

Record of the 3rd meeting of the EFSA MATRIX Discussion Group 1 on E-SUBMISSION

Held on 16/05/2017, EFSA, Parma, Italy

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 European Commission representatives to the meeting of the EFSA MATRIX Discussion Group 1 (DIG1) on E-SUBMISSION. All documents prepared by the MATRIX team were shared in advance and comments collected. The meeting aimed at an exchange of views and a discussion on the comments from the DIG1 members on the progress reached so far on MATRIX. 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. A 'tour de table' enabled the meeting's participants to introduce themselves. The draft records from the previous MATRIX DIG1 meeting were endorsed.

3. MATRIX Project – Dossier structure and dossier transfer (WP1 and WP3)

Jane Richardson, leading WP1, presented the key achievements reached as of today (structured dossiers, picklist, XML Table of contents and dossier backbone, business rules), the expectations for the upcoming months (dossier viewer, dossier builder, model dossiers, training) and the possible challenges.

B. Stadtbauer from ECPA presented the feedback from the Pesticides industries point of view.

Discussions took place on the adaptability of the GHSTS structured dossier to the various scientific areas (PESTICIDES, FEED, GMO), the level of the picklist (being able to be used in a global worldwide context), the self-contained dossiers, the human *versus* machine readable data to enhance the risk assessment, multiple users/senders, possible versioning of dossier and files. It was mentioned that eDossier builder was recently made publicly available by the Government of Canada/Health Canada. There is a general view that the proposed structured of dossiers following GHSTS and OECD standards is a way forward for the future allowing to submit data into different jurisdictions across the world in a standardized manner, although several industries representatives highlighted their lack of experience on the implementation and their concerns on the required effort to prepare their dossier in the adequate format. The particular difficulty of SMEs in following the standard format dossier was raised.

4. MATRIX Project – Workflows (WP2)

Valeriu Curtui, leading WP2, introduced shortly the comments received by the DIG1 members and presented the key achievements (complete process & workflows of 3 scientific workflows (FEED, GMO, PESTICIDES active substance), the expectations for the upcoming months and the possible challenges (reach simplification, respect the legal requirements of legislations, capture all possible scenarios, plan trainings).

S. Preniere from ANSES presented the feedback from a Member State point of view.

Participants suggested several adjustments to the workflows in order to capture specific steps performed by the Member States and/or the JRC-EURL. Member States asked whether MATRIX would act as a central repository for all the dossiers/applications at European level. Comments were collected on the need for accessibility for all relevant actors, possible simplifications (e.g. sanitisation process centralised by EFSA), clarify timelines, how actors will be kept informed and notified and the possible optimisation of the commenting tool. Concerns about the handling of confidential data were raised, although the issue is to be addressed in WG8 and DIG2. A proposal was made to create sub group per scientific area in order to optimise the detailed discussions specific to a unique workflow. The suggestion might be combined with the comments to be provided during and after the piloting phase. There is a general view that the workflows are well capturing the current working practices, including efficient proposals for simplifications (centralisation).

5. EC PRESENTATION

The EC representative presented the ongoing project *EC Innovation portal*, aiming at developing a public portal which will provide access to an eSubmission tool managing an electronic authorisation process of Regulated Products. The scope of the *EC Innovation portal* project is covering the entire workflow from submission of dossier to authorisation by the risk managers, is focusing on the Common Foods Authorisation Process (Regulation (EC) No 1331/2008 food additives, food enzymes and food flavourings) and Novel Food (New Regulation EU 2015/2283), with the ambition to expand afterwards to other areas (e.g. feed additives). The *EC Innovation portal* will have public and secured domains, controlled by one single sign-on for users (authentication and authorisation) that could be recognised by several applications (EC, EFSA...). The project is implemented in two phases. The first phase is used to analyse the needs and processes for all the domains and select a pilot domain where existing building blocks (submission, security, key applications information, status) can be used to implement an initial solution for January 2018. The second phase will be devoted to build a complete solution for the selected pilot domain. The experience from the pilot domain will be used for the planning and implementation of the other domains.

Both MATRIX and the EC Innovation portal have similarities (stakeholders, procedures and application dossier) and there is a real ongoing effort between EFSA/EC-SANTE to seek synergies and alignment towards common and interoperable solutions for the complete authorisation process where EFSA/EC-SANTE are involved. It was suggested to have a joint presentation of a possible common approach at one of the next DIG1 meetings.

Participants suggested the highest standardization possible so that the effort made from one side on the dossier structure following OECD international GHSTS and publicly available builder are useable in both systems. The step by step approach was acknowledgeable positively to address the needs of small, medium and big companies.

6. MATRIX Project Pilot and technical aspects

Juergen Sturma, MATRIX project manager, presented the planned periods of the pilots, the IT tools available, the real closed cases applications selected, explaining that each actor will “play” its role and will be asked to be available around 2H/day during the pilot phase. A pilot testbook will be available to all before the starting of the pilot.

- Pilot run 1: 26 June-7 July 2017 – only EFSA
- Pilot run 2: 24-28 July 2017 – EFSA + stakeholders
- Pilot run 3: 18-22 September 2017 - EFSA + stakeholders

The participants asked to be given access to the tool and platform several days before the pilot phase to verify accessibility, to test the accessibility of external actors also during pilot Run 1, to clarify the access in case an applicant is a consortium (e.g. FEFANA and CBI issue). It was clarified that one user account per company will be given, although it is possible to have several sub-accounts. It was agreed to provide EFSA, latest by 26 June, the exact names, contact details, e-mails of the actors and their potential back-up that will be involved in the pilot.

7. MATRIX Project – Communications and portal design (WP4)

Karine Lheureux, leading WP4, introduced shortly the key achievements (harmonised and simplified communication, EFSA letters performed within MATRIX in the form of a notification + link and authorised via the workflow), the expectations for the upcoming months and the possible challenges (feedback during pilots, two-ways communication).

Discussions took place on the flow of information and the possibility for the applicant to upload not only a document but also an accompanying letter, to submit spontaneously a letter / documents (e.g. not link to a specific task from the workflow). Questions were raised on the deadline linked to specific or negotiable deadlines, automatic reminders of deadlines, process to follow incase an actor needs more time to perform his tasks and if MATRIX would be used as a project management system. It was clarified that the tool has the functionality to work as a project management system for all applications, although this will be considered further in the second phase of MATRIX and that in all cases, the public information available in the EFSA Register of Question (RAW) remains unchanged. There is a general view that the proposed communication workflow is capturing the current working practices, including efficient proposals for simplifications (automatisation).

8. Closure remarks

All participants acknowledged the progress made and the challenges ahead to contribute to the development of the MATRIX project as the future platform for the management of applications for regulated products. EFSA thanked the members of DIG1 for their valuable and constructive comments which will allow to develop a pragmatic and close to business future platform for submitting applications for Regulated Products. EFSA will make all possible effort to consider, if feasible, the comments immediately during the pilot, or later with the pool of comments for after the pilot phase. Some comments targeted to the risk assessment phase will be considered during the next phase of MATRIX (MATRIX phase 2).

The next contributions will be expected during the pilot Run 2&3.

The next physical meeting will be held in Brussels, in October (exact data to be confirmed via a new Doodle survey).

The Chair thanked the members for their participation to the 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 Discussion Groups under <http://www.efsa.europa.eu/en/engage/stakeholders>).

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</i> | Bodo Stadtbäumer |
| <i>EuropaBio</i> | Nancy Podevin |
| <i>FEFANA - EU Association of Specialty Feed Ingredients and their Mixtures</i> | Giulio Bucci |
| <i>Food Supplements Europe</i> | Patrick Coppens |
| <i>OECD</i> | Sally Demarcellus (web connection) |

European Commission

EC DG SANTE Representatives
JRC/EURL Geel Representative

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 - MATRIX WP4 and DG1 Leader</i> | Karine Lheureux |
| <i>REPRO DBC - MATRIX WP2 Leader</i> | Valeriu Curtui |
| <i>DATA Unit - MATRIX WP1 Leader</i> | Jane Richardson |
| <i>PTT Unit - MATRIX WP3 Leader</i> | Angelo Simone Scottto |
| <i>Acting Head of FEED Unit - MATRIX WP8 Leader</i> | Manuela Tiramani |
| <i>Head of Pesticides Unit</i> | José Tarazona |
| <i>Head of GMO Unit</i> | Elisabeth Waigmann |
| <i>DTS Programme Manager</i> | Fabrizio Abbinante |
| <i>Assistant APDESK Unit</i> | Stefania Mori |

EFSA External consultants