA; ii) clarify the recommendations of the scientific output (if applicable); iii) clarify the sources of evidence and the factors that influenced the outcome. Post-adoption teleconferences/meetings are not meant to provide any scientific advice to applicants for future submission. The aim of the discussion is limited to the content of the final scientific output, as expressed by the Panel and/or EFSA.
Participants	• EFSA staff • Applicant • European Commission representatives (on an *ad hoc* basis)
Duration	2 hours (approximate timeline)
Outcome	The outcome of the teleconference consists in a follow-up letter drafted by the EFSA staff from the REPRO scientific unit in charge and addressed to the applicant including the main points of the discussion. The purpose of the follow up letter is to keep track in a transparent way of what has been discussed during the meeting.
Who can request the service	An applicant who has filed an application to EFSA and received a negative and/or inconclusive scientific output
When to request the service	After the publication of a scientific output on applications on EFSA's website
How to request the service	Concerned applicant shall send an e-mail to the EFSA scientific unit
Staff member in charge	REPRO scientific units' staff: • Contact details: EFSA directory

[11] This service is not applicable for Pesticides (i.e. Peer Review and MRL) as, according to the applicable Regulations, the applicant has the opportunity to provide comments on the scientific output during the consultation period performed by the European Commission.

3. Conclusions

The current EFSA's Catalogue of support initiatives gives a description of the various support initiatives that EFSA has put in place in the area of regulated products for applicants and other stakeholders. It also provides an analysis, for each support initiative, of the phase in which the support can be requested in the life-cycle of the application, the format and the parties involved. By describing the details for each support initiative, EFSA wishes to increase awareness on the matter and especially encourage an active accessibility to the different support initiatives in place for applicants and interested parties.

The work of EFSA on customer oriented approach is focussed on understanding needs, streamlining already available support initiatives and assessing the implementation of possible new ones. By opening up to a more constructive dialogue, EFSA will continue working in order to propose appropriate answers to stakeholders' expectations while remaining faithful to its main objective of providing independent scientific advice to the Risk Managers. To this aim some initiatives have already been implemented, while others are currently under consideration.

The proposed support initiatives currently harmonised and presented with this EFSA Catalogue will be updated and completed with newly developed services in the upcoming years, in view of arising needs and resources availability in EFSA.

Abbreviations

APDESK	Applications Desk
CC	Completeness check
CD ROM	Compact Disc Read-Only Memory
DVD	Digital versatile disc or digital video disc
EFSA	European Food Safety Authority
FEED	Feed additives
FIP	Food ingredients and packaging
GMO	Genetically modified organisms
MRL	Maximum Residue Levels
RA	Risk assessment
RAW	Risk assessment workflow
REPRO	Scientific Evaluation of Regulated Products
PAFF - SC	Plants, Animals, Food and Feed Standing Committee
PPR	Plant Protection Products and their Residues
USB	Universal Serial Bus

Appendix A – Relevant links

- **Register of Question database (RAW)**

Information about each request/mandate (e.i. specific application), including supporting documents and the current status of the application, is available in the Register of Questions database. The Register of Question is updated on a daily basis.

Link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL

Register of Questions tutorial video:
https://www.youtube.com/watch?v=K8OrZ1K8I7I&list=PLGDvgn1aAEEYFeahclGs7KEo9lzB9_w2k

- **Minutes of Working Group meetings**

The minutes of the Working Groups' discussions provide information on: the participants, (experts, EFSA staff, hearing experts when applicable); the issues discussed (specific applications listed with their unique EFSA question number, guidance documents, etc) including a synthetic statement on the status of the applications (e.i. identification of questions for additional information, draft ready for discussion in plenary…).

Links:

- FEED: Working groups of the Panel on Additives and Products or Substances used in Animal Feed
  http://www.efsa.europa.eu/en/feedap/feedapwgs.htm
- FIP: Working groups of the ANS Panel and of the CEF Panel
  http://www.efsa.europa.eu/en/fip/fipwgs.htm
- GMO: Working groups of the Panel on Genetically Modified Organisms
  http://www.efsa.europa.eu/en/gmo/gmowgs.htm
- NUTRITION: Working groups of the Panel on Dietetic Products, Nutrition and Allergies
  http://www.efsa.europa.eu/en/nda/ndawgs.htm
- PESTICIDES: Working groups of the Panel on Plant Protection Products and their Residues
  http://www.efsa.europa.eu/en/pesticides/pesticideswgs.htm

- **Agendas and minutes of Plenary meetings**

An overview of the REPRO Plenary meetings dates for the entire year is available on the APDESK web section:http://www.efsa.europa.eu/en/applicationshelpdesk/apdeskplenaryinfosessions.htm

The agendas and minutes of the Plenary meetings of each EFSA Panel are published on EFSA website.
http://www.efsa.europa.eu/en/news/events.htm

Links:

- FEED: http://www.efsa.europa.eu/en/feedap/feedapmeetings.htm
- FIP: http://www.efsa.europa.eu/en/fip/fipmeetings.htm
- GMO: http://www.efsa.europa.eu/en/gmo/gmomeetings.htm

- NUTRITION: http://www.efsa.europa.eu/en/nda/ndameetings.htm
- PESTICIDES: http://www.efsa.europa.eu/en/pesticides/pesticidesmeetings.htm

- **Pesticides Peer Review**

Since August 2002, EFSA has been responsible for the EU peer review of active substances used in plant protection products. This task is carried out by EFSA's Pesticides Unit in line with procedures and deadlines set out in EU legislation. The link to the EFSA website section is: http://www.efsa.europa.eu/en/pesticides/pesticidespeerreview.htm

- **Other relevant links for Pesticides:**
  - **Review of active substances:** http://www.efsa.europa.eu/en/pesticidespeerreview/activesubstancesrev.htm
  - **Summary dossiers and rapporteur Member State assessment reports:** http://www.efsa.europa.eu/en/pesticidespeerreview/assessmentreports.htm
  - **Pesticides peer-review experts meetings:** http://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsmeetings.htm