

Record of the meeting of the EFSA MATRIX Discussion Group 1 on E-SUBMISSION

Held on 23/11/2016, Brussels

09.00 – 16.00

1. Welcome and round table presentation

The chair, Karine Lheureux (EFSA, APDESK Unit) and Guilhem de Seze, Head of the REPRO Department (EFSA, REPRO) welcomed all the participants and the Commission representatives to the meeting of the EFSA MATRIX Discussion Group 1 (DIG1) on E-SUBMISSION. The objectives of the meeting were to present an overview of the MATRIX project, the objectives of DIG1, get to know each other among members, to present the general principles and discuss the draft documents being developed in the meetings of the MATRIX Work Packages (WP). The DIG1 is a consultative body, embedded into the EFSA Stakeholder Engagement Approach to foster engagement, stimulate exchange, discussion, consultations and to draw lessons learned.

2. Adoption of the agenda

The agenda was agreed together with an overview of the main topics to be discussed. A 'tour de table' enabled the meeting's participants to introduce themselves.

3. Presentation of the MATRIX project and DIG1

The project manager, Juergen Sturma, presented the MATRIX project, being an EFSA transformational project that will allow EFSA to move towards an electronic-based submission and evaluation of applications for regulated products, the various phases (stage I: from Q3 2016 to Q3 2017, stage 2: from Q3 2017 to Q2 2019), the expected deliverables and the high level milestones for each phase and the project organisation.

The DIG1 is a consultative body that is accompanying EFSA in its path toward the electronic management of applications for regulated products and will discuss, challenge and consult on the approach and technical aspects of MATRIX. The scope of MATRIX DIG1 is focusing on the work of WPs 1, 2, 3, 4 and on the first pilot planned for FEED, PESTICIDES and GMO.

All participants welcomed the initiative and the opportunity given to contribute during the development of the MATRIX project. Some participants mentioned that initiatives to rationalise the workflow on applications are also ongoing at national level. Engaging early with the various actors involved in the management of regulated products was highly appreciated.

4. Presentation of the MATRIX work packages - overview

The work package leaders presented their respective work package.

Jane Richardson, leading WP1 on dossier structure, presented the general principles aiming at defining for each regulated product, a structured dossier with a certain proportion of structured data. The structured data will make use when possible of existing standards, support the scientific risk assessment process and allow automation. The expected benefits are the efficiency gain during the risk assessment, the use of structured data according to international standards, the full transparency on how data are considered and used in risk assessment and automation of communication. To illustrate the presentation, a *modified* FEED dossier¹ was presented following the GHSTS structured format.

Discussion took place on the availability of a dossier builder, the use of SSD2 XML for structured data which is EFSA specific versus recognized standard, and the possibility of the future system to recognize already assessed document/study as a way to enhance efficiency in the risk assessment or limit the resubmission of document/study already submitted and assessed. The issue of dossier builder and substance/product identification (ID) was raised.

Tom Meyvis, leading WP2 on workflows, presented the general principles to develop electronic workflows from the submission of the dossier/application until publication of the scientific output, respecting all legal requirements and including the full monitoring of the application status. The WP2 aims at identifying and developing building blocks that will be used to construct the various workflows, also aiming to identify as many common building blocks as possible between workflows.

Participants highlighted that the expected gain in efficiency is perceived higher during the risk assessment than for the administrative workflows. It was asked whether EFSA would act as a "front desk" for the Pesticides dossiers and whether there would be a central repository for all the dossiers/applications at European level. Discussion took place on the importance to develop a flexible system that will allow adapting to the requirements of the various legislations and workflows.

Angelo Simone Scotto, leading WP3 on file transfer, presented the general principles of WP3 aiming at developing an easy and efficient way to exchange documents with EFSA, including the ability to upload dossiers both as a single package or file-per-file, in a controlled way, allowing (automatic) submission check as early as possible.

Discussion took place on the potential issue linked to the extensive size of some dossiers (e.g. Pesticides), the opportunity to give a reference to a unique document (which would allow to refer to this exact document in another dossier). Some participants mentioned the experience gained in other agencies in document identification and the usefulness for the risk assessment. Recommendation was made to contact other EU bodies or other agencies to learn from their experiences.

Karine Lheureux, leading the WP4 on communication, presented the general principles under development for future communication. The MATRIX platform will be used for all future communication types related to the application life cycle., Automation of communication will be largely implemented, including notifications with link to the document uploaded or updated.

Participants favoured the notification system. Discussions took place on the need to include an indication of the content of the notification (e.g. acknowledgement of receipt, validity, adoption...), to allow a quicker and less formal communication for small administrative issues; suggestions were made to include the communication between Member States and EFSA as part of the MATRIX system. It was clarified that the

¹ FEED dossier modified by EFSA to only show publicly available information

communications restricted to the actors involved in the process of an application will be tackled via the MATRIX system while the information made available to the public domain remains unchanged.

5. Presentation of the MATRIX work packages - details

Jane Richardson presented the details of a *modified* FEED dossier². In the presentation, a structured dossier following GHSTS standard was presented as well as *modified* structured data from a specific study. The example was used to illustrate the way dossier could be visualised, the metadata linked to a dossier and to demonstrate the capacity to implement the GHSTS format to dossiers from various areas of regulated products.

Participants asked on the possibility to keep the specificity of each area of the regulated products in the structured dossier, they also mentioned the need to accompany the area without experience in structured dossier towards this future path. It was mentioned that a road map of implementation might be developed by EFSA to focus the effort in a step wise approach, starting from the submission of a full dossier in a structured dossier until the submission of a specific study with structured data. It was acknowledged that the presentation of data in a structured way will improve considerably the risk assessment process. The issue of versioning of an application and/or evolving content of an application during the life-cycle of an application was raised.

Tom Meyvis presented the detailed workflows developed by the WP2 for the pilot phase on FEED, GMO, PESTICIDES. The detailed workflows are used by EFSA to identify the interactions with the various actors in the process and to identify the possible simplification. After this analysis an electronic workflow will be created as backbone for the applications management in EFSA.

6. Concluding remarks

All participants welcome the initiative and opportunity given to contribute to the development of the MATRIX project as the future platform for the management of applications for regulated products.

The DIG1 members were informed that, as part of the MATRIX project, two new activities were planned for early 2017: the establishment of the WP8 dealing with confidential data and the upcoming establishment of a second Discussion Group (DIG2) on OPEN DATA to be chaired by Hubert Deluyker. Call for membership for the DIG2 will be performed during Q1 2017.

The next physical meeting will be held in Parma, end April-mid May (exact data to be defined and confirmed via Doodle survey) and separate telephone conferences might be held to discuss further specific topics.

The Chair thanked the members for their participation to the kick-off meeting of MATRIX DIG1 and informed that the final agenda, list of participants and short record of issues discussed will be posted on EFSA webpage (section [EFSA/stakeholders/consultative groups](https://www.efsa.europa.eu/en/stakeholders/consultative-groups)).

Next meeting: planned for April-May 2017

Annex: List of participants

² FEED dossier modified by EFSA to only show publicly available information

List of participants

Member States

<i>BVL Germany</i>	Herbert Köpp
<i>ANSES France</i>	Sebastien Preniere
<i>DGISAN Italy</i>	Michele De Martino
<i>RIVM The Netherlands</i>	Marco Gielkens

Industry Associations and OECD

<i>CEFIC - The European Chemical Industry Council</i>	Ralf Eisert
<i>ECPA - European Crop Protection Industries</i>	Bodo Stadtbäumer
<i>ELC - Federation of European Speciality Food Ingredients</i>	Thomas Janssen
<i>EuropaBio</i>	Nancy Podevin
<i>FEFANA - EU Association of Specialty Feed Ingredients and their Mixtures</i>	Yara Antonissen
<i>Food Supplements Europe</i>	Patrick Coppens
<i>UEAPME - European Association of Craft, Small and Medium Sized Enterprises</i>	Birte M. Day
<i>OECD</i>	Sally Demarcellus

European Commission

<i>EC DG SANTE Representatives</i>
<i>JRC/EURL Geel Representative</i>

European Food Safety Authority

<i>Head of Scientific Evaluation of Regulated Products Department</i>	Guilhem De Seze
<i>MATRIX Project Manager</i>	Jürgen Sturma
<i>Head of APDESK Unit</i>	Karine Lheureux
<i>Scientific Adviser</i>	Hubert Deluyker
<i>Head of Pesticides Unit</i>	José Tarazona
<i>Scientific Officer of GMO Unit</i>	Hermann Broll
<i>PTT Programme Manager</i>	Fabrizio Abbinante
<i>REPRO DBC - MATRIX WP2 Leader</i>	Tom Meyvis
<i>DATA Unit - MATRIX WP1 Leader</i>	Jane Richardson
<i>PTT Unit - MATRIX WP3 Leader</i>	Angelo Simone Scotto
<i>Assistant APDESK Unit</i>	Stefania Mori
<i>External consultant Lot2</i>	Enric Staromjeski Torregrosa
<i>External consultant Lot2</i>	Riccardo Pallozzi

Apologies

<i>Head of Legal and Regulatory Affairs</i>	Dirk Detken
<i>Stakeholder Relations Officer</i>	Goran Kumric
<i>Acting Head of FEED Unit</i>	Manuela Tiramani