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

Applications were **submitted by post in cd room, paper, usb key...**

During the process a lot of **emails were exchanged between Applicant, EC, EFSA, MS including sometimes supplementary application data** – make difficult to keep track of application updates
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
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 (Food System Common Authorisation Procedure)**

- **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

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

- **Applicant**
  - preparation
  - submission

- **Central and secure storage**

- **Validation**

- **Risk assessment**

- **Risk management**

- **Outcome**

- **MS CAs**

- **EFSA**

- **EC**
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**

- **EC**
  - Create applications and indicate if a file is considered confidential and the reason why
  - Submit and follow-up their own application
  - Withdraw application
  - Receive and perform completeness check of applications
  - Request additional information (RFI)
  - Perform risk management
  - Participate to consultation period (TF)

- **MS CA**
  - Notified of any new acknowledged application
  - Read only access
  - Participate to consultation period (TF)
  - Request additional information (RFI)
  - Participate to consultation period (TF)

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

- **Applicant**
  - Create applications and indicate if a file is considered confidential and the reason why
  - Submit and follow-up their own application
  - Withdraw application
  - Receive and perform completeness check of applications
  - Request additional information (RFI)
  - Perform risk management
  - Participate to consultation period (TF)
  - Terminate application
Existing Functionalities

- Private dashboard
- Application management
- Consultation
- Audit trail
- Zip extract
- Email notifications
- Request for additional information (RFI)
- Workflow
Part 2

FSCAP e-submission system - DEMO

21 January 2020
• **Novel food authorisation** process flow

• **Applicant** submit an application and answer **Request For additional Information (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

New Application

Validity check EC

Suitability check EFSA

Risk assessment EFSA

Risk management EC

Request for additional information

Reply to additional information

Read only access MS

STOP

Withdrawn

outcome
- Authorised
- Refuse authorisation

1 New Application

2 Validity check EC

3 Request for additional information

4 Reply to additional information

5 Suitability check EFSA

6 Request for additional information

7 Reply to additional information

8 Risk assessment EFSA

9 Risk management EC

30 W days

9 Months

7 Months

Withdrawn

Authorised

Refuse authorisation
FSCAP demo questions / feedback?
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
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*)

- **FSCAP**
  - Confidential and non-confidential version
  - Submission
  - Valid

- **EFSA**
  - Dissemination
  - Confidentiality assessment

- System/system interfaces

- **EFSA Public portal**

- **Public**

- Applicant
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 ?
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