Update on the MATRIX project

Management Board Meeting
20 June 2018

efsa
European Food Safety Authority

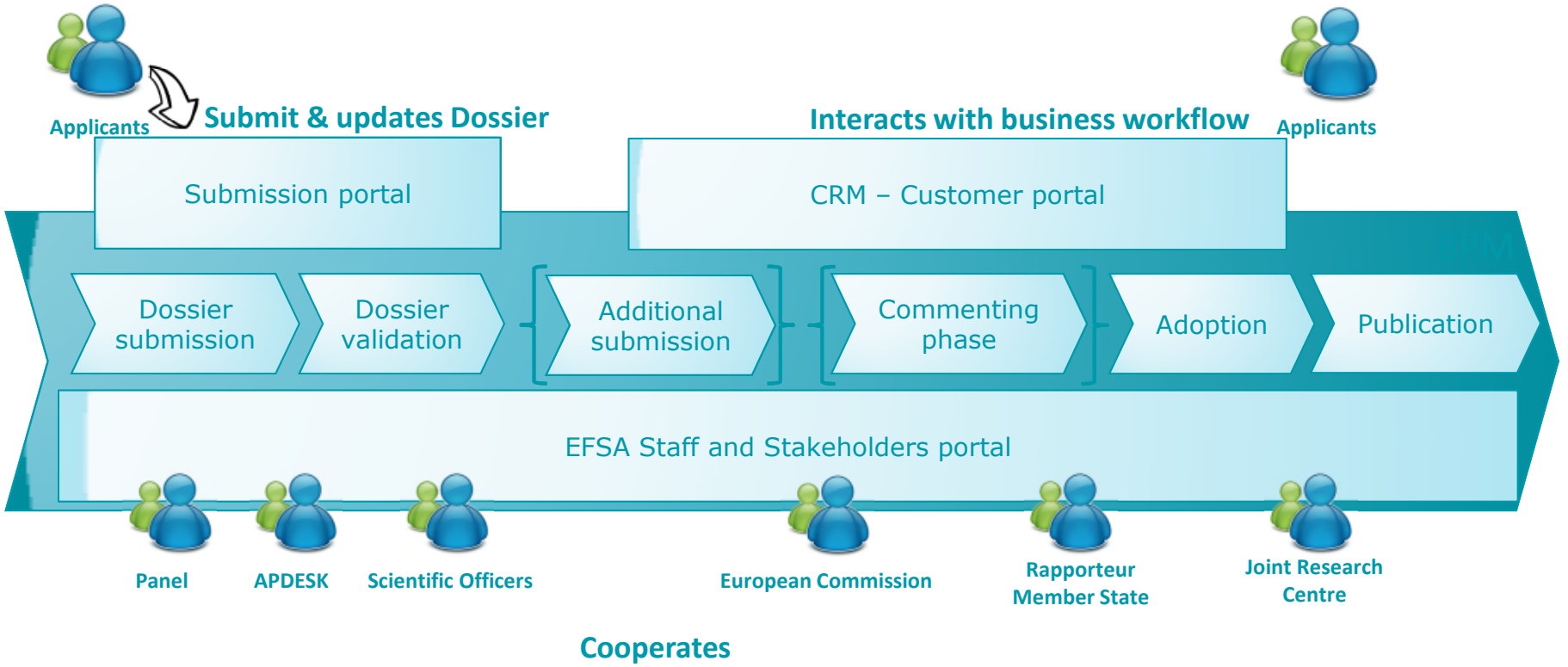
High level requirements

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

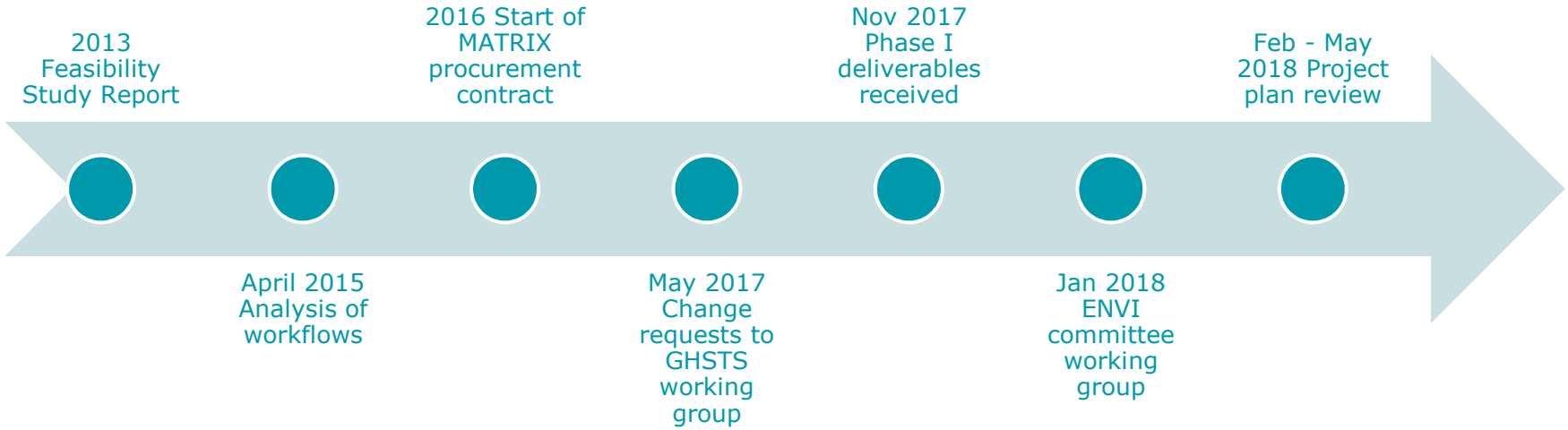
Transparent evidence management and structured data to support the scientific assessment

Improved communication with all stakeholders

MATRIX – Business Process Mapping



MATRIX internal EFSA timeline



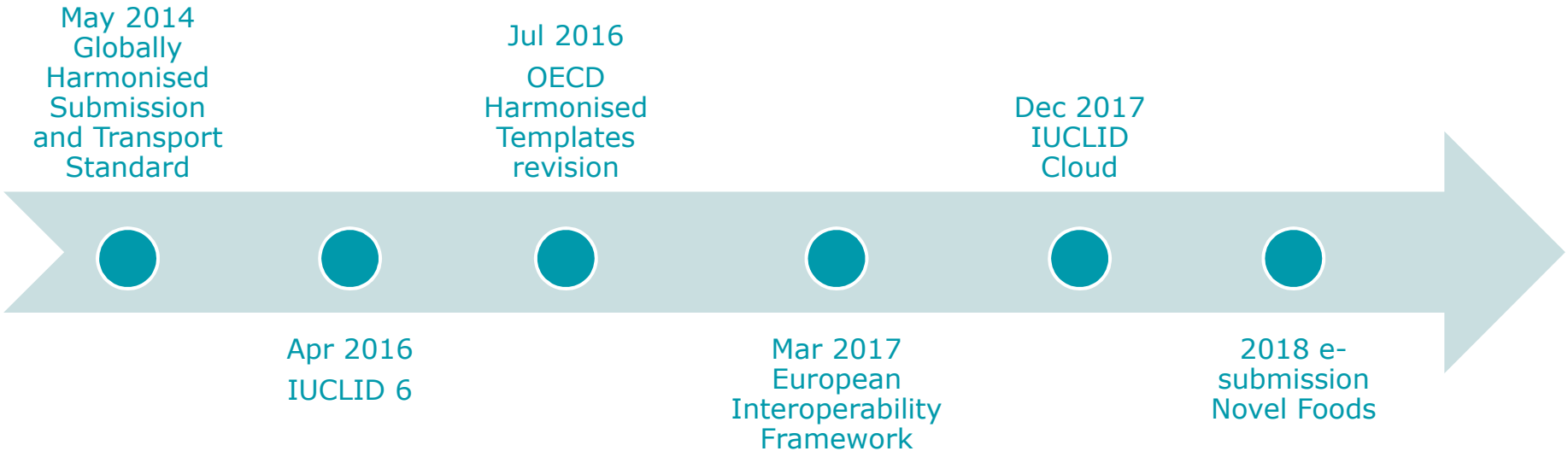
Phase I Deliverables

- 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 PDF Adobe — Study report XML — OECD 23-1 XML — SSD2 Modified
	Safety	Safety for the consumer	Acute toxicity PDF Adobe — Study report XML — OECD 60 XML — SSD2 Modified

- OECD Harmonised Templates
- Global Harmonised Submission Transport Standard

SANTE - Food system Common Authorisation Procedure application

CURRENT PLAN