EFSA Discussion Group on E-SUBMISSION (MATRIX Project)

Terms of Reference (ToR)

1. Background

Since 2012, EFSA is exploring the feasibility to develop for the organisation an electronic platform for the management of all the applications for regulated products received by EFSA in the context of the various sectorial legislations. The project is called the MATRIX Project and is a transformational organisational project aiming to provide EFSA and applicants with more efficient regulated products assessment processes. In particular, the project aims to provide applicants with a more efficient solution for regulated products applications by improving the process, particularly the management of the application lifecycle and digital dossiers, enhancing the submission of applications in electronic formats, the management of applications' administrative workflows and the communication between EFSA and applicants (Matrix-IP Phase I) as well as the support to risk assessors and integration with the Scientific Data Warehouse of EFSA (Matrix-IP Phase II). An overview of the MATRIX-IP Phase 1 action plan is provided in Annex.

The targets for Matrix-IP Phase I are[1]:

- 2016: Digital dossier management solution and pilot of the regulated product workflow
- 2017: Automation of regulated product workflows for a first set of areas
- 2018: Automation of regulated product workflows for the remaining set of areas
- 2019: Support to risk assessment process and connection to scientific data warehouse completed

Engagement with stakeholders in the areas of Regulated Products being one of the EFSA strategic objectives for 2020[1], being addressed on various occasions by Stakeholders, EFSA is suggesting to launch a **new Discussion Groups** (DG) for the entire duration of the MATRIX-IP project to discuss and consult external stakeholders on the technical aspects of the MATRIX-IP Project. The discussion group (**DIG1 E_SUBMISSION**) will be set up to discuss and consult external stakeholders on the technical aspects of the MATRIX Project (actions 1-2-3-4-5). Additional discussion group(s) will be created throughout the project, as the discussion group (**DIG2 OPEN DATA**) on open dossiers (action 6).

The objectives of the Discussion Group is to:

- Foster the engagement of stakeholders;
- Enhance the quality, clarity and usability of the electronic platform to be developed for the management of applications for regulated products;
- Draw lessons for future engagement with stakeholders.

The present document relates exclusively to the creation of the Discussion Group 1 called DIG1 E-SUBMISSION related to actions 1-2-3-4-5.

1 EFSA Single Programming Document 2016 – 2019
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1619.pdf

2. Terms of Reference

Members of the Discussion Group E-SUBMISSION shall:

- Provide timely contributions to the proposals developed in the MATRIX-IP actions 1, 2, 3, 4 and 5 (see Annex) and presented for consultation on administrative and technical aspects based on their expertise, at different stages of the projects;
- Contribute to the collection of critical requirements based on experience and knowledge;
- Attend specific meetings (dedicated Discussion Group meetings/teleconferences) and contribute actively by providing feedback on experience;
- Nominate volunteers. Two pilot phases targeting 3 scientific areas per time will be running and will involve maximum 20 volunteering applicants, MSs, EC. These volunteers will be testing the various workflows, functionalities, communications flow...
- Discuss the achievements, issues and lessons learned from the Pilot Phase and identify future opportunities.

The Discussion Group E-SUBMISSION is a consultative body. The members are not responsible for the final requirements and design of the E-Submission platform which remains a responsibility of EFSA.

3. Composition of the Discussion Group

The Discussion Group on E-SUBMISSION is created under the umbrella of the EFSA Stakeholder Engagement Approach. It will be composed of a maximum of ten representatives from the EFSA Stakeholder Consultative Platform (identified via EFSA stakeholder platform), a maximum of five representatives from the Member States (identified via the EFSA Advisory Forum) and a maximum of five representatives from the European Commission (identified via the EC Unit D1). Additional members might be considered during the project.

Representatives of the Stakeholder Consultative Platform: The group shall be composed, as far as possible, of representative of organisations directly impacted by the submission and processing of applications within EFSA, covering the whole food and feed chain, and covering all areas of Regulated Products (FEED, FIP, GMO, NUTRI, PESTICIDES, BIOHAZ). The candidates shall be selected on the basis of their experience in submitting applications for EFSA (directly, or via the EC/MS), experience in similar projects and their strong motivation. Representatives of organisations who are not members of the Platform can express their interest in taking part in the group through one of the member of the Platform. Members of the Platform are invited to decide among them which organisations are best placed to take part in the Discussion Group on E-SUBMISSION and propose candidates by sending the name, contact details and relevant experience in the field to MATRIX.DIG1.E-SUBMISSION@efsa.europa.eu, copying SHPlatformsecretariat@efsa.europa.eu.

Representatives of the Member States: The experts from the Member States shall be selected on the basis of the relevance of their involvement in the workflow on applications for Regulated products as well as their motivation. Members of the Member States are invited to propose candidates by sending the names and contact details of the candidates to MATRIX.DIG1.E-SUBMISSION@efsa.europa.eu copying ~~afsecretariat@efsa.europa.eu~~.

Representatives of the European Commission: The representatives from the European Commission shall be nominated by the DG SANTE unit D1 – Science, Stakeholder enforcement and by sending the names and contact details of the candidates to MATRIX.DIG1.E-SUBMISSION@efsa.europa.eu copying SHPlatformsecretariat@efsa.europa.eu.

4. Roles and responsibilities

The Discussion Group on E-SUBMISSION is coordinated by the APDESK unit with the support of the External Relation team and the MATRIX project team. Relations and feedback to the Stakeholder Consultative Platform will be assured through the participation of the Secretariat of the Platform in the group and its activities and regular presentations by the APDESK unit of the status of the MATRIX project (e.g. at the Stakeholder Engagement Approach meetings, the Roundtable with Industry associations meetings, the Advisory Forum meetings).

Responsibilities of the members of the Discussion Group on E-SUBMISSION are described in sections 2 and 5.

5. Expected deliverables and timelines

The Discussion Group on E-SUBMISSION will be running from September 2016 until May 2019, end of the work on the MATRIX-IP Phase 1 project.

The group is expected to:

- Contribute to the proposed action plan and selection of pilot case studies;
- Provide timely contributions to the proposals developed in the MATRIX work starting from actions 1, 2, 3, 4 and 5 (see Annex) presented for consultation on administrative and technical aspects and, then, on actions 6, 7, 8, 9, 10, 11 and 12;
- Contribute to the collection of critical requirements based on experience and knowledge;
- Attend specific meetings (dedicated Discussion Group meetings/teleconferences) and contribute actively by providing feedback on experience;
- Nominate volunteers. Two pilot phases targeting 3 scientific areas per time will be running and will involve maximum 20 volunteering applicants, MSs, EC. These volunteers will be testing the various workflows, functionalities, communications flow...
- Prepare a shared document to provide EFSA with feedback on the experience of the Discussion Group on E-SUBMISSION at the end of each year's project phase and at the end of the project. Members of the Discussion Group shall define together the format and the way to populate such report on behalf of the group.

Document history	
Document reference	Version 1
Prepared by	K. Lheureux (APDESK unit), Fabrizio Abbinante (PTT unit)
Reviewed by	J. Kleiner
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ANNEX: **OVERVIEW of the MATRIX Project**

Background

Given the increasing amount of applications submitted to EFSA over the past years and the amount of applications expected for the forthcoming years, EFSA and its REPRO Department evaluated the option of moving to an electronic management of applications system for all regulated products submitted to EFSA. EFSA considered that a transition from a predominantly paper-based to an electronic type of process for the regulated products applications is essential and will bring multiple benefits in terms of efficiency, quality and timeliness for the risk assessment processes as well as more resourceful and transparent communication amongst stakeholders, leading to more predictable workflows. Adherence to the values of scientific excellence, independence, openness, innovation and cooperation is in line with EFSA 2020 Strategy[3] and its vision of "Protecting consumers by providing independent scientific advises on risks on the food chain".

In 2012, the REPRO Department and its APDESK unit lead an internal feasibility study on the e-submission of applications to EFSA. The scope of this project was to investigate, analyse and propose the most feasible solutions to be implemented by EFSA. In 2013, the REPRO Department and its APDESK unit investigated the benefits of structuring data contained in applications of regulated products that would be handled in the future by an electronic management of applications system. Considering the complexity of issues deriving from the variety of workflows and the actors under the current EFSA's regulatory framework, an Organisational Development project called MATRIX was launched in January 2014 aiming to execute the abovementioned analysis and to prepare the implementation phase of the project. The MATRIX Project comprised two phases: the benefits analysis phase (MATRIX-AP) and the implementation phase (MATRIX-IP). In 2015, MATRIX-AP project phase concluded delivering an analysis and update of the EFSA's Regulated Products Workflows, a Benefit Analysis of internal and external stakeholders an analysis of the need to structure a dossier.

The overall recommendations of the MATRIX-AP were:

- Fully structured technical dossier with some structured data;
- Two phases project
  - First phase: structuring of the dossier, automation of dossier's submission, administrative workflows, communication with applicants and publication of relevant parts of the dossier;
  - Second phase: supporting the Risk Assessment process e.g. by improving data queries, data analysis and data mining across Dossiers and integrating relevant scientific data into the Data Warehouse (DWH);
- Dynamic Case Management approach to meet the MATRIX system requirements which are Processes/Workflows flexibility, Goal-oriented and Collaboration.

3 EFSA Strategy 2020 – Trusted science for safe food
http://www.efsa.europa.eu/sites/default/files/160316a-a3.pdf

Objectives

The MATRIX-IP project, aims to provide EFSA and applicants with more efficient regulated products assessment processes including, in particular, the submission of applications in electronic formats, the automation of applications' administrative workflows and the communication between EFSA and applicants (MATRIX-IP Phase I), as well as the support to risk assessors and integration with the Scientific Data Warehouse of EFSA (Matrix-IP Phase II).

The targets for Matrix-IP Phase I are[4]:

- 2016: Digital dossier management solution and pilot of the regulated product workflow
- 2017: Automation of regulated product workflows for a first set of areas
- 2018: Automation of regulated product workflows for the remaining set of areas
- 2019: Support to risk assessment process and connection to scientific data warehouse completed

The objectives of MATRIX-IP phase I are the following:

- To identify and harmonise the regulated products' dossiers structure for all food sector areas[5], covering the different dossiers' sections and partially some dossiers' data (administrative and scientific);
- To define the confidential and non-confidential parts of the technical dossier and to consider the possibility to automate the publication of non-confidential version of the technical dossier on EFSA website;
- To automate the submission to EFSA of Dossiers and Pesticides Draft Assessment Reports and automation of exchange of documents for sanitization;
- To automate the regulated products administrative workflows via a BPM platform;
- To automate the communication with applicants, Member States and European Commission
- Dossier editors provided to applicants.

These objectives shall be met only in the context of EFSA's regulated products assessment and for all food sector areas, namely: PESTICIDES, GMO, FIP[5], FEED, NUTRI and BIOHAZ[6].

4 EFSA Single Programming Document 2016 – 2019
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1619.pdf

5 Are excluded from the food sector areas the re-evaluation of food additives (generic authorisation) for which no applicant is identified.

6 The BIOHAZ panel (in RASA) is dealing with dossiers assessing alternative treatments for animal-by-products (ABP's).

Action plan

The following actions are foreseen for the Project MATRIX-IP phase 1:

Q1-2016 - Q2-2017

- Action 1: Structuring of dossiers in all food sector areas
- Action 2: Definition of the "to be" administrative workflows in all food sector areas
  - PESTICIDES, GMO and FEED (first)
  - FIP, NUTRI, BIOHAZ (second)
- Action 3: Pilot of the administrative workflows for PESTICIDES, GMO, FEED
- Action 4: Pilot of the file transfer for PESTICIDES, GMO, FEED
- Action 5: Pilot on communication to applicants for PESTICIDES, GMO, FEED
- Action 6: Prepare for a possible automation of publication of non-confidential parts of the dossier for applicable sector areas

Q2-2017 - Q4-2018

- Action 7: Implement and deliver final solutions (administrative workflows, file transfer, communication) to PESTICIDES, GMO, FEED
- Action 8: Pilot of the administrative workflows for FIP, NUTRI, BIOHAZ
- Action 9: Pilot of the administrative workflows for FIP, NUTRI, BIOHAZ
- Action 10: Pilot of the administrative workflows for FIP, NUTRI, BIOHAZ
- Action 11: Implement and deliver final solutions (administrative workflows, file transfer, communication) to FIP, NUTRI, BIOHAZ

Q1-2018 - Q2-2019

- Action 12: Define and implement a Dossier Editor for applicants
- Action 13: Implement the automatic publication of non-confidential information

Phase 1 will start with a **Blueprinting and Piloting Phase (Actions 1 – 6)** with the intent to set-up the minimum and critical set of functionalities for files transfer, automate the administrative workflows from reception of the dossiers to the conclusions of the risk assessment (via a BPM platform) and the related communication. The MATRIX-IP project foresees a *pilot phase*, first for GMO, PESTICIDES and FEED dossiers and, then for FIP, NUTRI and BIOHAZ. The risk assessment of the dossier or products or substances will not be covered in this phase but the related administrative steps will be simulated (e.g. stop the clock, sanitization, automated counting, etc..) to guarantee a complete blueprinting for the administrative workflow.

In addition, EFSA will establish one **discussion group** (DIG) with stakeholders for the entire duration of the MATRIX-IP project. The discussion group (DIG1 E_SUBMISSION) will be set up to discuss and consult external stakeholders on the technical aspects of the MATRIX-IP Projects (Starting from actions 1-2-3-4-5). Additional discussion group(s) might be created throughout the project if need arise (e.g. open dossiers data).

The first **6 actions** of the project are described below in details.

Action 1	Structuring of dossiers in all food sector areas, including the identification and harmonisation of structured sections of the dossiers
Description	For each Unit and food sector, the structure of the dossier will be defined as well as structured sections (administrative, scientific). As much as possible, similar data models used by different sector areas will be harmonised
Timeline	30/09/2016
Deliverables	Structure of the technical dossiers submitted to EFSA for all food sector areas
Discussion Group 1 E-SUBMISSION	The proposed structured dossiers in each sector areas will be distributed for consultation to the DIG1.

Action 2	Definition of the administrative workflow starting from GMO, PESTICIDES, FEED and then FIP, NUTRI and BIOHAZ
Description	Definition and analysis of the administrative workflows to be implemented. The workflow covering the entire administrative process from reception of the dossier to the conclusion of the risk assessment shall be considered.
Timeline	30/09/2016 for PESTICIDES, GMO, FEED 31/12/2016 for FIP, NUTRI and BIOHAZ,
Deliverables	Clear "to-be" process mapping the agreed administrative workflows
Discussion Group 1 E-SUBMISSION	The proposed workflow and Business Process Mapping (BMP) platform will be distributed for consultation to the DIG1.

Action 3	Pilot the workflows in the IT platform for 3 Sector areas: GMO, PESTICIDES, FEED
Description	Implementation of the agreed "to be" workflows in the BPM platform as pilot for GMO, PESTICIDES and FEED.
Timeline	31/05/2017
Deliverables	A subtotal of REPRO application workflows set-up in the platform (GMOs, PESTICIDES, FEED)
Discussion Group 1 E-SUBMISSION	Several volunteers from DIG1 will participate in piloting the workflows once implemented in the tool by EFSA.

Action 4	Definition of file transfer requirements and pilot implementation for GMO, PESTICIDES and FEED
Description	Definition of the file transfer requirements and protocols and testing of the platform functionalities required to cover all diversities of files transferred to EFSA as Regulated Products for GMO, PESTICIDES and FEED
Timeline	31/05/2017
Deliverables	File transfer platform fully operational with the sub total of REPRO submission piloted in the platform
Discussion Group 1 E-SUBMISSION	The proposed file transfer requirements and protocols will be distributed for consultation to the DIG1. Several volunteers will participate to the testing of the functionalities of the file transfer platform proposed.

Action 5	Definition of the communication to Applicants requirements and pilot implementation for GMO, PESTICIDES and FEED
Description	Automation of communications between EFSA and stakeholders regarding the applications life cycle piloted for GMO, PESTICIDES and FEED food sector areas;
Timeline	31/05/2017
Deliverables	A set of communication functionalities available in the system. A subtotal of REPRO communications with applicants are piloted in the platform (GMOs, PESTICIDES, FEED)
Discussion Group 1 E-SUBMISSION	The proposed communication to applicants' requirements and implementation will be distributed for consultation to the DIG1. Several volunteers will participate to the testing of the communication.

Action 6[7]	Analyse and prepare for possible automation of publication of non-confidential parts of the dossier for applicable sector areas
Description[3]	Identification of the confidential and non-confidential part of the technical dossiers and definition on "how" the information will be published and under which conditions. Consideration of the possibility to define and automate the publication of non-confidential parts of the dossier for applicable sector areas.
Timeline	31/12/2017
Deliverables[3]	Agreement of the sections of the technical dossiers that are considered as confidential business information and the parts considered non-confidential; Agreement on the ways information will be shared on the EFSA website: formats, licences, access rules, etc... Once decided, the non-confidential part of the dossier will published on EFSA website by means of *Action 13*
	The possibility and the ways to publish non-confidential part of the technical dossiers will be discussed.

7 Action 6 will be developed following the outcome of the TERA project, measures "6.4 Publication of all information received from applicants (except commercially sensitive data) and mention of gaps where they exist (C2)" for which an impact assessment in currently on going. The tasks to be included in Action 6 depend on the outcome of the impact assessment and the following discussions held in EFSA.