



SANTE Advisory group meeting

Update on FSCAP implementation



18-11-2020

Outline

1

Highlight FSCAP progress

2

FSCAP how it works and interacts with EFSA's systems
(Highlight on Dissemination & Confidentiality & NoS)

3

Supporting materials

Outline

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FSCAP how it works and interacts with EFSA's systems
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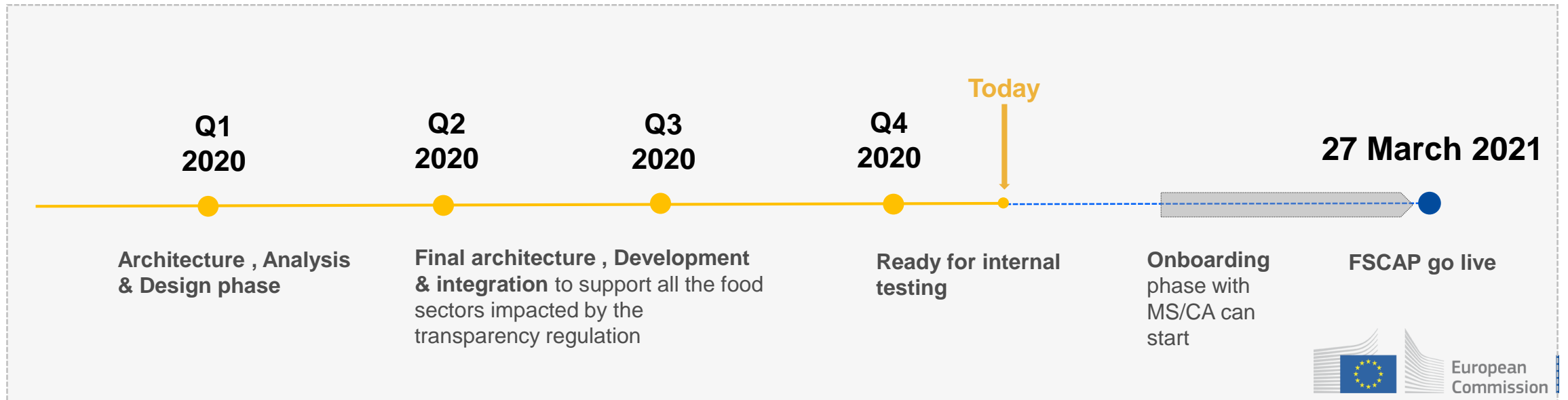
3

Supporting materials

Timeline

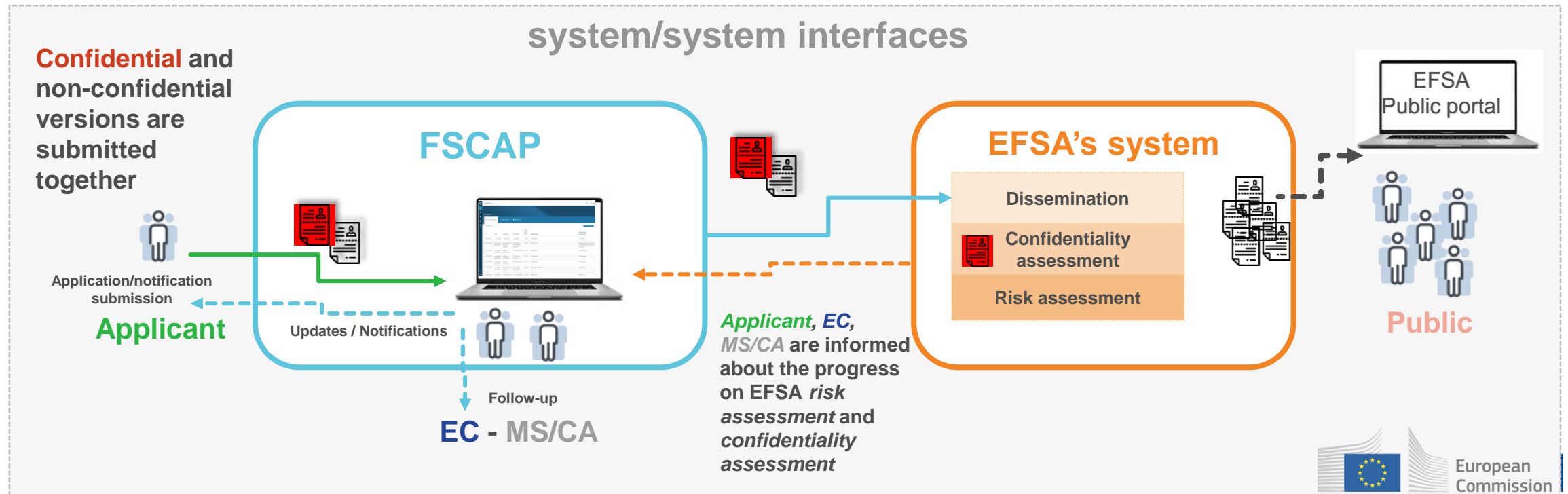
- FSCAP v2 single point of entry for applicants **to submit applications to Member States / Competent Authorities and European Commission - (PPP will use IUCLID)**
- FSCAP development and integration of new **food sectors impacted by the transparency regulation** in progress / final stage

KEY
MILESTONES



FSCAP & EFSA systems

- **Collaboration with EFSA** for proactive/public disclosure and confidentiality as required in the transparency regulation - *Most of the interactions are already developed and test in progress*
- FSCAP will **automatically transfer the application** to EFSA systems for public disclosure (when the application is considered valid) – *Already integrated and test in progress*



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Supporting materials

Main application procedures to be covered in FSCAP

- **Main authorisation procedures** cover : 7 food & feed sectors, 45 application types (including new application, renewal, modification ...)

- Sectors impacted for **EC**

Novel foods and Traditional foods , Food improvement agents (Food Additives, Food enzymes, Food flavourings), Infant Formulae – follow on formulae, Food Allergens, Nutrient sources, Feed Additives , GM food and feed – renewal

- Sectors impacted for **MS/CA** – FSCAP proposal for

GM food and feed – new , Smoke Flavourings , Health Claims , Food contact materials , GMO Directive

- **IUCLID** system will cover applications for **PPP/MRL**

How to access FSCAP ?

- **Applicant**
 - EU login
- **MS/CA**
 - EU login
 - Registered as MS/CA in FSCAP system (Information requested in the letter sent to all MS representatives.)

How to start with FSCAP as applicant ?

1. Go to FSCAP
2. Authenticate yourself with your EU login
3. Start creating your application
 1. the system will **guide you to select** the correct food /feed domain , authorisation type and application type
 2. the system will **help you to submit** to the correct recipient (EC or MS/CA)
4. Submit your application
5. Wait for notification about the progress and action to take

Selection page

The screenshot shows a 'Start new application' form with three dropdown menus. The first menu is set to 'Novel Foods', the second to 'Novel Food Authorisation', and the third to 'New Novel Food'. A 'Start process' button is located at the bottom of the form. A blue arrow points from the text below to the 'Start process' button.

Application submitted to
European Commission

The screenshot shows a 'Start new application' form with five dropdown menus. The first menu is set to 'Food Contact Material', the second to 'FCM- Substance to be used in plastic materials', the third to 'Application for the authorisation of a new FCM substance', the fourth to 'Belgium', and the fifth to 'Federal Agency for the Safety of the Food Chain'. A 'Start process' button is located at the bottom of the form. A blue arrow points from the text below to the 'Start process' button.

Application submitted to **MS/CA**
*Competent authority recipient is
selected by the applicant*

Fill in the Table Of Content

- Content structure created according to the selection

Food Contact Material

Food Contact Material Application
FCM 2020/5377

Draft With Applicant

Administrative Data

Summary

Technical Dossier

Technical Dossier

- + Pre-Application Information
- + Identity of Substance
- + Physical and Chemical Properties of Substance
- + Intended Application of Substance
- + Data on Migration
- + Data on Residual Monomers
- + Microbiology
- + Toxicology
- + List of annexes, references and checklist

AUTHORISATION TYPE
FCM- Substance to be used in plastic materials

APPLICATION TYPE
Application for the authorisation of a new FCM substance

Feed additives

Feed Additives Application
FED 2020/5212

Draft With Applicant

Administrative Data

Summary

Technical Dossier

Technical Dossier

- + Pre-Application Information
- + Scientific summary
- + Identity, characterisation and conditions of use of the additive methods of analysis
- + Safety of the additive
- + Efficacy of the additive
- + Post-market monitoring plan
- + List of annexes, references and checklist

AUTHORISATION TYPE
Feed Additives

APPLICATION TYPE
Application for the authorisation of a new feed additive or a new use of a feed additive

Novel food

Novel Foods Application
NF 2020/12261

Draft With Applicant

Administrative Data

Summary data

Technical Dossier

Technical Dossier

- + Pre-Application Information
- + Identity of the novel food
- + The production Process
- + Compositional data
- + Specifications
- + The history of use of novel food and/or its source
- + The proposed use(s) and use levels and anticipated intake
- + Absorption, Distribution, Metabolism and Excretion (ADME)
- + Nutritional information
- + Toxicological information
- + Genotoxicity
- + Subchronic toxicity

GMO Food and Feed

GMO Application
FFC 2020/5209

Draft With Applicant

Administrative Data

Summary

Technical Dossier

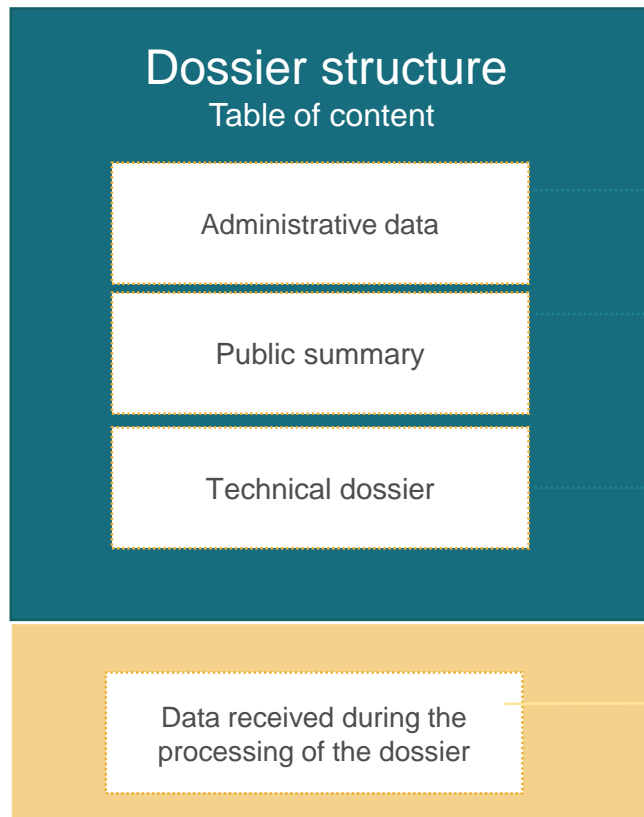
Technical Dossier

- + Pre-Application Information
- + Part I - General Information
- + Part II - Scientific Information
- + Part III - Cartagena Protocol
- + Part IV - Labelling
- + Part V - Methods of detection, sampling and reference materials
- + Part VI - Additional information to be provided for GM plants and/or food/feed containing or consisting of GM plants
- + Administrative Documents
- + List of annexes, references and checklist

AUTHORISATION TYPE
Food and Feed

APPLICATION TYPE
Application for authorisation of a new genetically modified food and/or feed

Dossier content structure



Contact details , subject of the request , existing legislation , cover letter ...

Public summary file

Depends on Food sectors /authorisation type and application type – always compliant with EU legislation and EFSA guidance(s)

All the data received during the processing of the dossier will be displayed and easily retrieved in the system. (confidentiality assessment request for clarifications , decisions .. , request for information)

Pre-application information

- All the information related to **pre-submission phase** and **provided by EFSA systems** can be inserted **manually** or **automatically retrieved by FSCAP** during the creation of the application (*Pre-application identification , Applicant contact details , EFSA notification of study identification*)
- **Applicant contact details** can be **manually inserted** but also **automatically retrieved by FSCAP** if the user creating the application has been registered as “contact” in EFSA system during the pre-submission phase.

Administrative Data Dossier saved at 12:23:59

1. Applicant's contact details ?

DLW SIT 07102020-1 Applicant 3

Your user account is linked to one or several organisation created in EFSA's user management system (Salesforce). You can select the organisation of your choice from the list and all the contact details will be automatically pre-populated for you. If the organisation is not listed, you can enter the information manually. Even if you select an organisation from the list you can still change the contact details.

Applicant Name	Email
<input type="text" value="type or select an applicant name"/>	<input type="text" value="dlwsit@efsa.europa.eu"/>
<input type="text" value="DLW SIT 07102020-1 Applicant 3"/>	Website
<input type="text" value="DLW SIT 07102020-1 Applicant 1"/>	<input type="text" value="www.example.com/test"/>
Address	Post code
<input type="text" value="Rue de Rivoli, Paris"/>	<input type="text" value="8870"/>
Country	
<input type="text" value="France"/>	<input type="button" value="Clear"/>

Pre-application information

- **EFSA Pre-Application ID and Study identifications** can be **manually inserted** or **automatically retrieved by the system** if the user creating the application has been recognised by FSCAP and has previously selected an applicant/organisation (the system will know which pre-application data to retrieve from EFSA system).
- The system **validates the correct format** to avoid any mistake.



– Pre-Application Information

Have you received a pre-application number from EFSA?

Yes No

Pre-Application Number

EFSA-ID-2020-12345678	Remove
EFSA-XXXXX	Remove

Pre-Application Number Invalid pattern

Add

Notification of Studies (NoS)

- The **notification of studies identifications (NoS ID)** received and grouped under a **pre-application ID** during the pre-submission phase can be linked to the study report file(s) within the application
- The system **will check that all NoS IDs are provided**, and/or a justification is given by the applicant for those study IDs not provided.
- The applicant will have to justify **pre-notified studies not provided** in the application

STUDY IDENTIFICATION

Have you received a EFSA study identification ?

Yes No

EFSA study identification

EFSA study identification

The applicant will have to justify **studies provided in the dossier that have no EFSA study Identification.**

Technical Dossier Dossier saved at 12:30

Pre-Application Information

Have you received a pre-application number from EFSA?

Yes No

Pre-Application Number

EFSA-ID-2020-12345678

Add

Please, provide information on studies that have been notified to EFSA (in the EFSA Notification of Studies Registry) but have not been provided in this dossier, as well as a justification for the reasons why this was not provided.

EFSA-2020-11111	The lorem ipsum est, en imprimerie, une suite de mots sans signification utilisée à titre provisoire pour calibrer une mise en page, le texte définitif venant remplacer le faux-texte dès qu'il est prêt ou que la mise en page est achevée. Généralement, on utilise un texte en faux latin, le Lorem ipsum ou Lipsum	Remove
EFSA-2020-22222	lorem ipsum lorem ipsum lorem ipsum lorem ipsumlorem ipsum lorem ipsumlorem ipsum lorem ipsumlorem ipsum lorem ipsumlorem ipsum lorem ipsum	Remove

Add

Files	Type	status	Date
1A-confidential- study report.pdf	Study Report	Confidential	15/11/2020 11:57

Metadata

Publicly Available

Yes No

Document type

Study Report Clear

STUDY IDENTIFICATION

Have you received a EFSA study identification ?

Yes No

Justification for not having an EFSA study identification

disclaimer EFSA study justification text

It is a long established fact that a reader will be distracted by the readable content of a page when looking at its layout. The point of using Lorem Ipsum is that it has a more-or-less normal distribution of letters, as opposed to using 'Content here, content here', making it look like readable English. Many desktop publishing packages and web page editors now use Lorem Ipsum as their default model text, and a search for 'lorem ipsum' will uncover many web sites still in their infancy. Various

Request confidentiality treatment

Files	Type	status	
- 1A-confidential- study report.pdf	Study Report	Non-confidential	<ul style="list-style-type: none"> Request confidentiality treatment Add data sharing agreement Update document Remove document and data
+ Metadata			

Request **confidentiality** treatment

Files	Type	status	Date
- 1A-confidential- study report.pdf	Study Report	Confidential	15/11/2020 11:57
+ Metadata			
- Confidentiality treatment			
Non confidential file			
2A-non-confidential - study report.pdf		15/11/2020 11:57	x
Grounds for confidential file			
+ Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and the applicant or the authorisation holder, where applicable x			
- Article 39(2)(c) of Regulation EC No 178/2002 - Commercial information revealing sourcing, market shares or business strategy of the applicant x			
Ground			
Article 39(2)(c) of Regulation EC No 178/2002 - Commercial information revealing sourcing, market shares or business strategy of the applicant Clear			
Justification		Excerpt of the text	
<p> Lorem ipsum has been the industry's standard quality text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged. It was popularised in the 1960s with the release of Letraset sheets containing Lorem Ipsum passages, and more recently with desktop publishing software</p>		<p> It was popularised in the 1960s with the release of Letraset sheets containing Lorem Ipsum passages, and more recently with desktop publishing software like Aldus PageMaker including versions of Lorem Ipsum</p>	
Related section			
Page 21, paragraph 2(a), line 5 and 6			
CONDITIONS CHECK LIST			
Potential harm <input type="checkbox"/> Yes			
the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree and that the harm that may be caused is of a significance corresponding to at least 5% of their total gross turnover for legal persons, or earnings for natural persons, in the year preceding that of the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant should provide a specific reason in the form of a free text in the respective Justification box on why they considered that any public disclosure would potentially harm their interests to a significant degree.			
Worthiness of legal protection: <input checked="" type="checkbox"/> Yes			
the document, information or data for which confidentiality treatment is requested is eligible for worthy of legal protection and has not been acquired in an unlawful manner.			

Give detail about the confidentiality request (The applicant shall clearly indicate the grounds, possible multiple grounds per file)

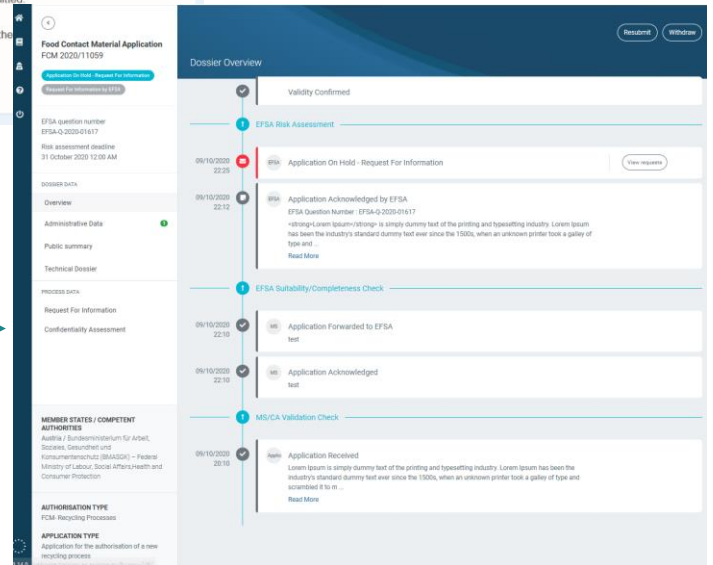
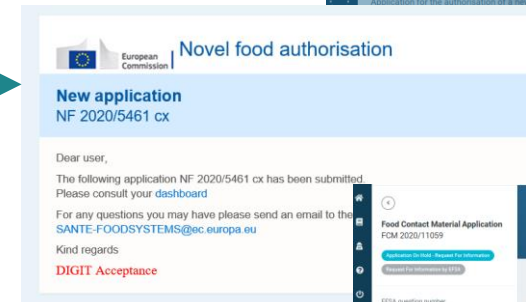
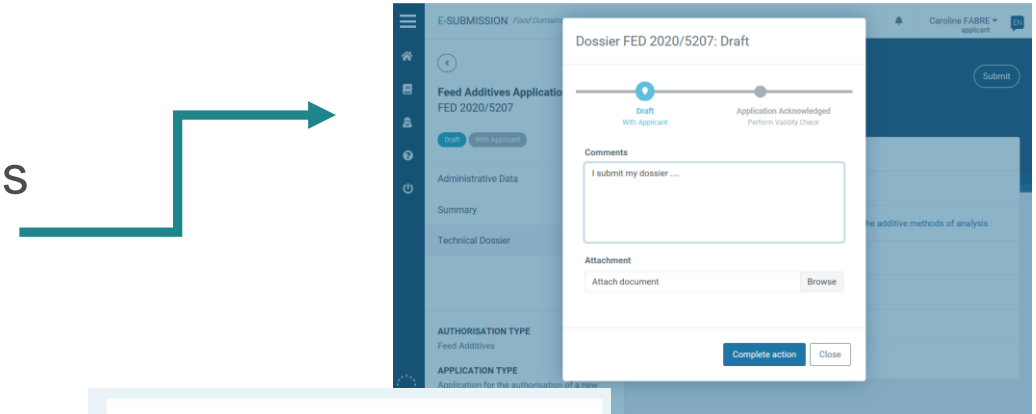
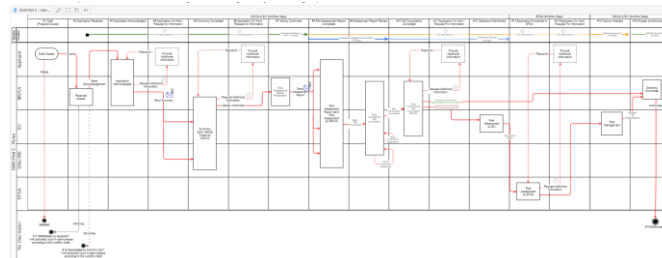
Confidential file + **non-confidential** version

1. Ground
 - a. Justification
 - b. Excerpt of the text
 - c. Related section
 - d. Conditions check list (potential harm...)

The same approach is foreseen for any additional/supplementary information provided by the applicant during the process.

Submit the application and follow the progress

- When the application is **ready** the applicant can **submit** and wait for notification about the progress and action to take
- EC or MS/CA will be **notified by email**
- All the stakeholders involved in the application can follow its progress with the “**overview**” timeline provided in the dossier – **Authorisation workflow depends on each food sector**



Request for Additional Information

- During the process the Authorities can send **request for additional information** to the applicant.
- Only the section(s) for which requests for additional information is requested is **unlocked** for the applicant, the rest remain read only.
- Additional/supplementary information is also subject to transparency/confidentiality provisions (i.e. **confidentiality can be requested by the applicant**)

The image displays three screenshots from the EFSA application portal, illustrating the Request for Information (RFI) process.

Top Screenshot: Dossier Overview
 Application: Food Contact Material Application (FCM 2020/12045)
 Application On Hold - Request For Information
 EFSA question number: EFSA-Q-2020-01162
 Timeline:
 - 23/10/2020 10:36: Application On Hold - Request For Information (Request for information by Camilla Villano)
 - 21/10/2020 11:32: Application Acknowledged by EFSA (EFSA Question Number : EFSA-Q-2020-01162, Subject of the request dossier 02)

Middle Screenshot: RFI for Data sharing agreement in place
 Dossier: FCM 2020/12045
 QUICK NAVIGATION:
 - Request for information (Created by EFSA at 23 October 2020 10:36 AM)
 - Response to request for information (Created by Applicant at 13 November 2020 7:22 PM)
 - Response to request for information (Created by Applicant at 12 November 2020 7:22 PM)

Bottom Screenshot: Request For Information - Technical Dossier
 Application: Food Improvement Agents Application (FIN 2020/13382)
 Application On Hold - Risk Management by EFSA
 EFSA question number: EFSA-Q-2020-01527
 Table of RFI requests:

Section	Requested	Answered	Closed	Action
RFI for List of annexes, references and checklist			●	View
RFI for Risk Management - organoPop			●	View
RFI for Overall conclusion on the safety of the proposed uses			●	View
RFI for Other studies			●	View
RFI for Subchronic toxicity			●	View
RFI for Genotoxicity			●	View
RFI for Intended use and use levels			●	View
RFI for Further processing			●	View
RFI for Manufacturing process			●	View
RFI for Identity and characterisation of the primary product -_probioidity			●	View
RFI for Pre-Application Information -_infoUnspecified			●	View
RFI for Pre-Application Information -_infoUnspecified			●	View
RFI for Identity and characterisation of the primary product -_probioidity			●	View
RFI for Genotoxicity			●	View

Confidentiality assessment

- The **confidentiality requests** provided by the applicant in the application and for any additional/supplementary information provided during the process, **will include the necessary information to perform the confidentiality assessment**
- **EFSA** will do the confidentiality assessment for applications where EFSA is requested for a scientific output and will communicate the result to the applicant through FSCAP
- **Commission** will do the confidentiality assessment in FSCAP in the limited cases where no scientific output is requested by EFSA
- **National Competent Authorities** will also be able to do the confidentiality assessment for **GMO directive (Part C)** in FSCAP

Confidentiality assessment

- The authority performing the confidentiality assessment will be able for each confidentiality request to:
 - Ask for **clarification(s)** from the applicant (if necessary)
 - Send a **draft decision** (the applicant will be able to send his comment / state his view on the draft decision (only for 2 weeks **from the date on which it was notified of the Authority's position** – after which the comment will not be possible)
 - Send the **final decision** and upload the **sanitised version (final non-confidential version)**

Confidentiality assessment progress can be followed in a specific section of the application

The screenshot shows the 'Confidentiality Assessment' section of the E-SUBMISSION Food Domains interface. The sidebar on the left lists various application components, with 'Confidentiality Assessment' highlighted by a dashed box and an arrow pointing from the text on the left. The main content area displays a table titled 'Confidentiality requests overview' for the 'Identity of the novel food' section. The table has columns for Documents, Confidentiality request(s), Clarification, Draft decision, Final decision, Action needed, and More. The table contains three rows of requests, each with a 'Clarification' column containing text and a 'Draft decision' column with a status indicator (e.g., 'pending', 'resolved', 'not agreed', 'accepted').

Documents	Confidentiality request(s)	Clarification	Draft decision	Final decision	Action needed	More
2017-0242 Draft Overview Dir Note.docx 2.pdf	Article 30(2)(a) of Regulation 1829/2003 and Article 2 of Regulation EU 2019/1381 - DNA sequence inf ... chapter 1	To be in phase with the regulation, the confidentiality of this section need to be part of current a ... One extra point to clarify. To be in phase with the regulation, the confidentiality of this section ...	pending		Reply	...
	Article 30(2)(a) of Regulation 1829/2003 and Article 2 of Regulation EU 2019/1381 - breeding pattern ... chapter 2	To be in phase with the regulation, the confidentiality of this section need to be part of current a ...	resolved	The reason for the confidentiality of this section to be not ok is due to the fact that you can no l...	Comment	...
2017-0242 Draft Overview Dir Note.docx 3.pdf	Article 30(2)(a) of Regulation 1829/2003 and Article 2 of Regulation EU 2019/1381 - breeding pattern ... chapter 2	To be in phase with the regulation, the confidentiality of this section need to be part of current a ... To be in phase with the regulation, the confidentiality of this section need to be part of current a ...	resolved	The reason for the confidentiality of this section to be ok is due to the fact that you can no longer ...	accepted	None

Dissemination

- Once the application is considered **valid** the **non-confidential version as submitted by the applicant will be automatically disseminated** and can be seen in EFSA public portal.
- Following the confidentiality assessment the non-confidential version as submitted by the applicant will be **replaced** automatically with the **final sanitised non-confidential version** provided by EFSA or MS/CA in the EFSA public portal.
- Dissemination also applies to **additional/supplementary information** provided by the applicant.

FSCAP

EFSA Public portal

Confidential version are **clearly marked** in FSCAP and will not be disseminated. **Only non-confidential version** and final sanitised version provided the Authorities (if any).

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Highlight FSCAP progress

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FSCAP how it works and interacts with EFSA's systems
(Highlight on Dissemination & Confidentiality & NoS)

3

Supporting materials

Supporting materials

- **8 Training modules** - Video tutorials will be accessible via FSCAP + EFSA's/EC's dedicated webpages and will be presented to the stakeholders.
- **General user guide** will be accessible via FSCAP + EFSA's/EC's dedicated webpages.
- **Specific user guide** per user role will be accessible in FSCAP.
- **Contextual help** (Help Notes) in different sections of the system will be available to guide the users during dossier preparation.
- **Helpdesk** will be provided for FSCAP-related questions.

Thank you



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