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

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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

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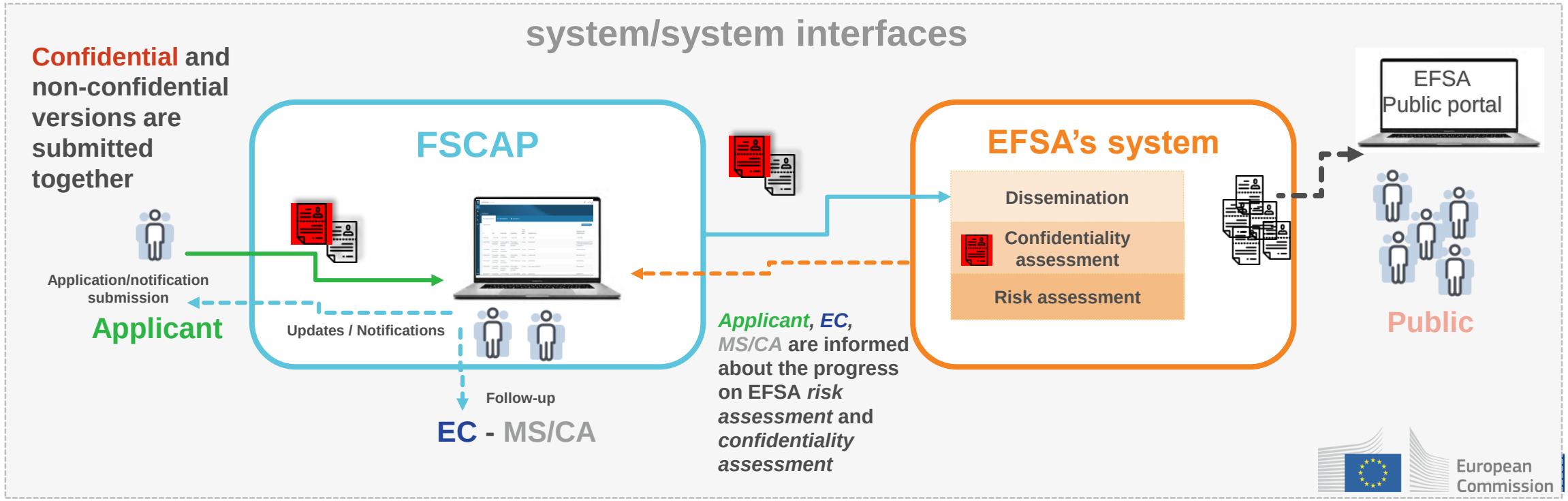
FSCAP & EFSA systems

- **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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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.)

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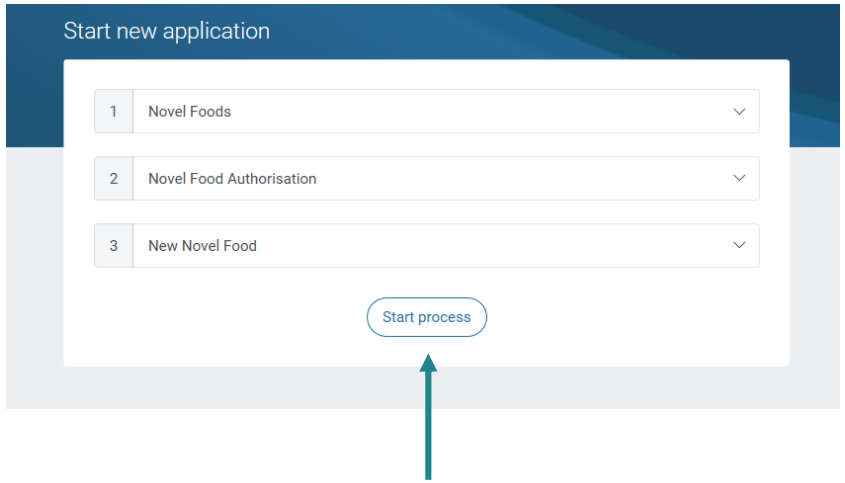
How to start with FSCAP as applicant ?

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



Application submitted to
European **C**ommission

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

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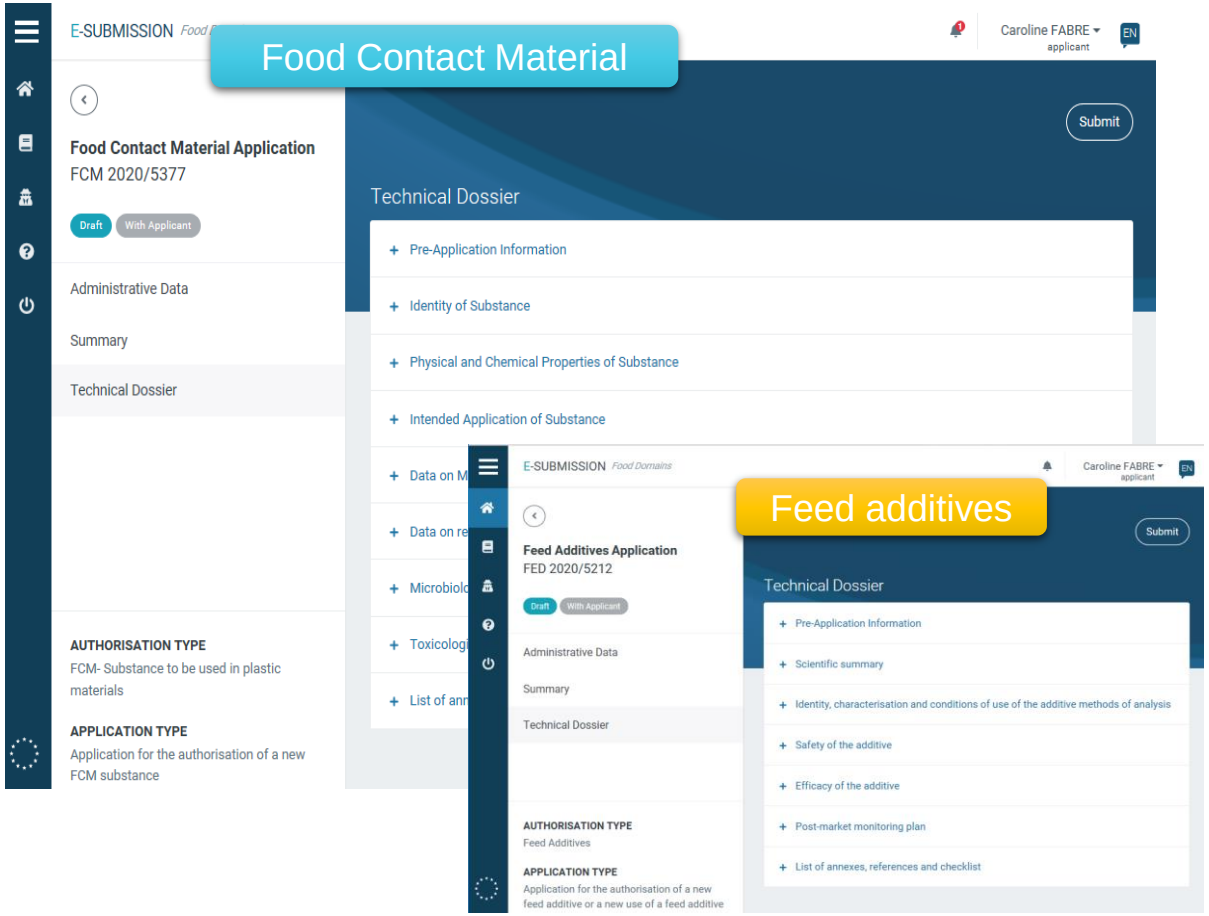
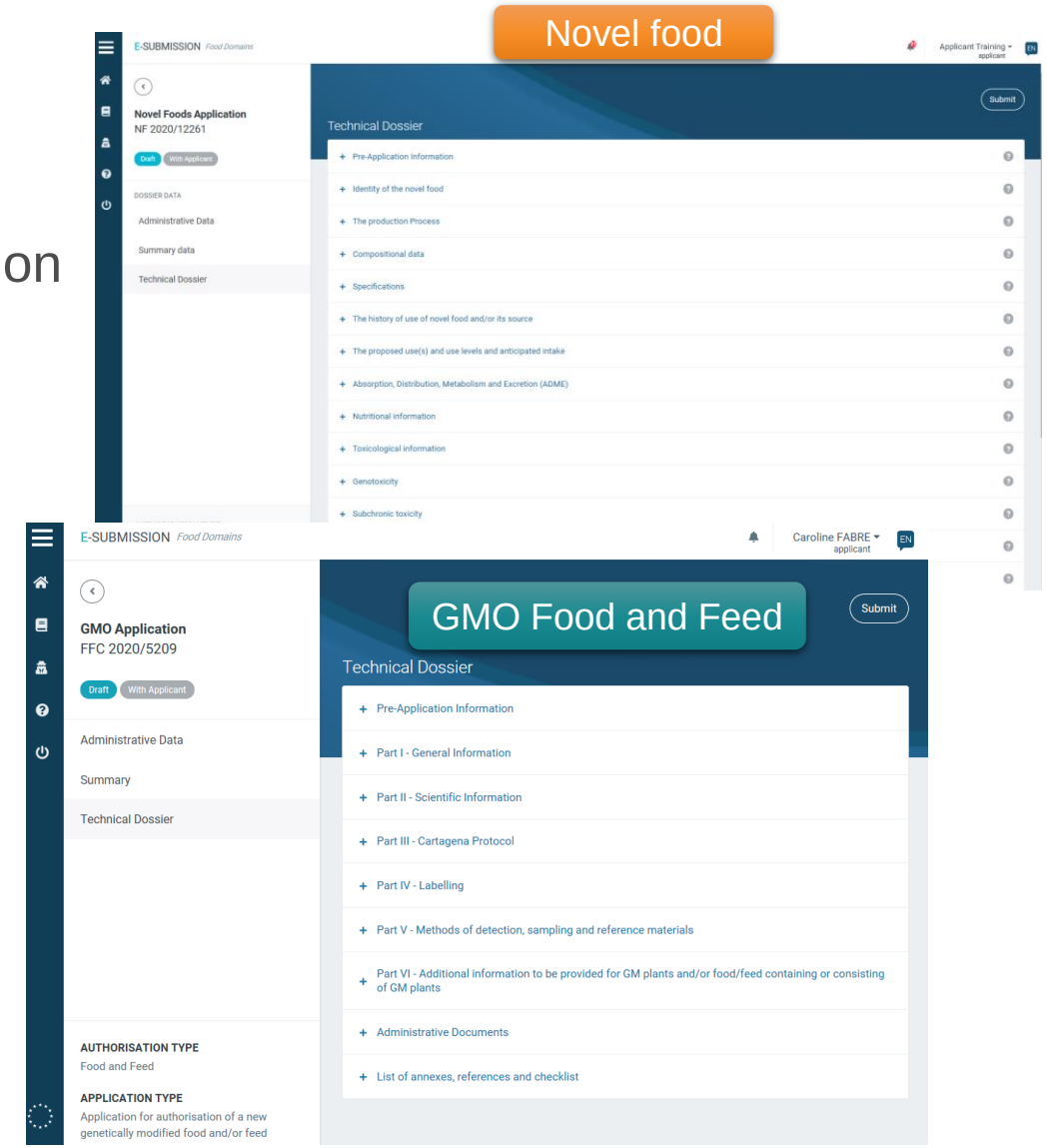
Fill in the Table Of Content

- Content structure created according to the selection





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Dossier content structure

Dossier structure

Table of content

- Administrative data
- Public summary
- Technical dossier

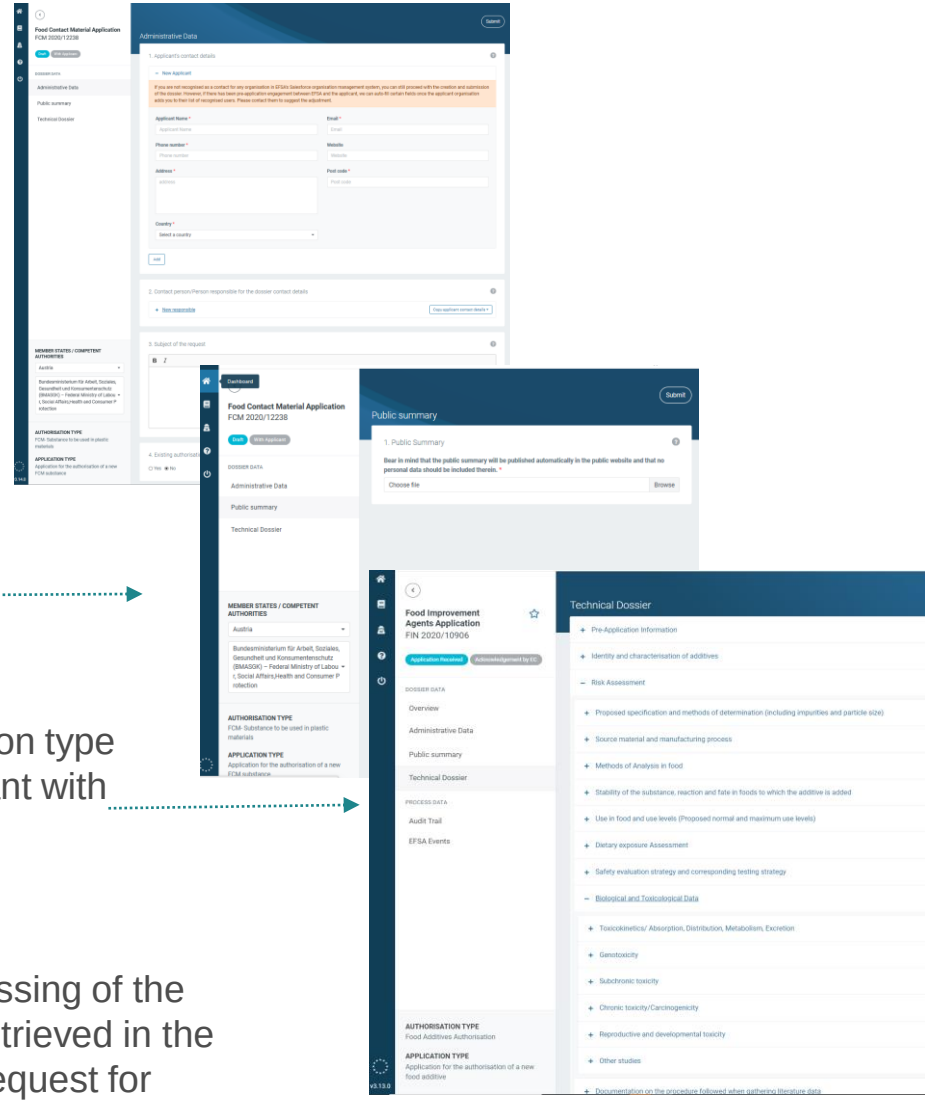
Data received during the processing of the dossier

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 ….)



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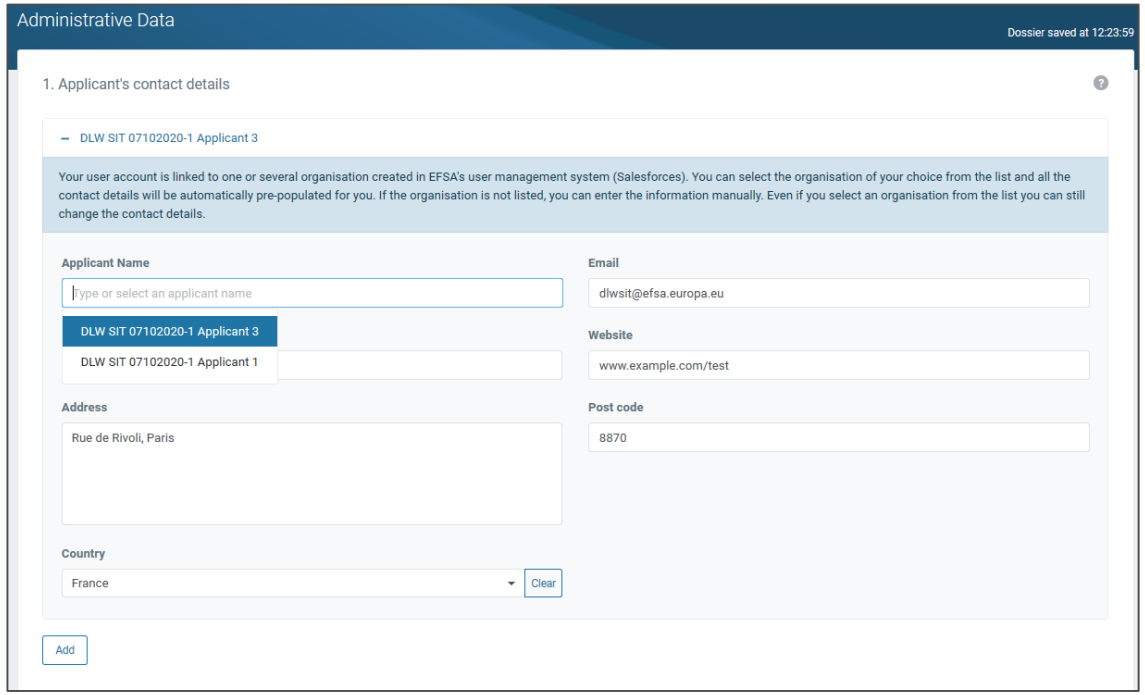
Pre-application information

- 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.



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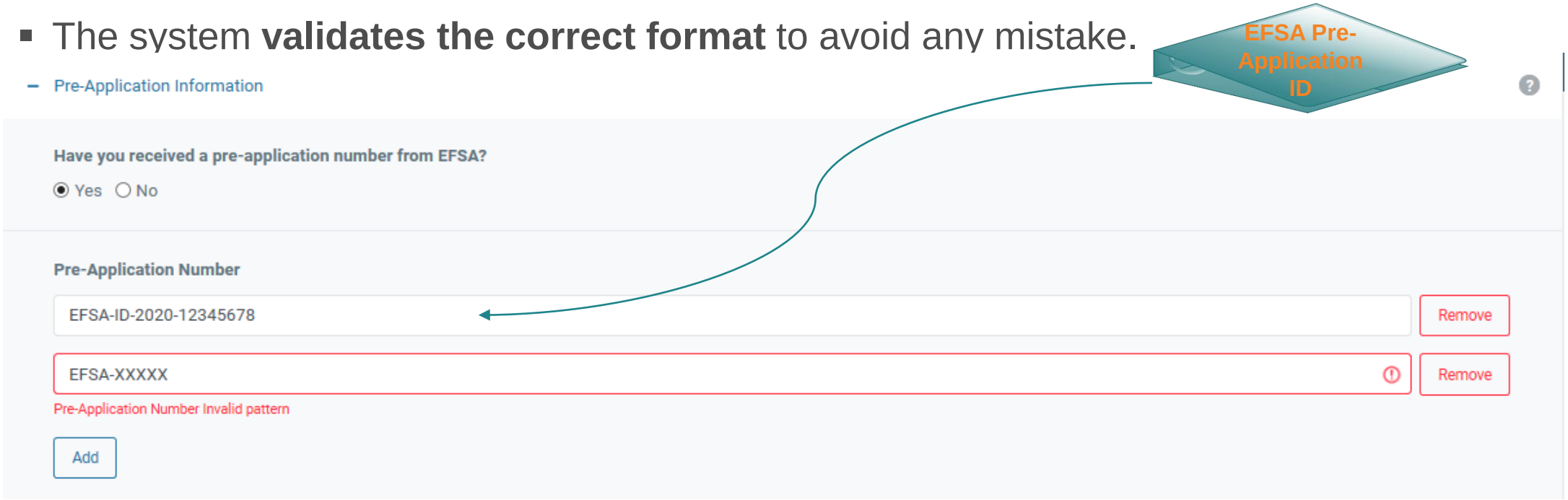
Pre-application information

- **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.



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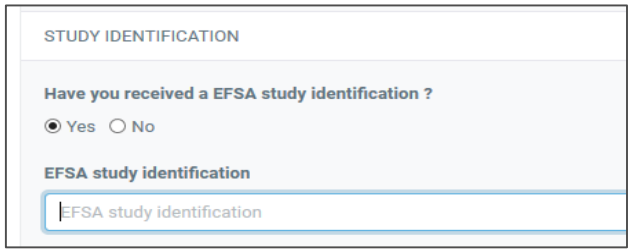
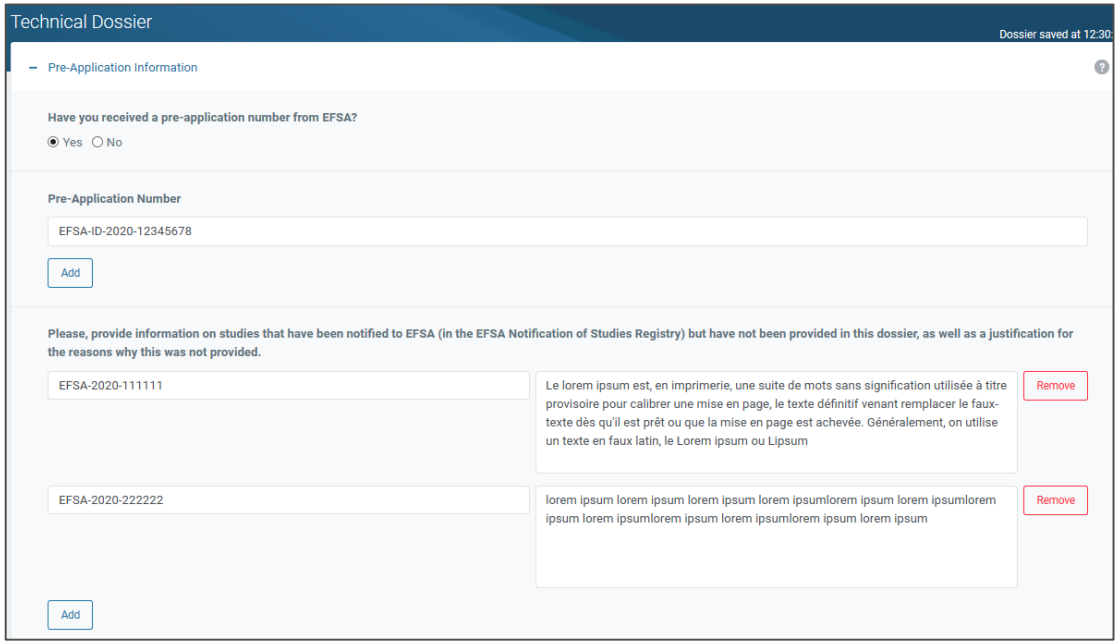
Notification of Studies (NoS)

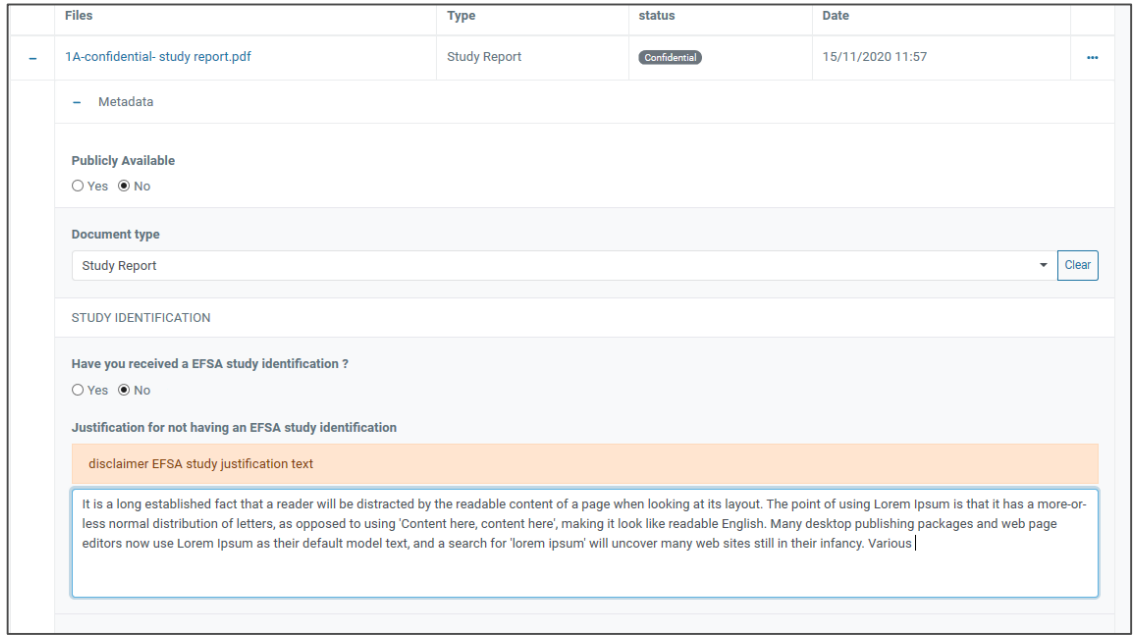
- The **notification of studies identifications (NoS ID)** received and grouped under a **pre-application ID** during the pre-submission phase can be linked to the study report file(s) within the application
- The system **will check that all NoS IDs are provided**, and/or a justification is given by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



- The applicant will have to justify **pre-notified studies not provided** in the application



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



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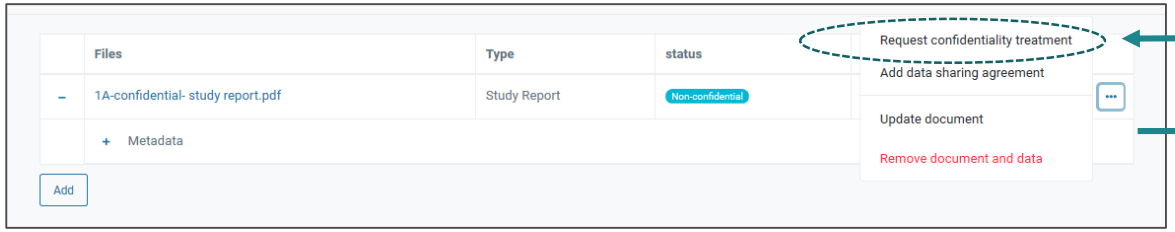
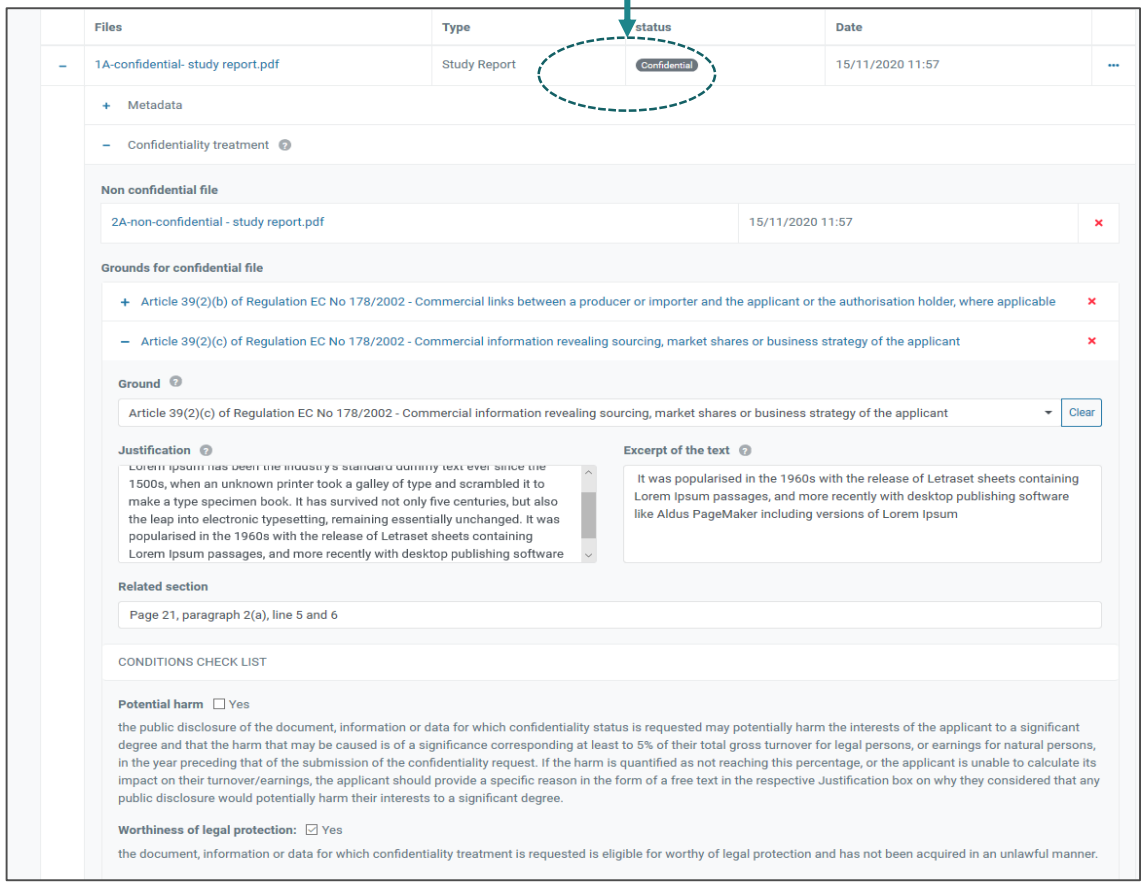
Request confidentiality treatment



Request confidentiality treatment



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

Confidential file + **non-confidential** version

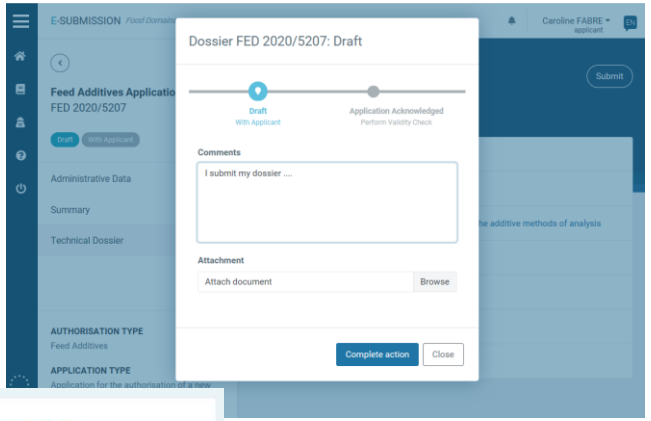
1. Ground
    a. Justification
    b. Excerpt of the text
    c. Related section
    d. Conditions check list (potential harm…)

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

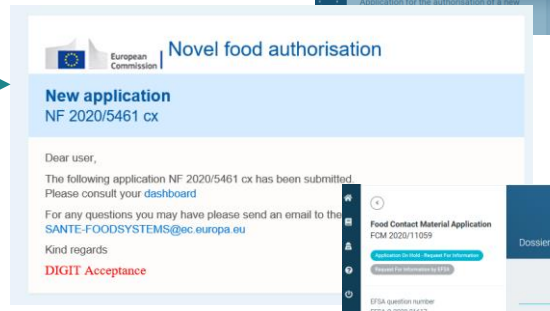
2

Submit the application and follow the progress

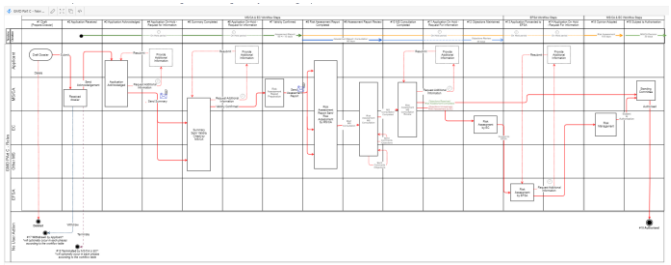
- When the application is **ready** the applicant can **submit** and wait for notification about the progress and action to take

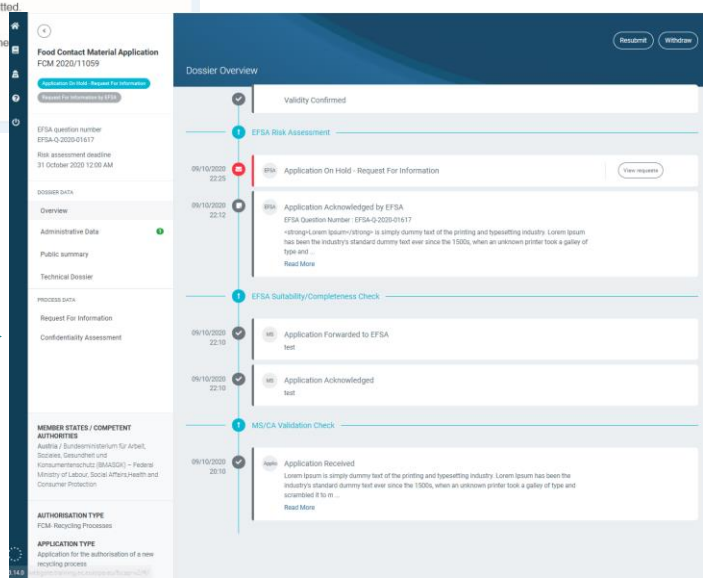


- EC or MS/CA will be **notified by email**



- 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*





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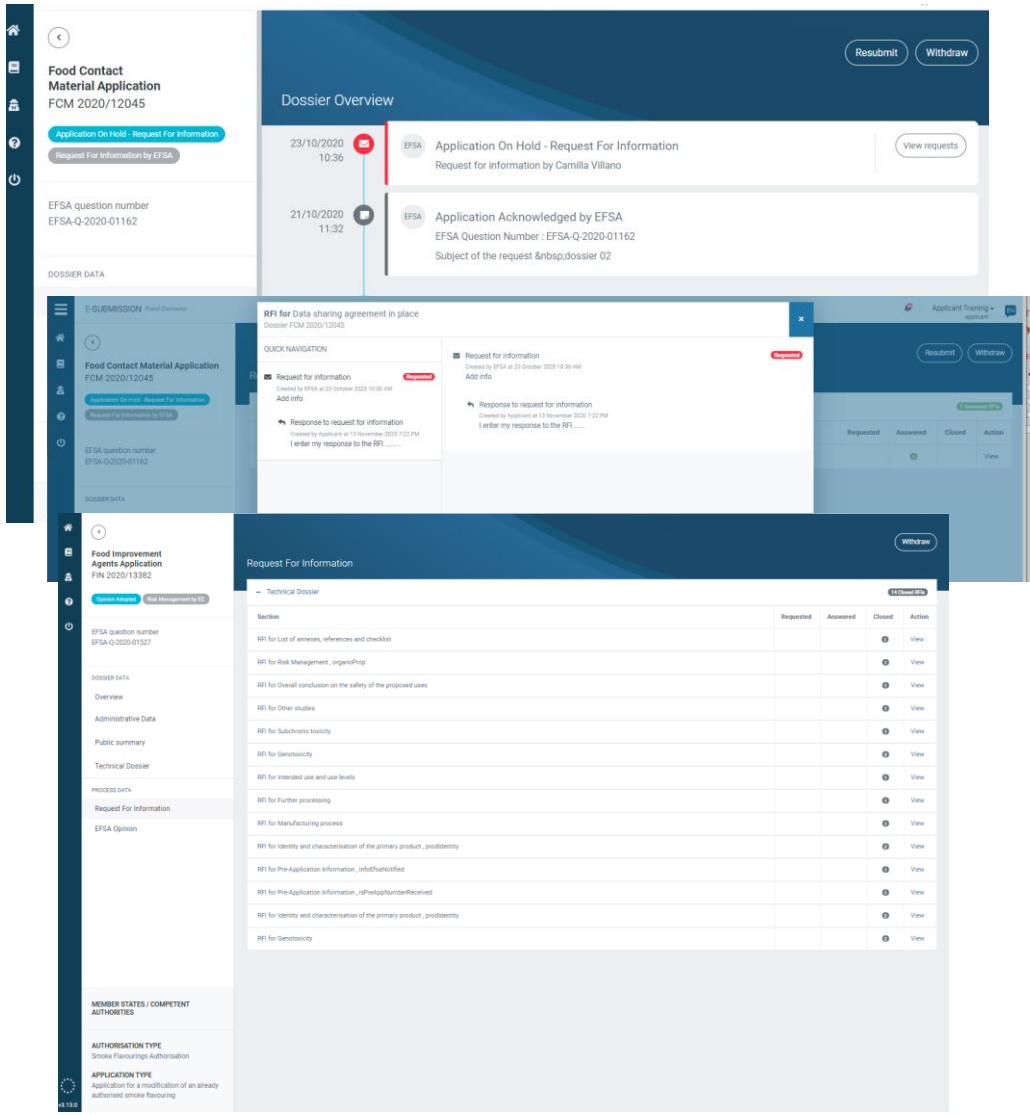
Request for Additional Information

- 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**)



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

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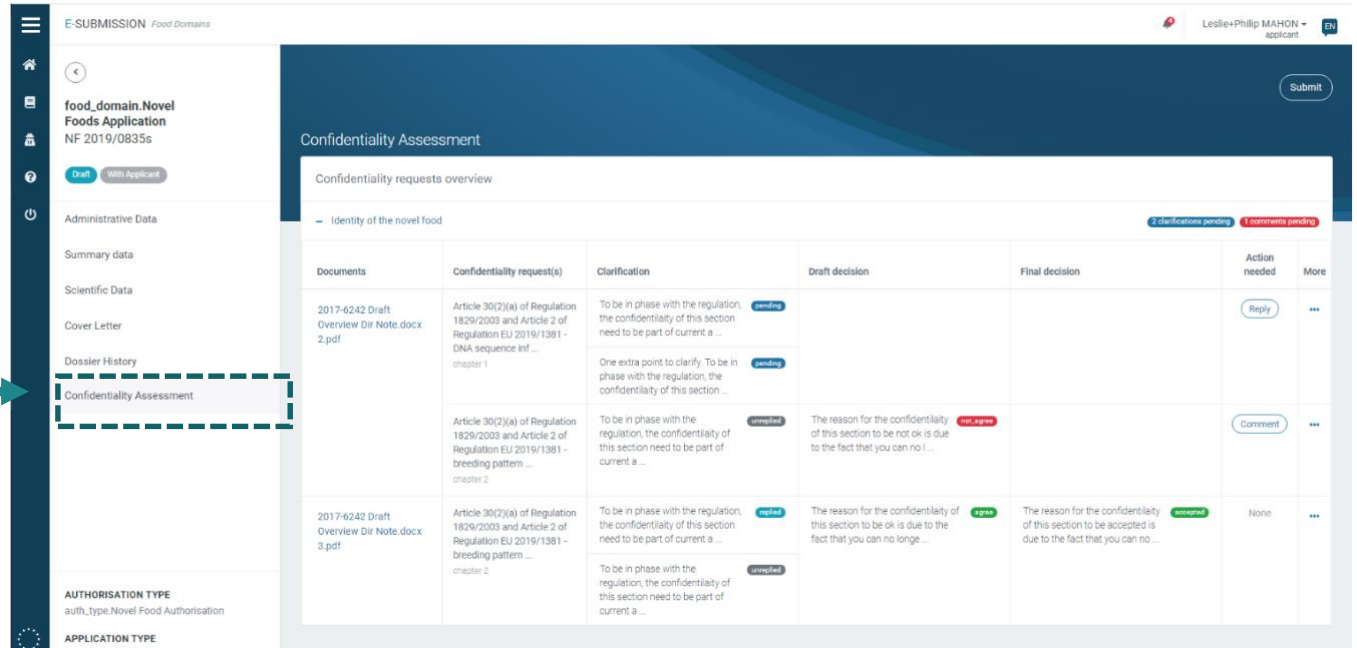
Confidentiality assessment

- 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



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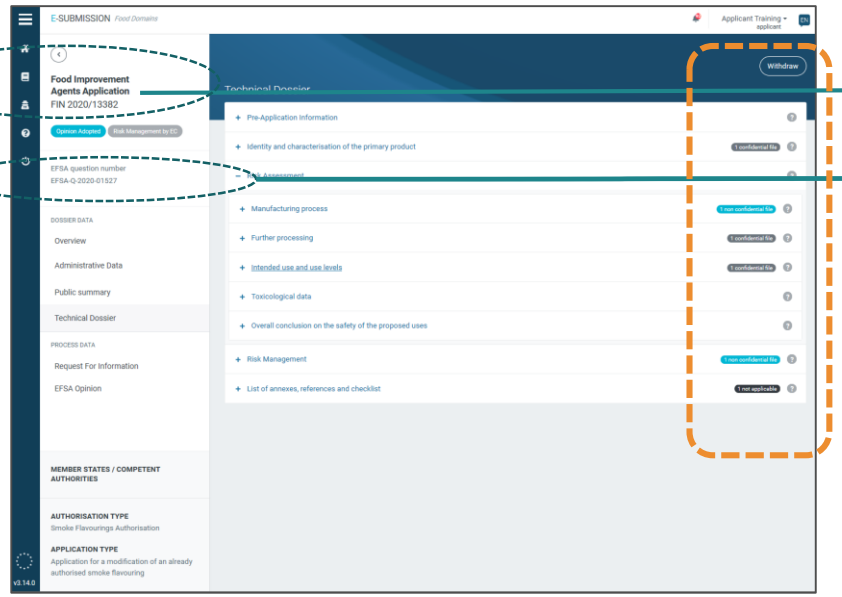
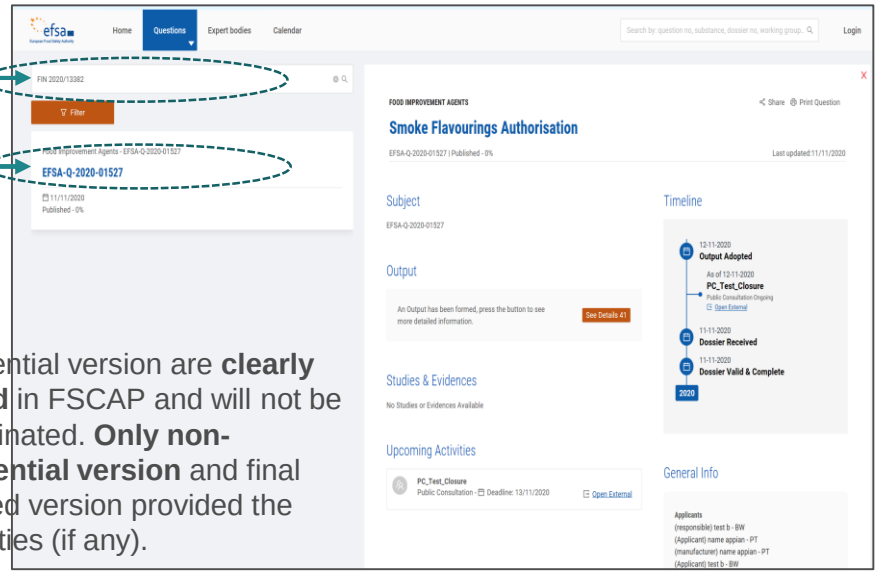
Dissemination

- Once the application is considered **valid** the **non-confidential version <u>as submitted by the</u> 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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3

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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