



Update on the MATRIX project

Management Board Meeting
20 June 2018

High level requirements



e-submission and tracking of the lifecycle dossier and authorisation process

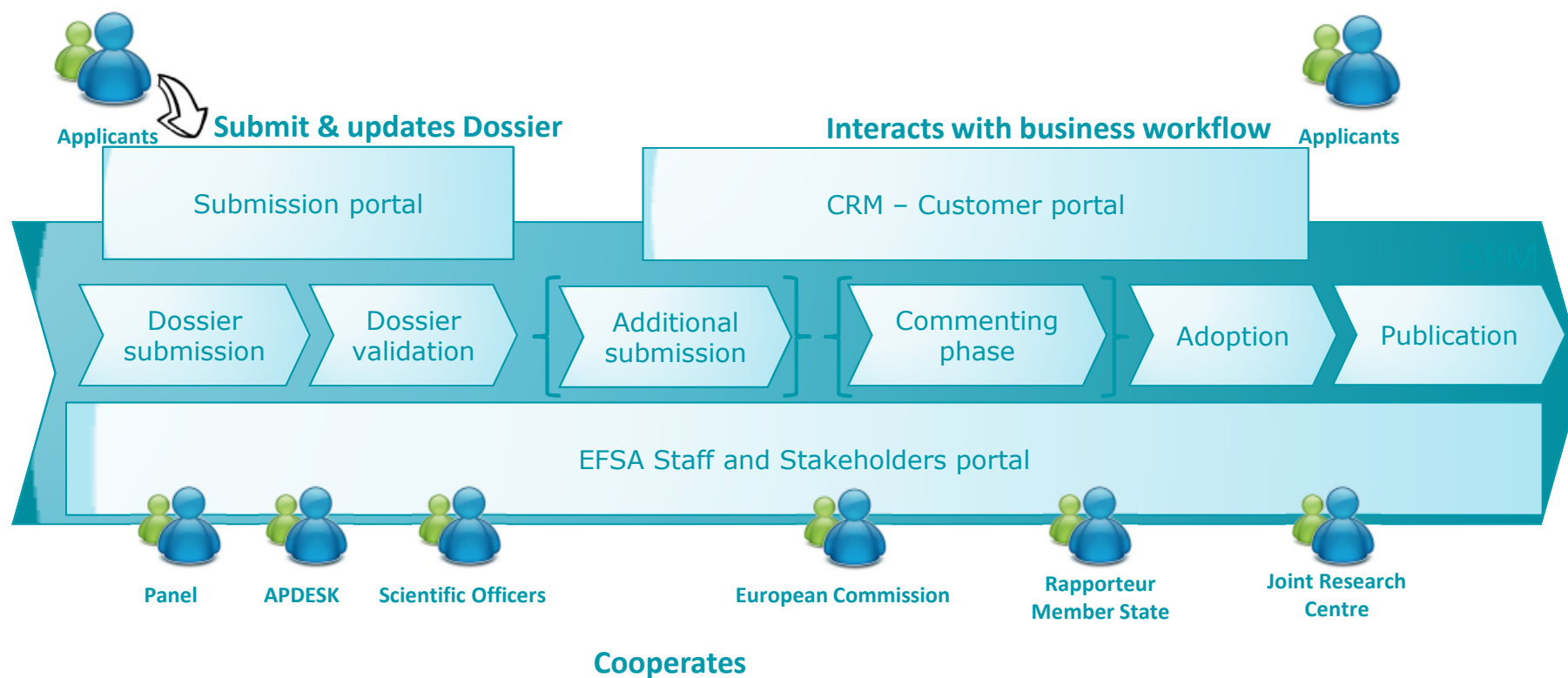


Transparent evidence management and structured data to support the scientific assessment

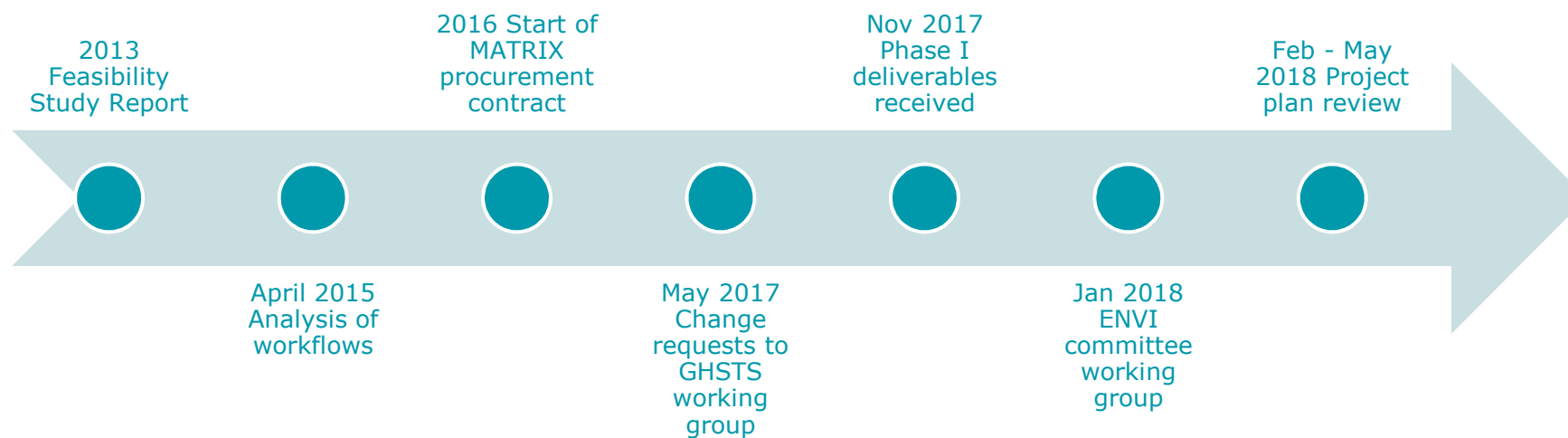


Improved communication with all stakeholders

MATRIX – Business Process Mapping



MATRIX internal EFSA timeline



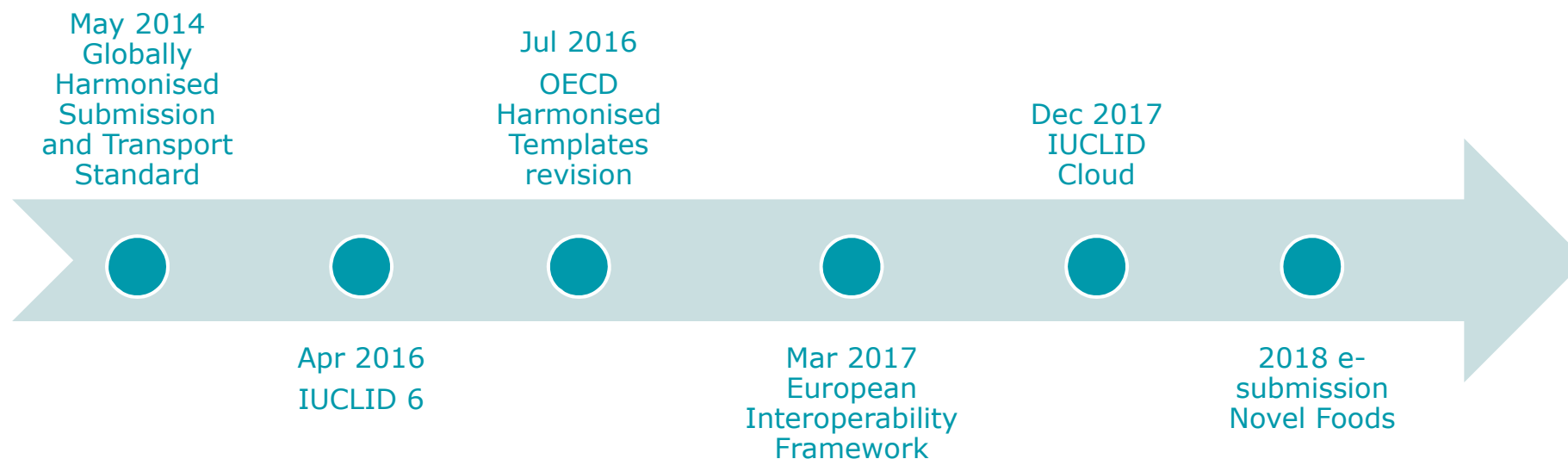
Phase I Deliverables

- Definition of dossier structure and identification of non-confidential parts (XML schema for all food sector areas)
- Revision of administrative workflows
- Pilot of administrative workflows, dossier transfer and communication to stakeholders
- Work flow, file transfer, collaboration tools and repositories installed for business tests
- Final report

Lessons Learned

- Take smaller steps
- Use agile and iterative development approaches
- Tighten supplier quality controls by planning more and smaller project phases (payment), with clear quality criteria
- Adapt project governance to high complexity and risks of the project
- Invest in training project team in the required competencies
- Design smaller dedicated project teams rather than large diffuse teams

Evolution of outside factors impacting MATRIX



Fitness Check of General Food Law

Scientific studies made public at an early stage

Confidential (personal data and intellectual property) respected

Access to studies in e-format

Register of studies

Consultation of stakeholders on submitted and planned studies

Vision: European Public Service for regulated product applications

Goal 1: Adopt a common standard for Applications and Dossiers







- *Internationally agreed standards that support dissemination and automation whilst protecting intellectual property*

Goal 2: Implement a single European Public Service for the Regulated Products Applications

- *A single point of information from submission to authorisation*
- *Secure electronic submission and storage of the dossier master copy*
- *Unique identifiers for Products, Substances, Actors (Legal entities), Studies*

Regulated product dossiers

Structured Dossier

Administrative data	Company			
	Product			
Table of contents	Identity, Characterisation and Conditions of Use	Identity of the substance	Analysis of impurities	
			 Study report	 OECD 23-1
				 SSD2 Modified
	Safety	Safety for the consumer	Acute toxicity	
			 Study report	 OECD 60
				 SSD2 Modified



- OECD Harmonised Templates
- Global Harmonised Submission Transport Standard



SANTE - Food system Common Authorisation Procedure application



The screenshot shows the EFSA SANTE - Food system Common Authorisation Procedure application interface. The top navigation bar includes a home icon and tabs for HEALTH, FOOD (selected), ANIMALS, PLANTS, and AMR. The left sidebar contains a menu for NOVEL FOOD with options: Legislation, Authorisation procedures, Novel food catalogue, and e-submission (highlighted in orange). Below this is an 'ALL TOPICS' button. The main content area features the title 'e-submission in accordance with the new Novel Foods regulation' in orange, followed by a 'Purpose' section. The purpose text states that the system allows applicants to submit novel foods applications and/or traditional foods notifications from third countries online, and that applicants can follow-up their applications until the outcome. A section titled 'How to submit a novel food application or a traditional food notification from a third country?' lists three steps: 1. Create or use an existing EU login account to access the system (link to EU login website); 2. Access a private board to create, submit, and manage applications; 3. Receive email notifications of progress. At the bottom, a link directs users to the e-submission system.

e-submission in accordance with the new Novel Foods regulation

Purpose

The e-submission system will allow the applicants to submit novel foods applications and/or traditional foods notifications from third countries online.

With this system the applicants will be able to follow-up their applications from the submission until the outcome.

How to submit a novel food application or a traditional food notification from a third country?

1. As a pre-requisite, the applicant has to create or use an existing EU login account in order to access the system. [EU login website](#)
2. With the EU login account the applicant will be able to access a private board, from where they can create, submit and manage their own applications.
3. The applicant will be notified by email (the one specified in the EU account) each time there is any progress made in their applications.

Go to the [e-submission system](#)

CURRENT PLAN

