Part 1

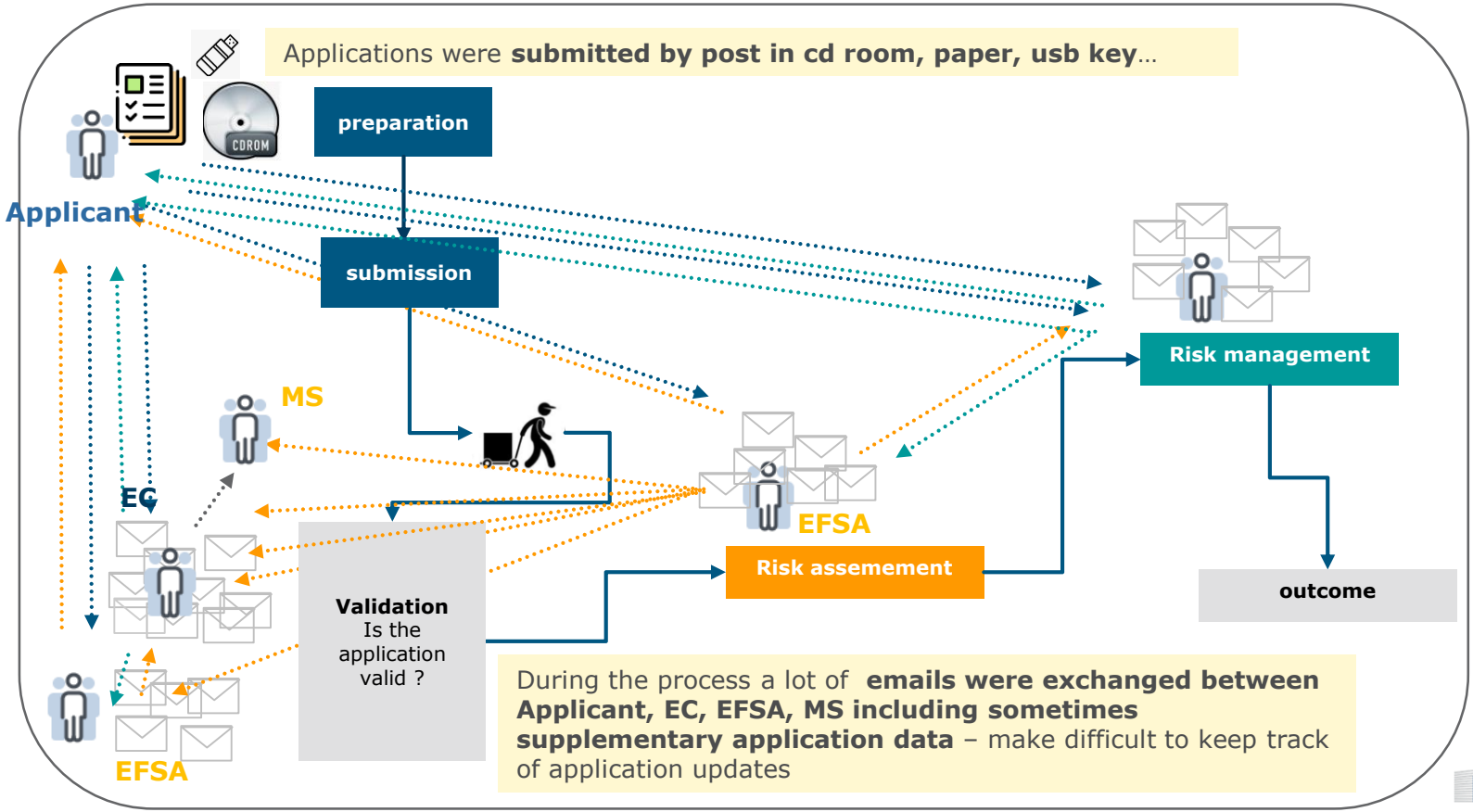
FSCAP
e-submission system

21 January 2020

Agenda

1. Novel Food authorisation process before FSCAP
2. FSCAP
    1. Context and status
    2. Users
    3. Functionalities
    4. Process Flow
    5. Support and guidance
3. FSCAP Demo
4. Transparency regulation impacts on food sectors and IT

Novel Food authorisation process **before** FSCAP : **Manual process**



Novel Food authorisation process **before** FSCAP : **Manual process**

Strengths and opportunities

- No enforcement on application content

Weakness and threats

- No enforcement on application content
- Traceability / Versioning
- Fragmented communication
- No Audit trail
- Security
- Disparate storage

FSCAP

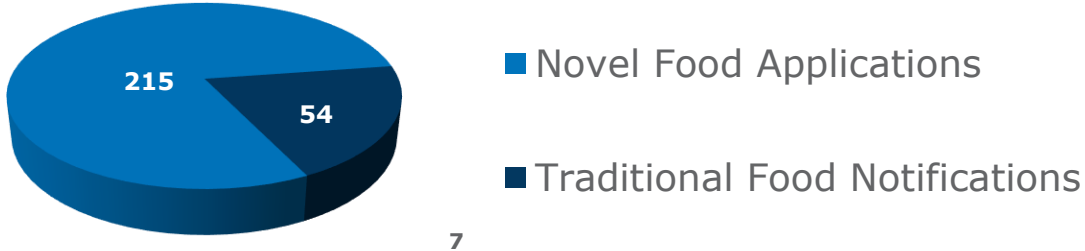
- Legal context
  - Regulation (EU) 2015/2283 **,** Commission Implementing Regulation (EU) 2017/2469 and 2017/2468 on **Novel Foods and Traditional foods.** Applicable from **01/01/2018**
  - Applications submitted to **EC**
  - **e-submission** mandatory *(Article 3 of Commission Implementing Regulation)*

FSCAP

- FSCAP (**F**ood **S**ystem **C**ommon **A**uthorisation **P**rocedure)
- **Web based system** allowing applicants to submit and follow-up the progress of their applications and authorities to perform their validation and assessment and interact with applicants.
- **Electronic** process
- **Operational** since : **January 2018**

FSCAP

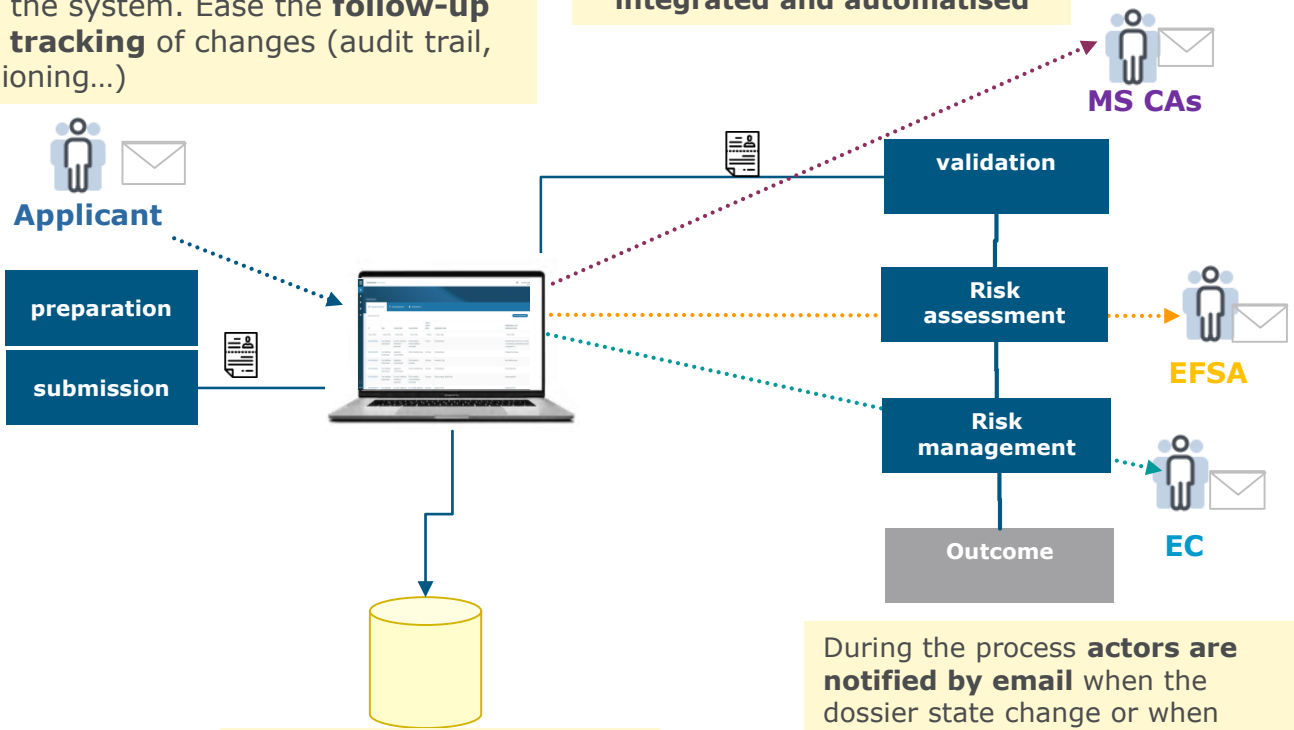
- Current **Food sector(s) covered** : Novel foods applications and traditional foods notifications
- **Used by** :
  - Applicants (Food operators),
  - Member States - Competent Authorities,
  - European Commission,
  - EFSA
- ***269*** applications submitted since January 2018



Novel Food authorisation process with FSCAP : **e-process**

Applications are **always accessed** thru the system. Ease the **follow-up and tracking** of changes (audit trail, versioning…)

Authorisation process is integrated and automatised



Central and **secure** storage

During the process **actors are notified by email** when the dossier state change or when they have to perform an action.

Novel Food authorisation process with FSCAP : **e-process**

Strengths and opportunities

- Traceability
- Structured real time communication
- Audit trail / Version control
- Security
- Central storage
- Enforcement on application content and flow
- Legal changes imply IT configuration

Weakness and threats

- Legal changes imply IT configuration

User role and tasks

FSCAP users

Applicant

- **Create** applications and indicate if a file is considered confidential and the reason why
- **Submit and follow-up** their own application
- ***Withdrawn*** *application*

EC

- **Receive** and perform completeness check of applications
- **Request additional information** (RFI)
- Perform **risk management**
- **Participate** to consultation period (TF)
- ***Terminate*** *application*

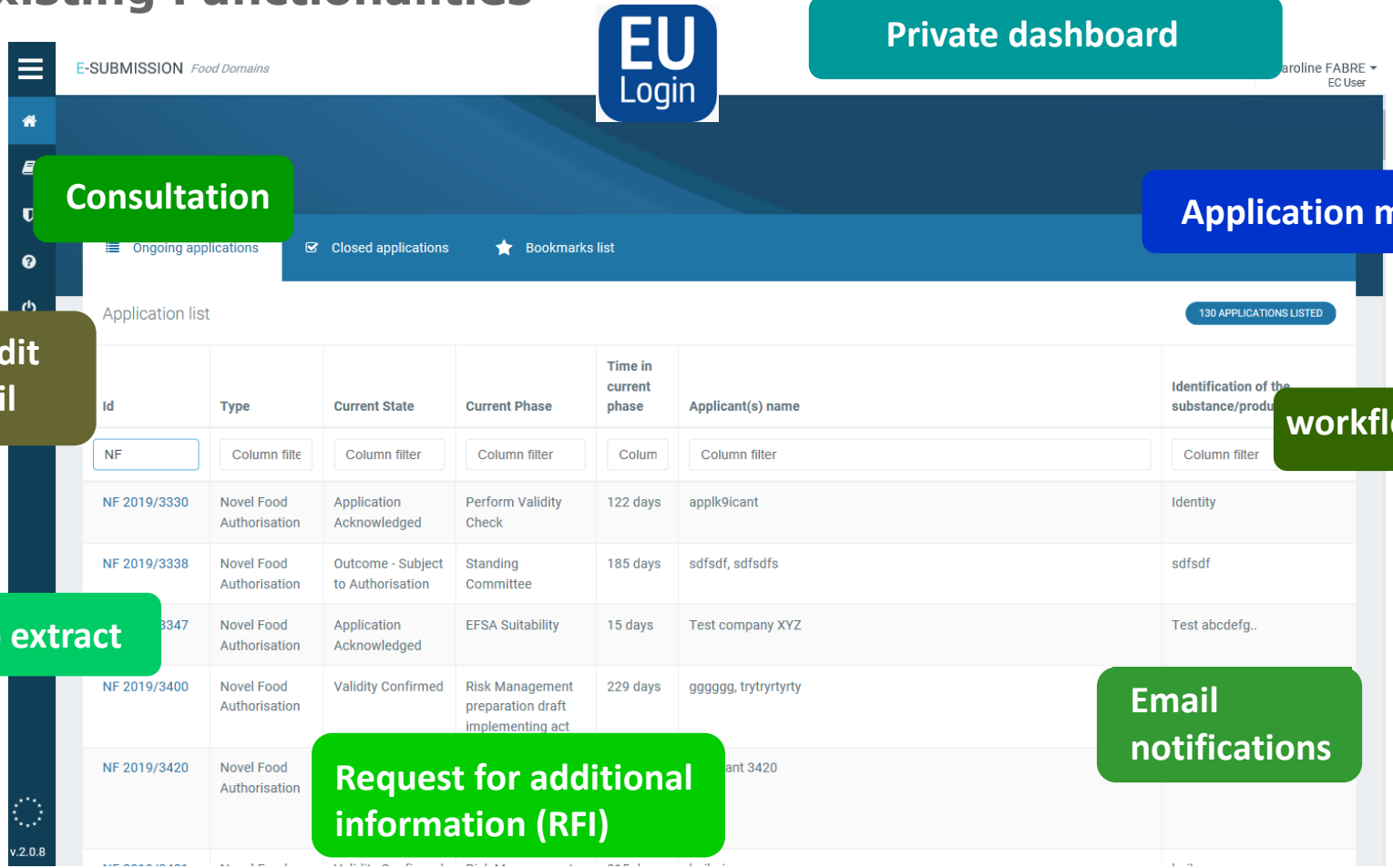
MS CA

- **Notified** of any new acknowledged application
- **Read only** access
- **Participate** to consultation period (TF)

EFSA

- Perform **suitability check**
- Perform **risk assessment**
- **Request additional information** (RFI)
- **Participate** to consultation period (TF)

Existing Functionalities



Part 2

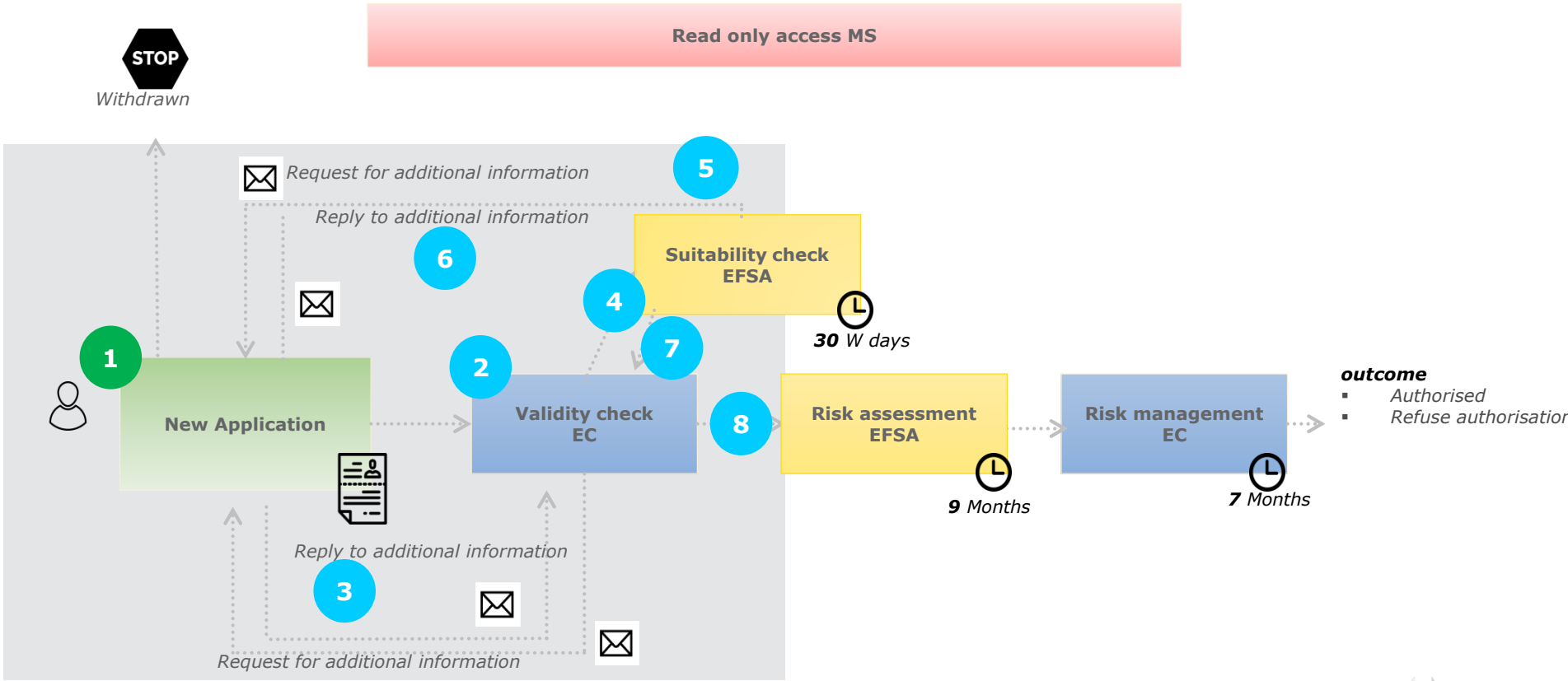
FSCAP
e-submission system - DEMO

21 January 2020

FSCAP - DEMO

- **Novel food authorisation** process flow
- **Applicant** submit an application and answer **R**equest **F**or additional **I**nformation (RFI)
- Application **validation** (completeness check by EC and suitability check by EFSA)
- EC transfers the application to **EFSA risk assessors** to perform the **risk assessment**

FSCAP - Demo


Read only access MS
STOP
Withdrawn
Request for additional information
Reply to additional information
Reply to additional information
Request for additional information
1
2
3
4
5
6
7
8
New Application
Validity check EC
Suitability check EFSA
30 W days
Risk assessment EFSA
9 Months
Risk management EC
7 Months
outcome
Authorised
Refuse authorisation

FSCAP demo questions / feedback ?

DG SANTE Directorate-General for Health and Food safety

Part 3

Transparency regulation impact

What next?

Transparency regulation has impact on food sectors

- **Impact** for applications received by MS and by EC
- Food sectors impacted for **MS**
  - ***GM food and feed – new applications*** *(Regulation (EC) 1829/2003)*
  - ***Smoke Flavourings*** *(Regulation (EC) No 2065/2003)*
  - ***Health Claims*** *(Regulation (EC) No 1924/2006)*
  - ***Food contact materials*** *(Regulation (EC) No 1935/2004)*

  - ***GMO Directive*** *(Directive 2001/18/EC)*
  - ***PPP Regulation*** *(Regulation (EC) No 1107/2009)*

Transparency regulation has impact on food sectors

- Food sectors impacted for **EC**

  - ***Food improvement agents*** *(Regulation (EC) 1331/2008)*
  - ***Novel foods and Traditional foods*** *(Regulation (EC) No 2015/2283)*
  - ***Infant Formulae - Follow-on formulae*** *(Regulation (EU) No 609/2013)*
  - ***Food Allergens*** *(Regulation (EU) No 1169/2011)*
  - ***Pesticides Basic substances*** *(Regulation (EC) No 1107/2009)*
  - ***Feed Additives*** *(Regulation (EC) 1831/2003)*
  - ***GM food and feed - renewals*** *(Regulation (EC) 1829/2003)*

Transparency regulation has IT Implications

- **Electronic submission**
- Increased **confidentiality processing** requirements
- **Dissemination** of non-confidential data in searchable and readable format

Electronic submission

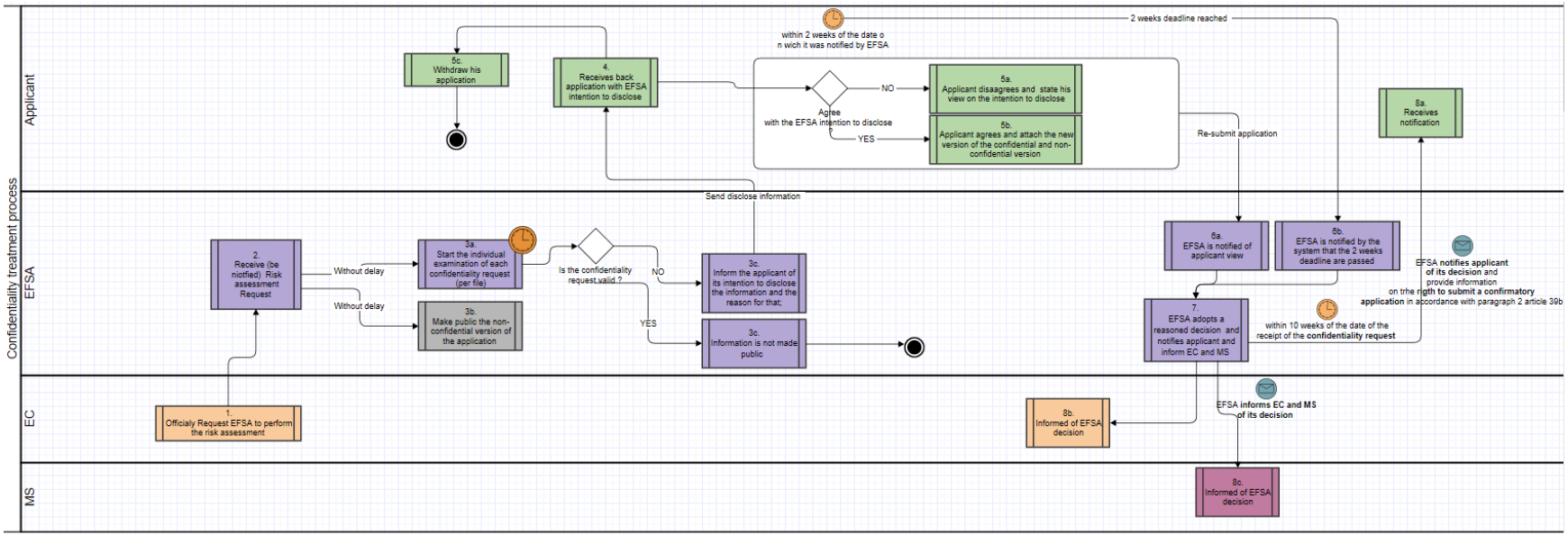
- *FSCAP exists and is proven*
- *FSCAP provides facility to manage end-to-end process*
- Will be extended to the food sectors impacted by the transparency regulation
- Will be expanded beyond manual data entry:
  - Structured application upload (such as XML format)
  - Machine to Machine submission

Confidentiality Processing

- *Basic confidentiality process already in place*
- Will support **more information** on confidentiality requests (meta data)
- Will support **multiple requests** per document
- Will force inclusion of **non confidential version** of document

Confidentiality Processing

- Will support new confidentiality **process steps and deadlines**



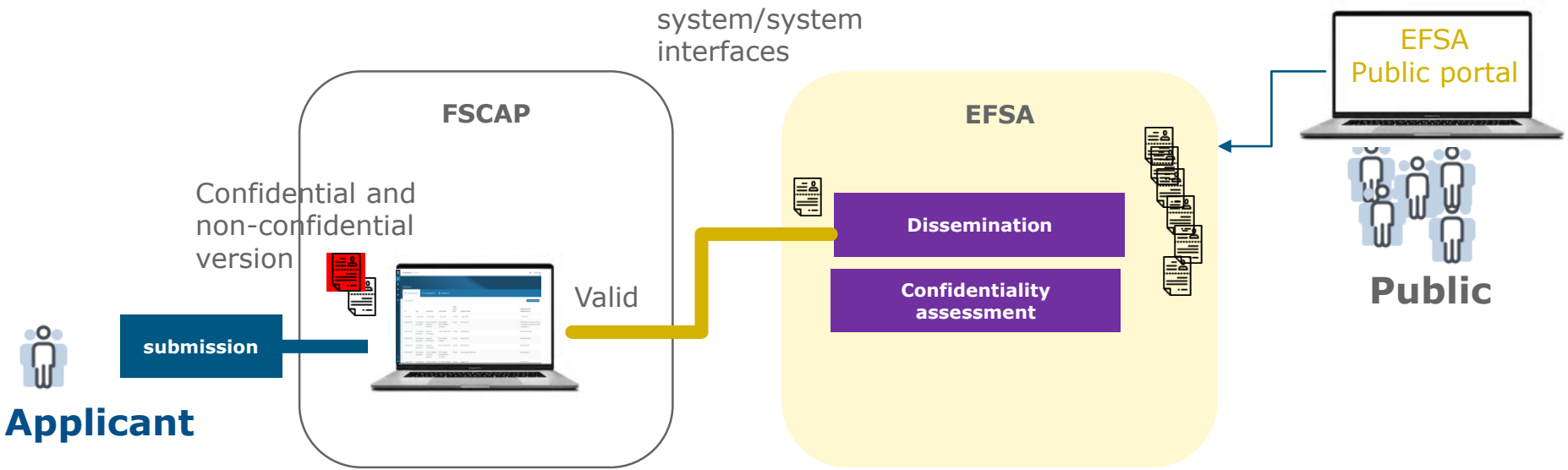
European Commission

Dissemination

- *Applications are **submitted** through FSCAP (for novel foods)*
- Will **control** that application data are readable and searchable
- Will **automatically transfer the application** to EFSA system for dissemination (EFSA responsibility) when it is considered valid

Dissemination - progress

FSCAP system and EFSA systems **full integration** to ease the dissemination process (*on going*)



What next ?

1. Continue **FSCAP / EFSA system to system integration**

2. Analyse the **needs** for each food sector, application structure and workflow specificity *(already started by EC and EFSA):*
    - Applications **submitted to the MS CAs**, which are then **forwarded without delay to EFSA** *(GM food and feed (new), smoke flavourings, health claims and FCM)*
    - Applications **submitted to the MS CAs** and for which CAs are **more involved in the process** *(GMO Directive and PPP)*
    - Applications **submitted to EC** *(Food improvement agents, novel/traditional foods, feed additives, GM food and feed (renewals) etc.)*

Questions ?

DG SANTE Directorate-General for Health and Food safety

Discussion

- What is the situation in your Competent Authority ?
  - Electronic system in place ? (Purpose , sectors covered , process , functionalities, communication…)
- Deadline to received feedback : **7 February 2020**
- **Sante-science-transparency@ec.Europa.eu**