



User Guide: E-Submission Food Chain platform

A hands-on guide to electronically submitting food-chain dossiers for EU authorisation using the E-Submission Food Chain (ESFC) platform.

User Guide V1.0
27 March 2021

Disclaimer: The information provided in this user guidance is designated to provide helpful information on the usage of the E-Submission Food Chain platform. This user guidance is not meant to be used, nor should it be used, as interpretation of any official legislative documents. For legal information, please consult the Transparency Regulation and the sectorial legislations on the food and feed domains. For any information related to EFSA practical arrangements, please consult the EFSA website.

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WARNING

Our goal is to keep this information timely and accurate. For this reason the document is subject to change without notice. Please ensure you refer to the **online version** available [here](#), rather than a downloaded copy.

User Guide and support material: https://ec.europa.eu/food/safety/general_food_law/training-and-support_en

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Welcome to the User Guide



The food chain is increasingly complex. The EU's food policy has been built around high food safety standards that serve to protect and promote the health of the EU consumer.

The implementation of Regulation (EU) 2019/1381 on the transparency and sustainability of EU risk assessment in the food chain (“Transparency Regulation”) is central to strengthening the reliability, objectivity and independence of submitted studies. A key component in this process transparency is the **E-Submission Food Chain (ESFC)** platform for food chain authorisations.

Launch the platform: **ESFC**

How has the system evolved?

The previous submission method was based around paper and CD-loaded data. From 27 March, 2021, that system ends. The **ESFC** platform will operate for all food domains, excluding plant protection products and MRLs, which will use **IUCLID**, providing all stakeholders and actors with a structured and transparent time-controlled process.

The platform demands the same level of detail from applicants as the former process, however it provides food business operators an electronic method of submitting, tracking and interacting with the assessors throughout their application, as well as supporting them

in complying with the Transparency Regulation, linking to revised EFSA guidance documents.

Authorisation process principles

The input procedures for all food sectors are broadly similar and defined by legislation. Risk Assessment is performed by the European Food Safety Authority (EFSA) – the independent agency responsible for the risk assessment – whereas Risk Management and ultimate approval or rejection are carried out by the European Commission (EC) or Member States (MS).

1. All submitted dossiers are funneled through the ESFC platform to the body which is legally charged to receive them – either a Member State Competent Authority (MS-CA) or EC. The path depends on the food domain.
2. Once there is a mandate to proceed, EFSA proceeds with the Risk Assessment and produces a Scientific Opinion.
3. The EC or MS may, as the risk manager, use the published opinion as basis for deciding on its authorisation.

The main benefits of the e-submission process

Only through the ESFC platform can a food operator submit its dossier to gain EU-wide authorisation – or a renewal or modification of an existing authorisation.

- The authorisation procedure has been streamlined and centralised.
- Applicants submit, and can follow-up, the progress of their applications, and assessors can perform their tasks with trackable Applicant interactions – i.e. Requests for Information (RFI).
- The systems enables an audit trail and central data storage.
- Confidentiality requests can be made and justified line by line.
- Process efficiency is improved by establishing deadlines for the risk assessment – a more timely and predictable authorisation procedure.



NOTE

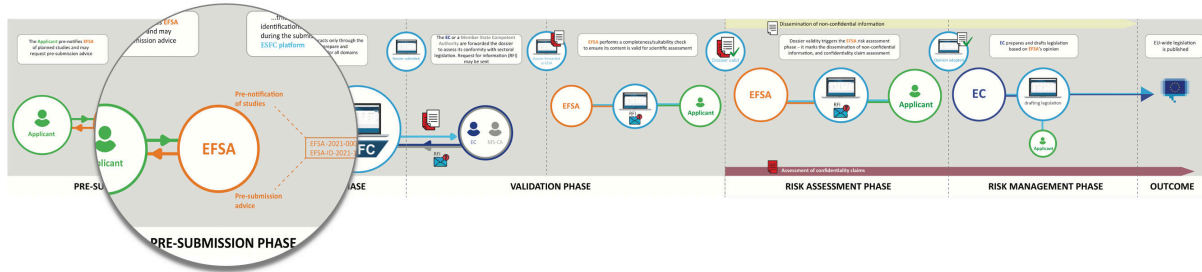
Please note that applicants should use **IUCLID** plant protection products and MRL submissions. You will find more information about the IUCLID system in the [EFSA Toolkit](#).



TIP

Because notifications arrive by email, to minimise avoidable delay or missing a response/comment window, the Applicant should ensure that all of its ESFC platform users maintain and monitor a stable IT environment (i.e. following mailbox filtering and spam protocols etc).

Pre-submission phase



Applicants can benefit prior to submitting their dossier by receiving renewal pre-submission advice or by requesting general pre-submission advice from EFSA. More information is available in EFSA's [Practical arrangements on pre-submission phase and public consultations](#).

The process will be streamlined if the applicant ensures that its registered user list is up-to-date in EFSA's [ConnectEFSA](#) user management portal. Once the dossier input begins, the e-submission platform may recognise the user based on EFSA's information for that Applicant, and pre-populate or prompt certain fields. Please note that this facility is currently disabled, so Applicants should manually input all the information.

Pre-submission engagement with EFSA

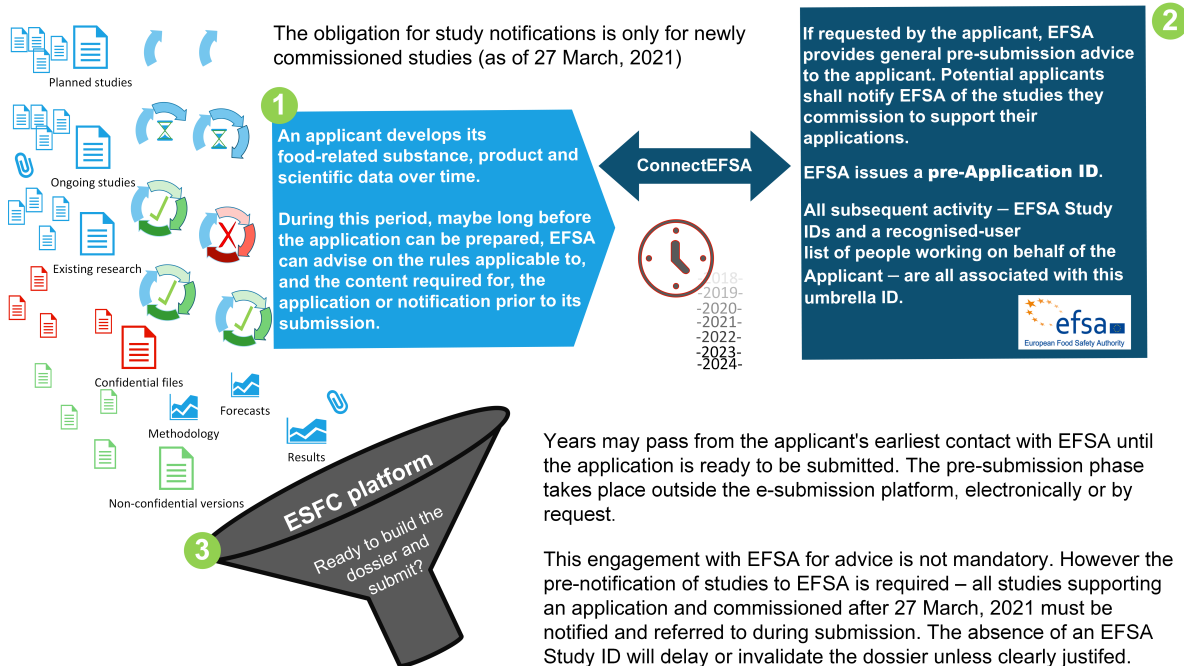


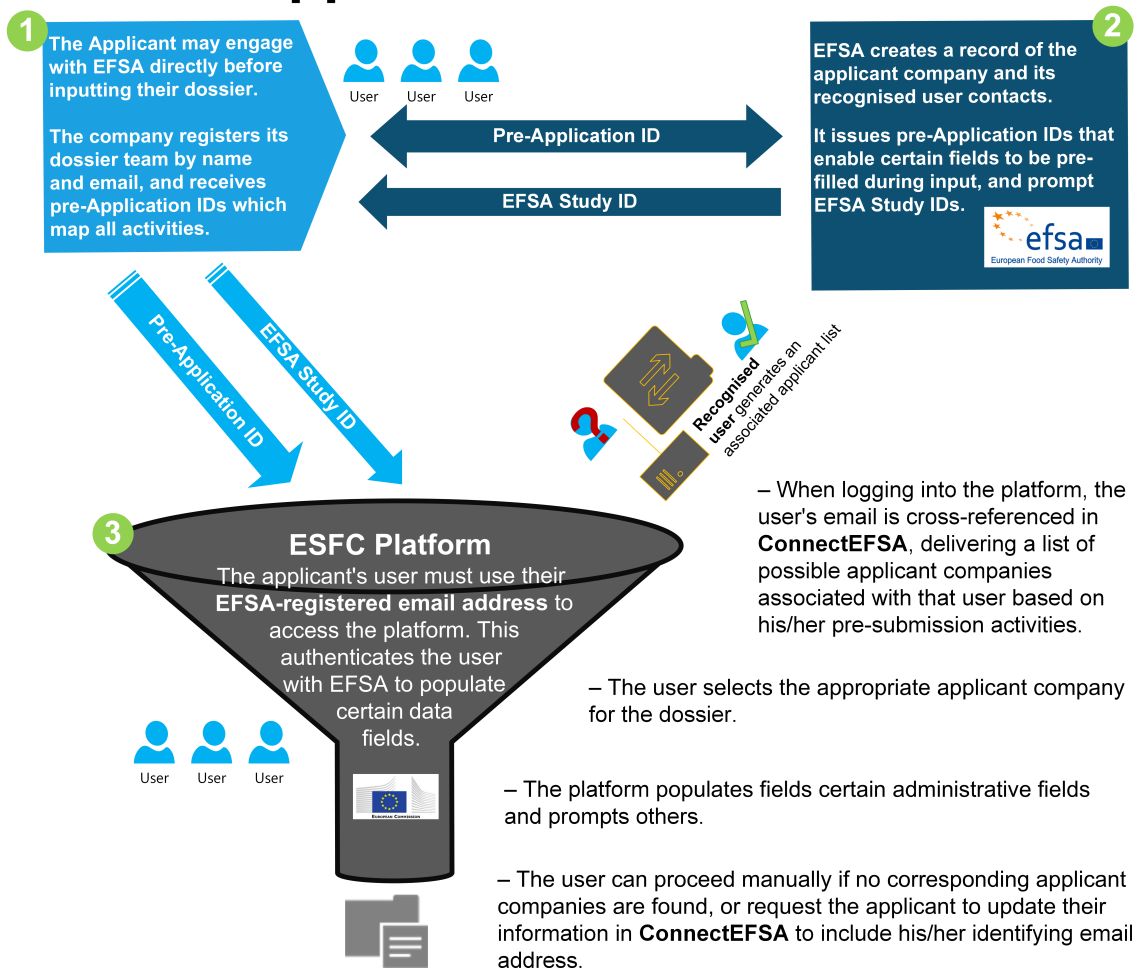
Table 1. Wider insights and resources

Practical arrangements on pre-submission phase and public consultations
Applications helpdesk
Ask EFSA a question & FAQs
OpenEFSA portal

User recognition

Understanding this step will simplify your dossier submission. If an applicant company sought pre-submission advice from EFSA and/or has some studies notified, it would have set up an EFSA access account. This would require an 'administrator' main contact to list his/her team by their individual email addresses in the **ConnectEFSA** portal. These contact people would create and input the dossier. This information should be kept up-to-date in the portal.

User & Applicant connected



The ESFC platform will require each user to have a personal **EU login** to access and create a dossier. Because a single user may represent a range of food operating companies, the platform cross-references the user's email address against a list of companies who have registered the same email in **ConnectEFSA**.

The user selects the appropriate company from the dropdown to be the 'Applicant' of the dossier. [See the steps here \(page 12\)](#).

With the user identity and applicant company established, the e-submission platform can pre-load certain contact fields, and prompt various ID fields, with data generated during the pre-submission interactions.

If you are preparing the Applicant's first dossier and/or there was no requirement for any pre-submission advice (i.e. you do not have any pre-Application ID or EFSA study IDs), you can proceed with the dossier completion manually. The only prerequisite for accessing the platform is obtaining an EU login.



NOTE

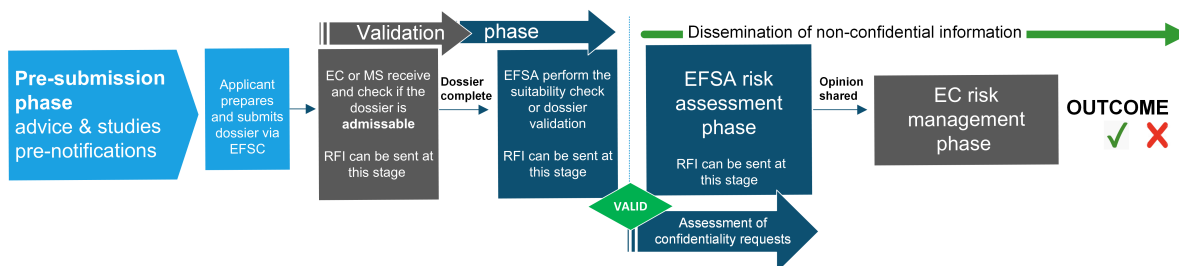
There can be multiple users for one dossier, see [Manage dossier access \(page 10\)](#).



IMPORTANT

The user recognition function is currently disabled. Applicants can still proceed, and input the information manually. We will inform you via the ESFC platform, and in this guidance, once the function is enabled.

Ready to submit



The ESFC platform has been developed to allow applicants submit and follow-up on dossiers through one online web interface. It displays each domain's content structure as required for scientific risk assessment, and integrates the transparency requirements laid down in law. It also:

- provides a clear structure for requesting confidentiality treatment
- displays contextual help for each section based on EFSA guidance.

Launch the platform: **ESFC**



NOTE

The Autosave function ensures that the encoded content is saved automatically. There is no 'Save' button on the platform. **Dossier saved at 20:18:19**



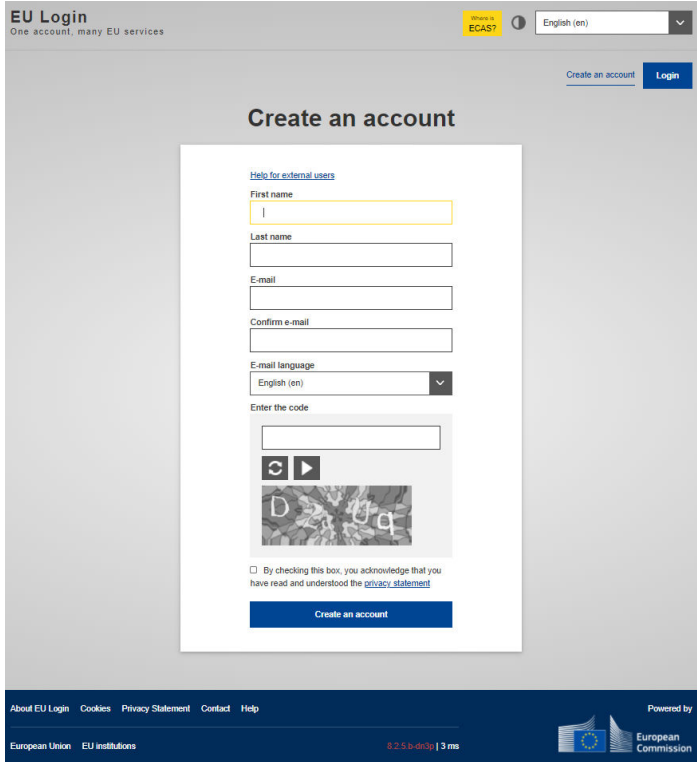
TIP

In order to access the platform, you need an **EU Authentication Login account (page 8)**.

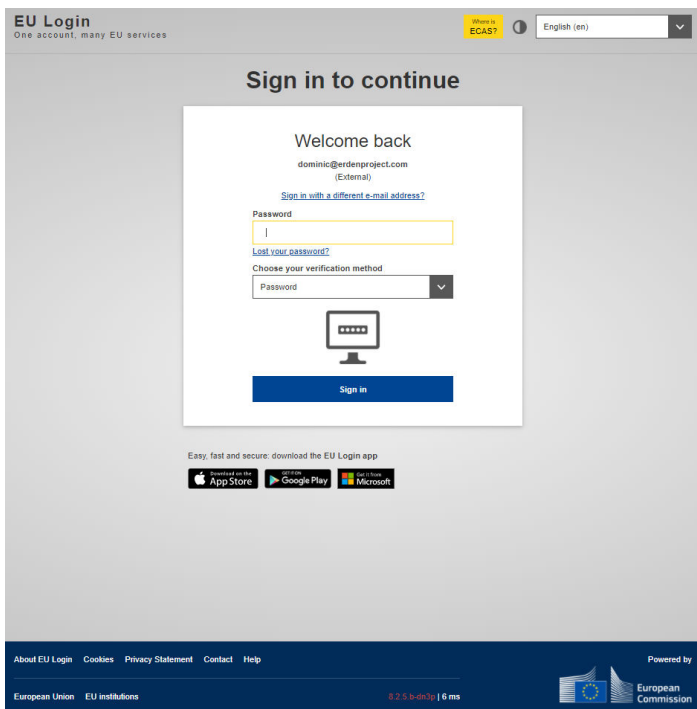
How to log in

You need an EU Authentication Login to access the ESFC platform.

If you don't have an EU Login account, please use [this link](#):



If you already have a user account for EU Login, you can log directly into the ESFC platform via [this link](#):

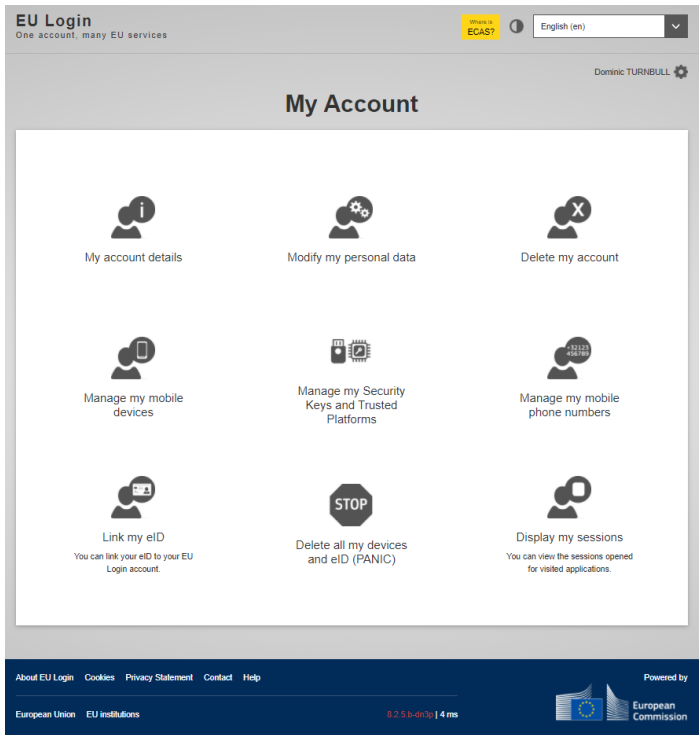




NOTE

The account will become inactive after six months if not used, but still accessible. You will be prompted to create a new password.

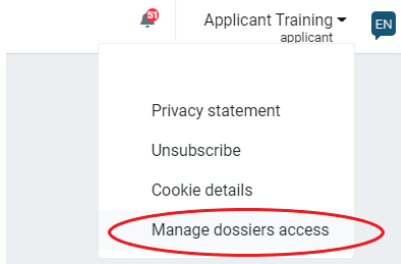
If you want to change your EU Login password, or edit your EU authentication login account, click [here](#).



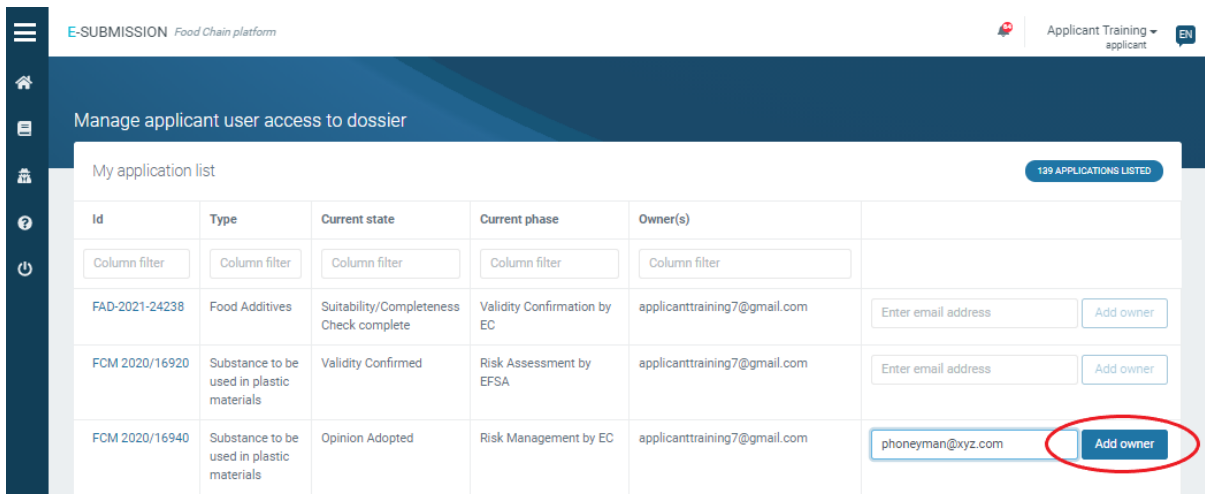
Dossier access management

The ESFC dashboard will present all ongoing and closed dossiers. The dashboard 'owner' can add team members to any of their dossiers. New users must be added with the same email address as their EU login. Thereafter, these new users will be able to contribute to the dossier's development – indeed they will hold the same user rights as the dossier owner. All users will receive notification emails.

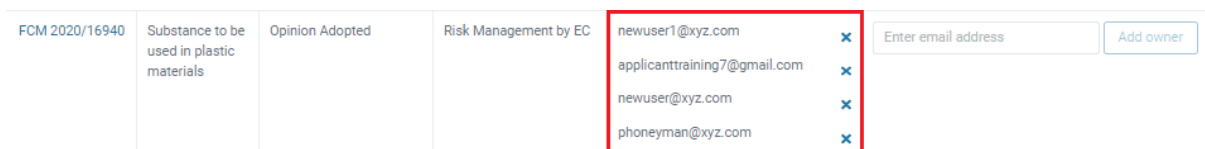
1. Provide access to other users by clicking the '**Manage dossiers access**' option in the top-right dropdown menu '▼'.



2. Click '**Add owner**' and input their email address. This must be the same as that used to perform their EU login.



3. You can add multiple users, which appear with equal weight. All share the same dossier editing status.



- Click the 'x' to remove a dossier user. Note that you will always be required to retain at least one user.

The screenshot shows the 'Manage applicant user access to dossier' page. A modal dialog box asks: 'Do you really want to delete the owner newuser@xyz.com?'. Below the dialog is a table with columns: Id, Type, Current state, Current phase, and Owner(s). The table lists three applications. The third application, FCM 2020/16940, has four users listed in the 'Owner(s)' column: newuser1@xyz.com, applicanttraining7@gmail.com, newuser@xyz.com, and phoneyman@xyz.com. Each user name has a small 'x' icon next to it, which is highlighted with a red box in the original image. To the right of the table, there are input fields for 'Enter email address' and 'Add owner' buttons.



NOTE

Around 90% of users who will actively input a dossier are consultants, not directly employed by a single applicant. They often act on behalf of multiple food business operators. Therefore it is important that the user relationship to each applicant is clear from the outset.



TIP

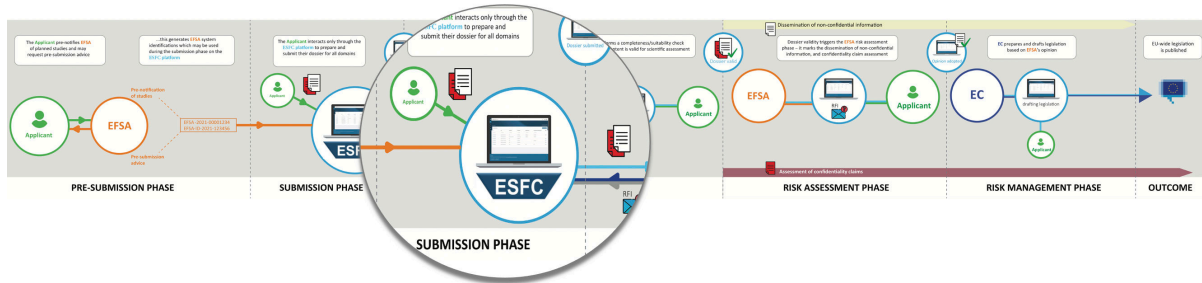
Users who have been given access will obtain complete access in 'edit' mode. In the future we foresee a 'read-only' alternative.




WARNING


If you transfer the dossier to another person, and delete then all other users, make sure in advance that their email address is correct, accessible, and they are able to log into the ESFC platform – because theirs will become the **only** dossier access-point once you complete the action.

How to build your dossier



A "dossier" is an application or notification submitted to the platform. The procedures for this, as well as the data requirements for all food sectors, are defined by the respective legislation and/or EFSA guidance documents.

 **NOTE**
 Please note that for plant protection products and MRL submissions, applicants should be using the IT tool **IUCLID**. You will find more information about the IUCLID system in the **EFSA Toolkit**.

 **TIP**
 If certain fields do not apply in the context of your dossier, for example in the case of a submission supporting a modification or extension of an already existing authorisation, you can check the **'Not applicable'** box, then provide a suitable explanation in the text field that appears. You will notice a disclaimer stating that this entry will be publicly available.

The applicant is expected to submit a complete application, including all relevant information available at the time of submission. Once submitted, the dossier is locked and cannot be edited unless requested to do so by an authority.

An applicant or authorisation holder may, however, submit supplementary information to support their dossier. **Contact EFSA directly** for guidance on how to submit the additional data.

 **TIP**
 Go to **User Recognition (page 5)** to better understand how to simplify the input process.

Food Contact Materials

Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called Food Contact Materials (FCMs). Food contact materials are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use.

Table 2. Application type and legislation

Authorisation type	Application type	In accordance with
Substance to be used in plastic FCM	Application for the authorisation of a new substance	Regulation (EC) 1935/2004
	Application for the extension of use of an already authorised substance	
Recycling Process	Application for the authorisation of a new recycling process	Regulation (EC) 1935/2004
	Application for the modification of use an already authorised recycling process	
Regenerated Cellulose Film	Application for the authorisation of a new substance	Regulation (EC) 1935/2004
	Application for the extension of use of an already authorised substance	
Active & intelligent Materials	Application for the authorisation of new substance(s)	Regulation (EC) 1935/2004
	Application for the extension of use of already authorised substance(s)	



TIP

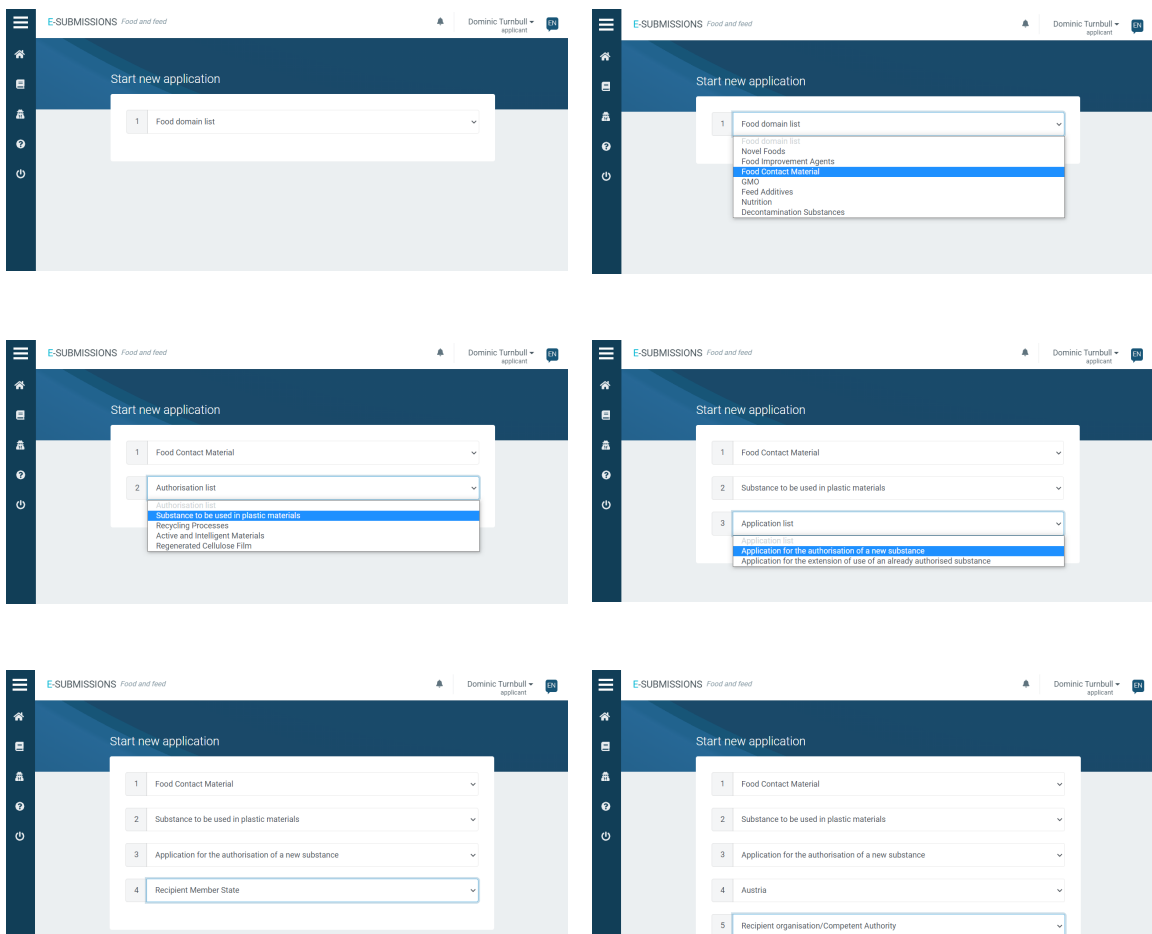
All dossier types selected in this category will generate a template built according to EFSA guidance and legislation. We use the sub-domain '**Substance to be used in plastic**' to demonstrate the submission process. Other FCM application types follow the same input procedures.

Getting started

Create a dossier: Substance to be used in plastic materials

The follow procedures and interactions with the ESFC platform are applicable for all domains.

1. According to EFSA guidance and EC regulation, the distinct domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose your domain, in this example we select **Substance to be used in plastic materials**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**.



- Complete the administrative data. Note the mandatory fields (*). If your login email is associated with one or more applicant companies, a list will drop down. From this you can select the appropriate Applicant. The system assigns a dossier number that remains throughout the process. The top-right notification bell indicates activity. **Note: The user recognition function is currently disabled. Applicants can still proceed, and input the information manually.**

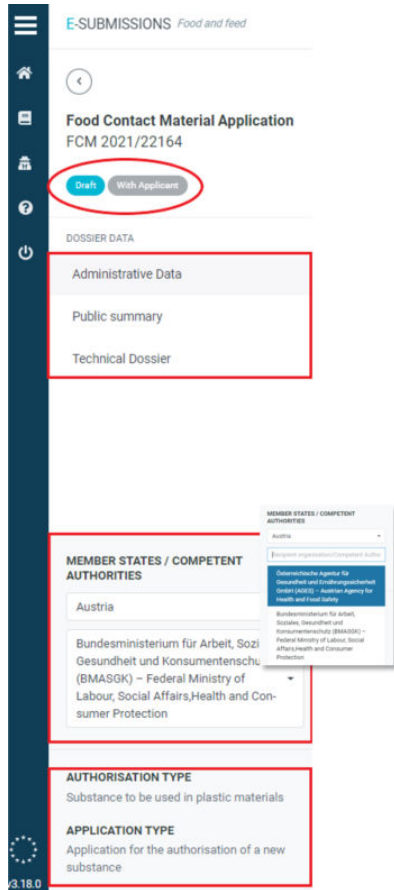
The screenshot displays the 'Administrative Data' form in the E-SUBMISSIONS Food and feed platform. The form is titled 'Applicant's contact details' and includes a 'New Applicant' section. A note states: 'If you are not recognised as a contact for any organisation in EFSA's Salesforce organisation management system, you can still proceed with the creation and submission of the dossier. However, if there has been pre-application engagement between EFSA and the applicant, we can auto-fill certain fields once the applicant organisation adds you to their list of recognised users. Please contact them to suggest the adjustment.'

The form contains the following fields:

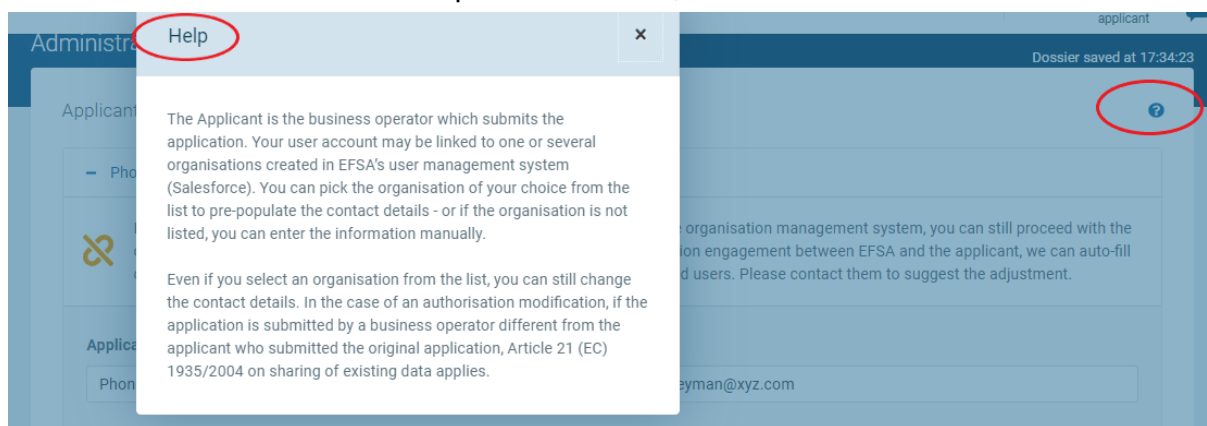
- Applicant/Company name ***: A dropdown menu with a red box around it, showing a list of applicants including 'DLW SIT 07102020-1 Applicant 1' and 'DLW SIT 07102020-1 Applicant 3'.
- Email ***: A text input field labeled 'application.Email'.
- Phone number ***: A text input field labeled 'application.Phone number'.
- Address ***: A text area labeled 'Address'.
- Country ***: A dropdown menu labeled 'Select a country'.

The interface also features a sidebar with navigation options, including 'Food Contact Material Application FCM 2021/22164', and a top navigation bar with a notification bell icon and the user name 'Dominic Turnbull applicant'.

- The top of the left pane shows the dossier status and phase. The three dossier sections (Administrative Data, Public summary, Technical Dossier) remain throughout. Your selected MS-CA displays, but you can select an alternative MS-CA, if one exists, via the dropdown menu that appears. The bottom section displays the authorisation and application type.



- Click the '?' to see contextual help for the section, if available.



- Click on **'Copy applicant contact details'** to duplicate the Applicants' data inserted in *step 2*, in case the person responsible is working in the same company as the Applicant. Fields can be manually overwritten.

Contact person/Person responsible for the dossier contact details *

— New responsible

Copy applicant contact details

Name of contact person / Person responsible: Peter Honeyman

Name of the entity/organisation *: application.Name of the entity/organisation

Email *: application.Email

Phone number *: application.Phone number

Website: application.Website

Address *: Address

Post code *: application.Post code

Country *: Select a country

- Enter the **'Subject of the request'**. You may consult the contextual help '?' for additional information.

Subject of the request *

B I

- If there is authorisation history to the subject of this dossier, click **'Yes'**, then indicate the related Member State. Select the status, then browse to and upload relevant documents with supporting information.

Existing authorisations at MS level

Yes No

Austria Clear Search for a status authorisation Browse

authorisation is mandatory

Add

- Under consideration
- Withdrawn
- Authorised
- Rejected
- Expired

Existing Authorisations in non-EU countries

- Click **'Add'** to detail other Member States where the subject of the dossier has history, and upload documents as before.

Existing authorisations at MS level

Yes No

Country	Status	File Name	Actions
Austria	Authorised	Austria Auth XYZ.png	Remove
Belgium	Authorised	Belgium Auth XYZ.png	Remove
Croatia	Search for a status	authorisation	Browse Remove

Add

Existing Authorisations in non-EU countries

- If a data-sharing agreement is available relating to the entire dossier, click the **'Yes'** radial. Click **'Add document'** for multiple agreements.

Data sharing agreement in place

Yes No

Files	Type	Status	Date
- Data sharing Agreement for XYZ-Add.pdf		Non-confidential	24/03/2021 16:44
- Metadata			

Publicly Available ?

Yes, IRP owned/acquired Yes, IPR NOT owned No

Document type * ?

Select a document type

- Indicate for each document whether it is **'Publicly available'**, or whether there are related IPR considerations. The default setting is **'no'**. For more information on how IPR impacts disclosure, read the chapter [Intellectual Property Rights \(page 94\)](#).

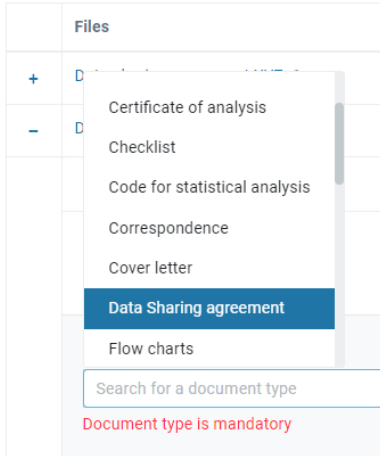
Publicly Available ?

Yes, IRP owned/acquired Yes, IPR NOT owned No ✓

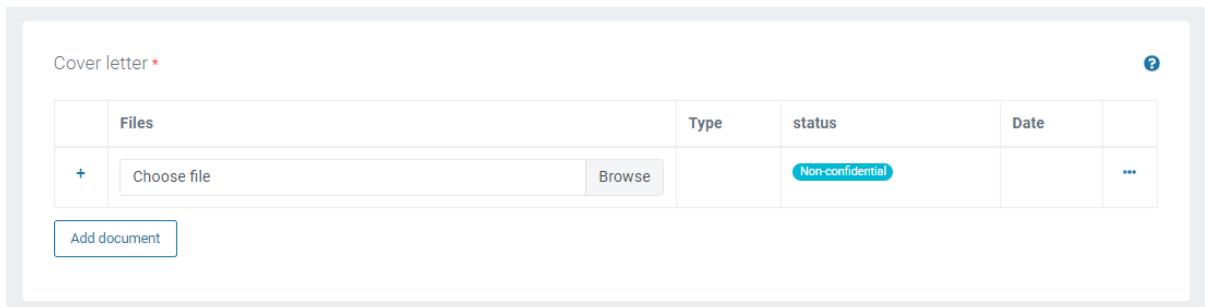
11. Now identify the '**Document type**' via the metadata dropdown (see [Appendix A \(page 115\)](#)). In this instance, select '**Data Sharing agreement**'.

Data sharing agreement in place

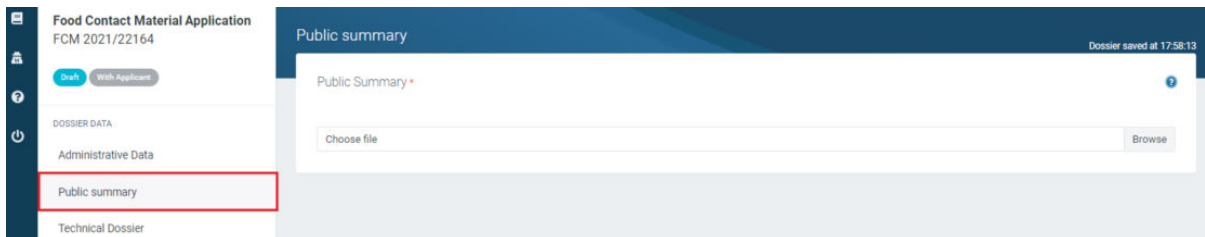
Yes No



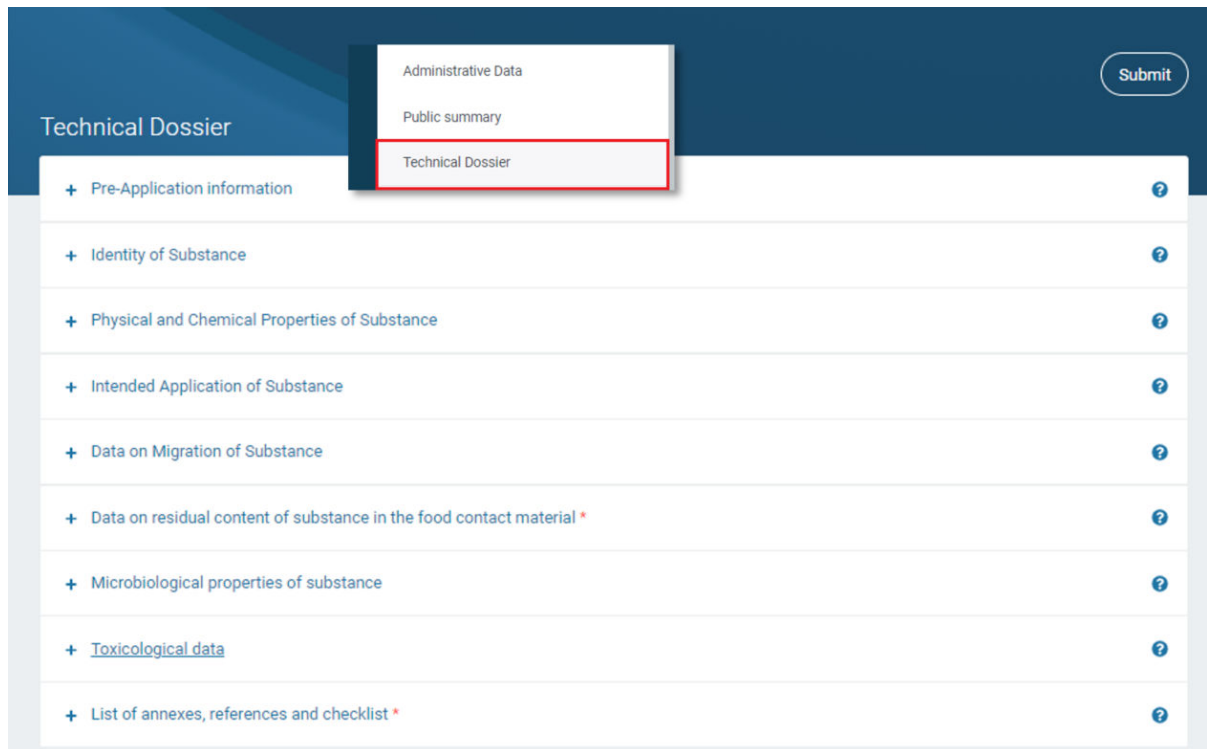
12. Upload the cover letter.



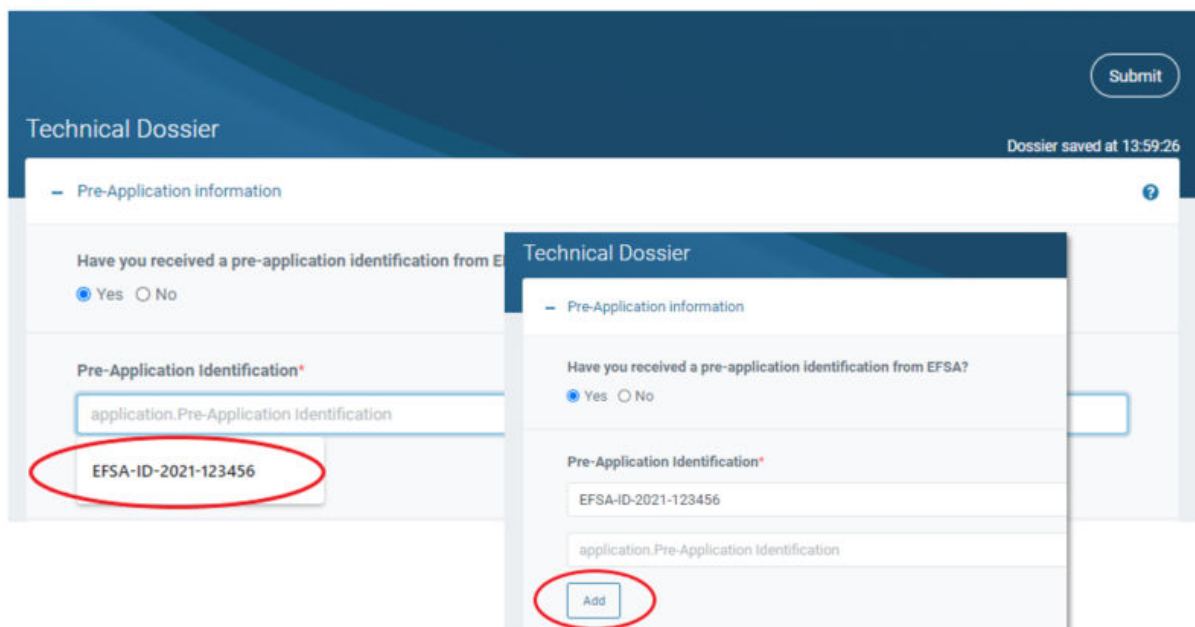
13. Click the '**Public summary**' tab, upload a public summary.



14. Click to the **'Technical dossier'**. The table of contents reflects the sections required by legislation and/or outlined in EFSA guidance.



15. If the Applicant engaged with EFSA during the pre-submission phase, they would have been assigned a pre-Application Identification number. Please input it here. Note the format. Click **'Add'** to include multiple IDs.



16. If the Applicant notified a study which was withdrawn or otherwise is not present within this dossier, input its EFSA study ID here, including a justification for why it has been omitted. Click **'Add'** if there are multiple study omissions.

If necessary, please provide the study identifications of studies that have been notified in the database of study notifications (established by EFSA) that have not been included in this application and/or have been withdrawn from the database. In addition, please provide justifications explaining the reasons why these studies were not included or withdrawn, respectively.

The justification for the non-inclusion of pre-notified studies is not subject to confidentiality rules and will be disseminated once the dossier is validated. So please consider this to be a public document in terms of personal and confidential information.

EFSA-2021-00001234

Justification ⓘ

Justification is mandatory

Add

17. When you upload a file in any section, you must select the metadata **'Document type'** from the dropdown menu. If you upload a study report, select **'Study Report'**. This will launch some additional fields (e.g. EFSA study ID, Study type, Title, authors etc.)

Used as antimicrobial agent
 Yes No

Adding a file is optional

Files	Type	status	Date
Study Report XYZ.png		Non-confidential	23/02/2021 15:05

— Metadata

Publicly Available
 Yes No

Document type * ⓘ

Select a document type

Document type is mandat

- Operating Procedure
- Other
- Owner- License Information
- Publication
- Raw Data
- Scientific Summary
- Study design
- Study Report**
- Summary report

Add document

18. Input the **Study ID** as assigned by EFSA when the study was notified. The system will present ID prompts based on the studies notified on behalf of the Applicant, if the user is recognised in ConnectEFSA. Then complete the study ID type and identifier.

Adding a file is optional

Files	Type	status	Date	
- Study Report XYZ.png	Study Report	Non-confidential	23/02/2021 15:05	...

- Metadata

Publicly Available
 Yes No

Document type [?](#)
 Study Report Clear

STUDY IDENTIFICATION

Have you received a EFSA study identification ?
 Yes No

EFSA study identification
 EFSA-2021-00001235

Study ID type
 Select a study ID type application.Value +

19. Complete the study fields, with related dates and values. These entries will be disseminated.

STUDY DETAILS [?](#)

Study type *
 Select a study type ⓘ
Study type is mandatory

Title
 XYZ study title here

Study completion date *
 Enter a study completion date ⓘ
Study completion date is mandatory

Study quality type *
 Select a study quality type ⓘ
Study quality type is mandatory

Study guidelines
 Search for a study guidelines
 OECD Guidelines
 EFSA Guidelines
 Other Guidelines

Vertebrate study
 Yes No

Add document

20. You can upload non-confidential files. By default the green badge indicates 'Non confidential'. You can also upload files in which you will make one, or multiple, requests for confidentiality. Click the three dots and select '**Request confidentiality treatment**' once each is uploaded. The badge will now indicate 'Confidential'. See [How the request confidentiality \(page 99\)](#) for more details.

Files	Type	Status	Date	
+ Non-confidential data version.png		Non-confidential	23/03/2021 0	Request confidentiality treatment
- Confidential data version.jpg		Non-confidential	06/04/2021 1	Update document
- Metadata		Confidential		Remove document and data

Publicly Available ⓘ
 Yes, IPR owned/acquired Yes, IPR NOT owned No

21. When you select from a dropdown menu '▼', type a key word and options will be presented if that word exists in the database. Here we see the free-typing option available for substance selection. But note that in some cases there is a 'closed list' of selections.

Technical Dossier Submit
 Dossier saved at 14:27:09

+ Pre-Application information ⓘ

- Identity of Substance ⓘ

- Identification of substance(s) * ⓘ

- natural

Class type
 substance organism

Name of substance
 natural ▼ Clear

Identifiers
 Genus ▼ Clear

ap applic

Natural mixture of talc and chlorite (NTMC) +

Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt

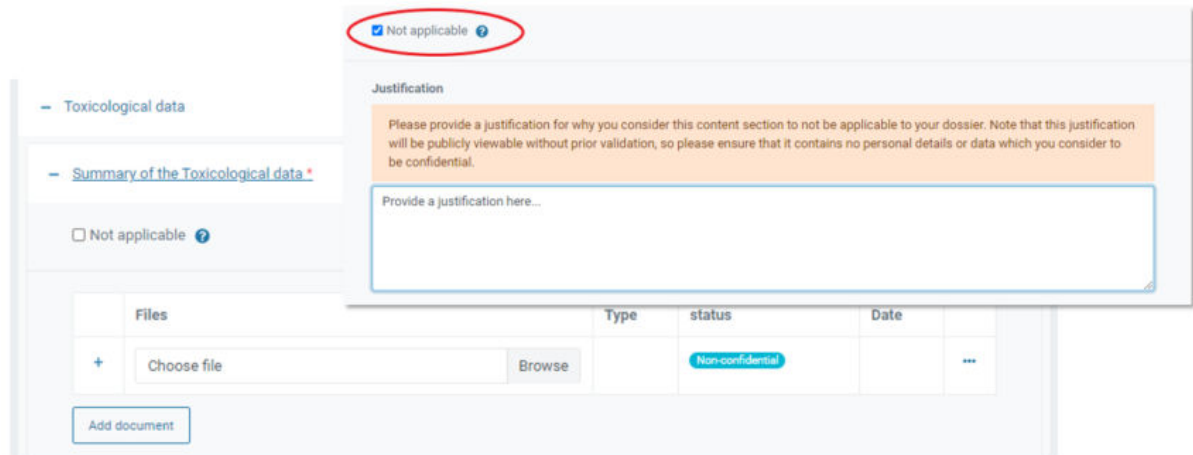
Rosemary extract liquid of natural origin

Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates

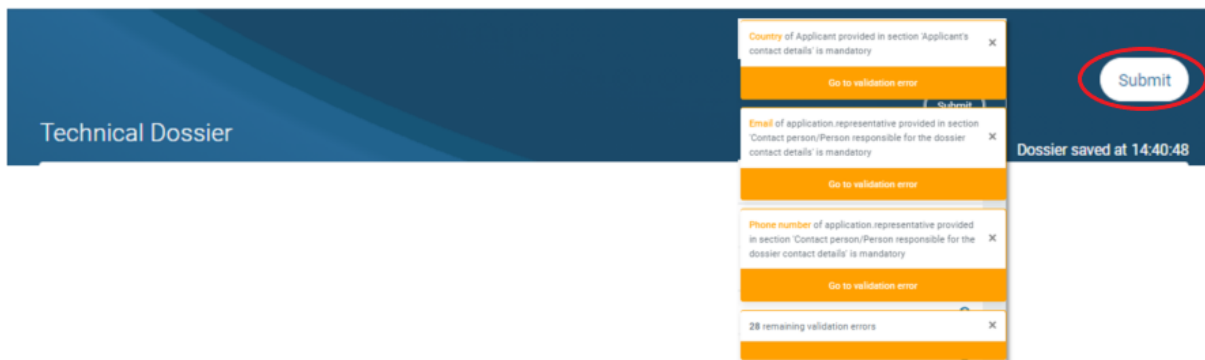
sugar, natural ⓘ

+ application.additiveOrMonomerHeading *

22. Some mandatory fields may not apply to your dossier. Click **'Not applicable'** and provide a justification.



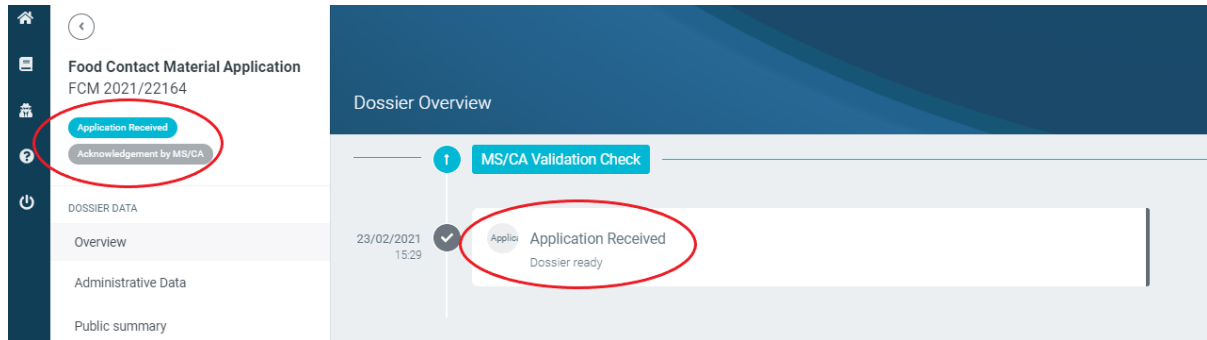
23. When all dossier sections have been completed, click **'Submit'**. If mandatory fields remain incomplete, error messages will appear. These needs to be addressed. Click on **'Go to validation error'** to arrive at each blocking section.



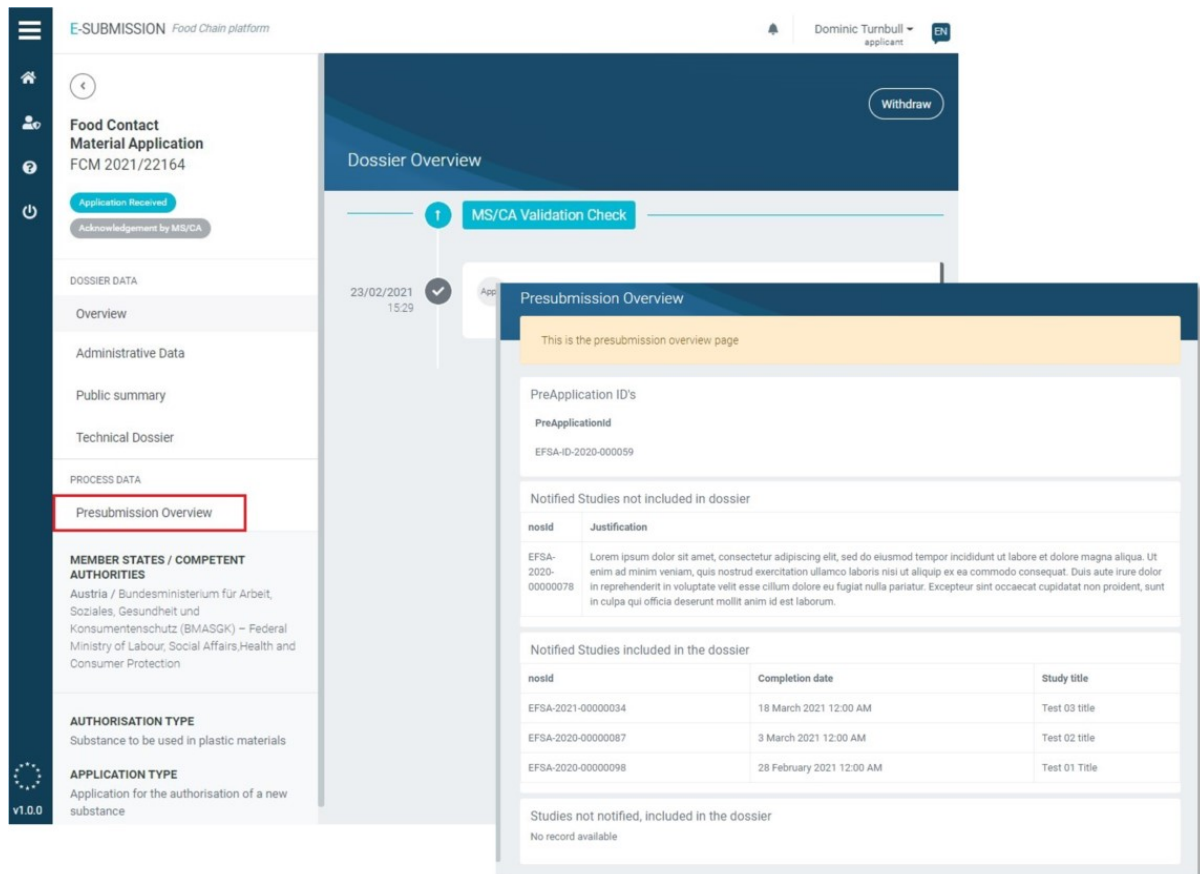
24. Click **'Submit'**, then add a final message in the box which displays. Click **'Complete action'** to send. The dossier is sent and cannot now be edited without invitation.



25. The dashboard status changes to '**Application received**'. Acknowledgement will follow, then the validation process begins. You now need to wait. For any action taken in relation to your dossier, a relevant entry will appear in your timeline. If an action is required from you, you will receive a notification.



26. A 'Pre-submission overview' tab appears, which collates on one screen the data, as input, relating to the pre-submission phase.





NOTE

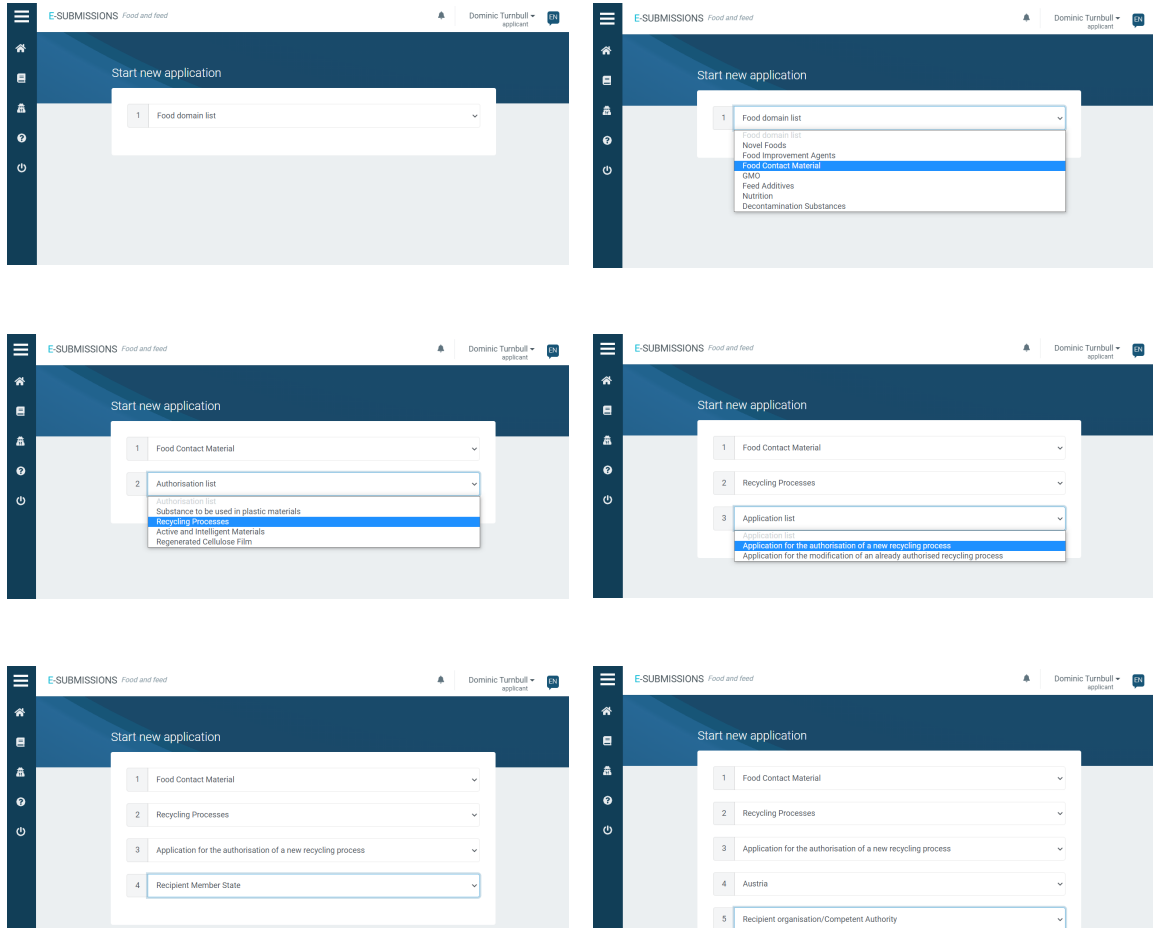
EFSA guidance: Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials.

Notes for Guidance: For the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials.

EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Recycling Processes

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose your domain type **Recycling Processes**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**.



- The Technical Dossier section is structured according to legislation and/or guidance and is unique to each domain.

The screenshot displays the 'E-SUBMISSIONS Food and feed' interface. The user is logged in as 'Dominic Turnbull applicant'. The main content area is titled 'Technical Dossier' and contains a list of sections: 'Pre-Application information', 'Identity of Process', 'Specific Information', and 'List of annexes, references and checklist'. The sidebar on the left shows the 'Technical Dossier' section highlighted with a red box. Other sections in the sidebar include 'Draft With Applicant', 'DOSSIER DATA', 'Administrative Data', 'Public summary', 'MEMBER STATES / COMPETENT AUTHORITIES' (set to Austria), and 'AUTHORISATION TYPE' (Recycling Processes). The application type is 'Application for the authorisation of a new recycling process'.



NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



NOTE

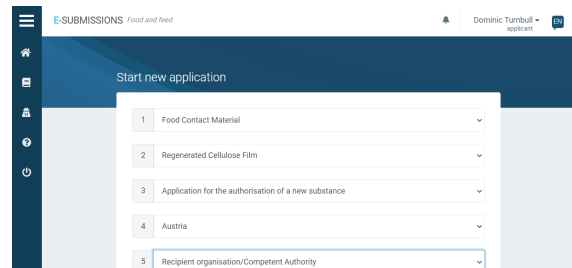
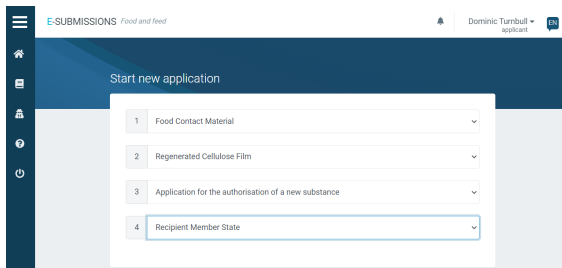
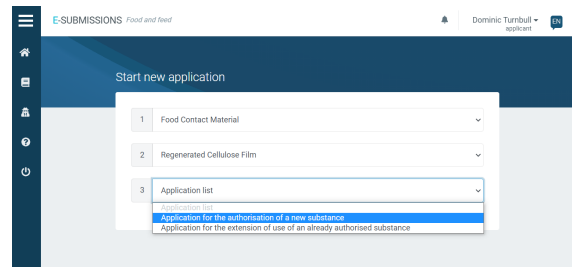
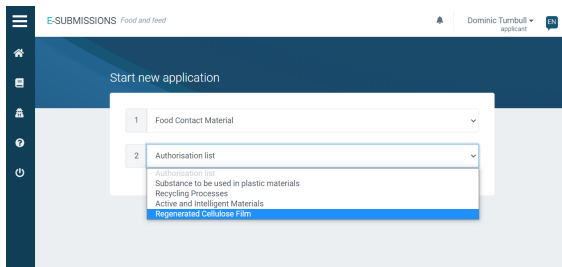
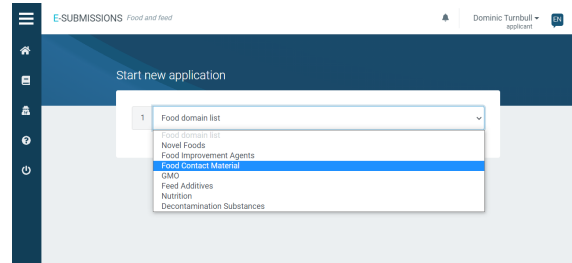
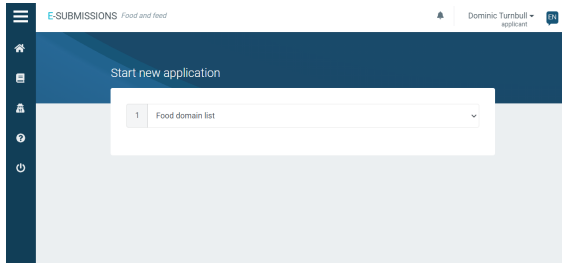
EFSA guidance: Guidelines on submission of a dossier for safety evaluation by EFSA of a recycling process to produce recycled plastics.

You can only apply for the authorisation of a complete recycling process.

EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Regenerated Cellulose Film

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose **Regenerated Cellulose Film**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**.



- The Technical Dossier section is structured according to legislation and/or guidance, and is unique to each domain.

The screenshot displays the E-SUBMISSIONS Food and feed platform interface. On the left sidebar, the 'Technical Dossier' section is highlighted with a red box. The main content area shows the 'Technical Dossier' section with three expandable items: 'Pre-Application information', 'General/Scientific Information *', and 'List of annexes, references and checklist *'. A 'Submit' button is visible in the top right corner.



NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

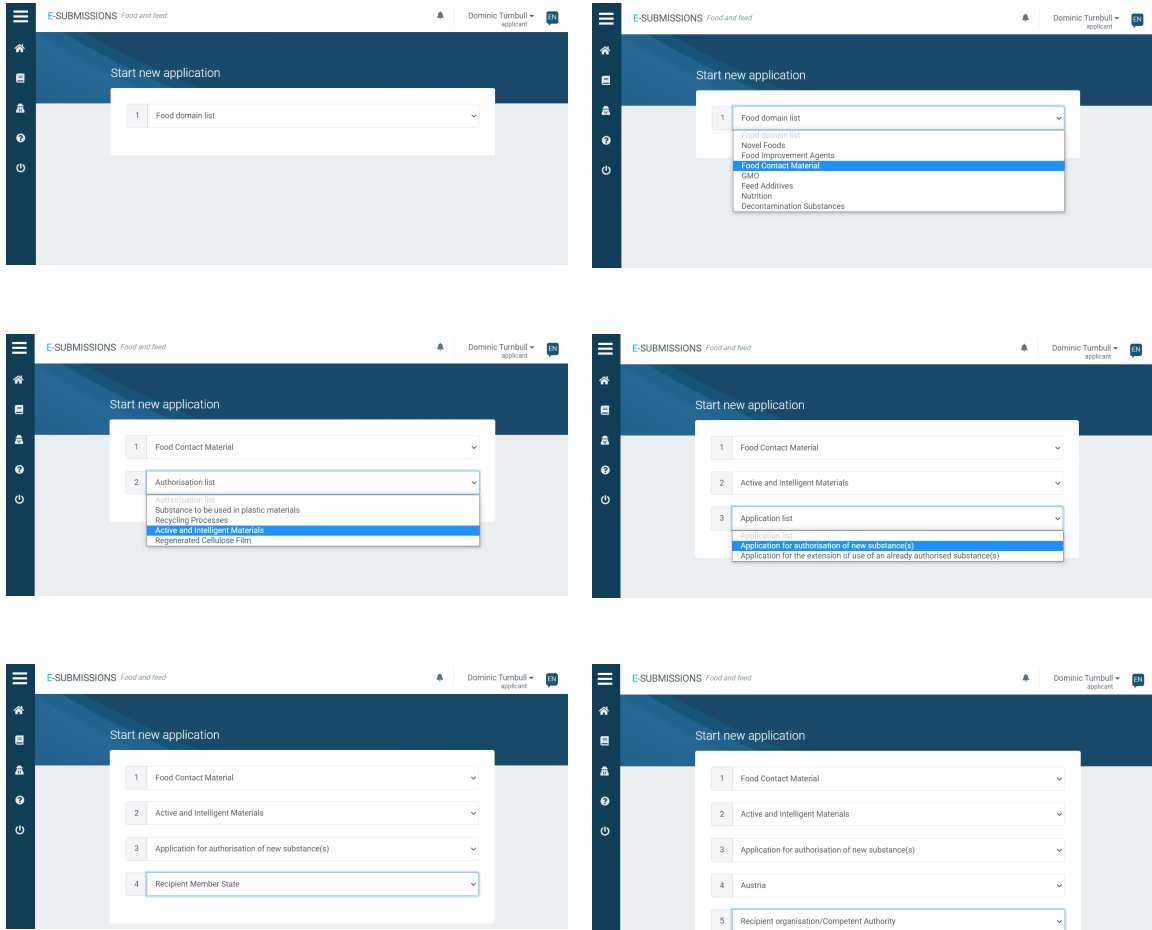


NOTE

EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Active & Intelligent material

1. Your domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose **Active & Intelligent material**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**



- The Technical Dossier section is structured according to legislation and/or guidance, and is unique to each domain.

The screenshot shows the user interface of the E-Submission Food Chain platform. On the left, a sidebar contains navigation options: Home, Back, Application details (Food Contact Material Application FCM 2021/23157), Draft status, Dossier Data (Administrative Data, Public summary, and Technical Dossier - highlighted with a red box), Member States / Competent Authorities (Austria, Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz (BMASGK) - Federal Ministry of Labour, Social Affairs, Health and Consumer Protection), Authorisation Type (Active and Intelligent Materials), and Application Type (Application for authorisation of new substance(s)). The main content area is titled 'Technical Dossier' and lists the following sections: Pre-Application information, Composition, structure and working principle of the active and intelligent material or article, Identity of the active or intelligent substance(s), Physical/chemical characteristics of the active and/or intelligent substance(s), Manufacturing process of the active or intelligent substance(s) and materials and articles, Intended use of the active and intelligent materials and articles, Migration data, Toxicological data, and List of annexes, references and checklist. A 'Submit' button is visible in the top right corner.



NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



NOTE

EFSA landing page for all **Regulations and Guidance documents**.

Food Improvement Agents

Food improvement agents are chemical substances which are used as food additives, food enzymes, flavourings, smoke flavourings and sources of vitamins and minerals added to food.

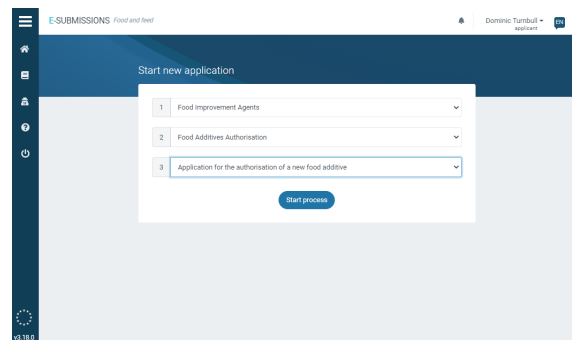
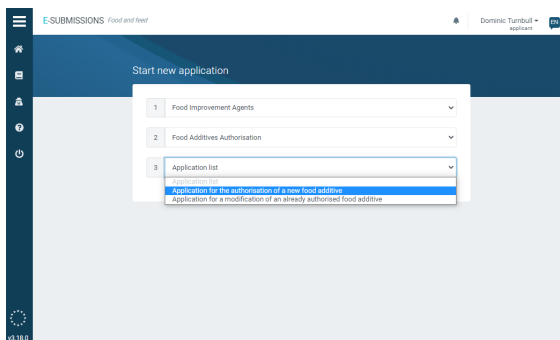
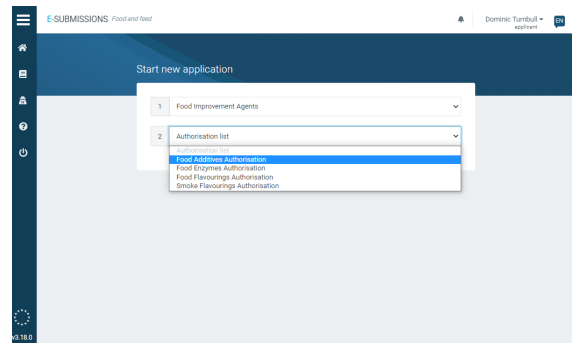
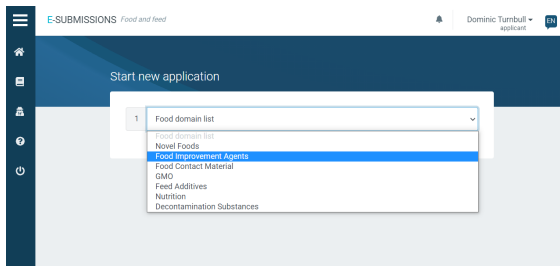
Table 3. Submission types and legislation

Authorisation type	Application type	In accordance with
Food Additives	Application for the authorisation of a new food additive	Regulation EC 1331/2008 Regulation (EU) 234/2011
	Application for the modification of an already authorised food additive	Regulation (EC) 1333/2008
Food Enzymes	Application for the authorisation of a new food enzyme	Regulation EC 1331/2008 Regulation (EU) 234/2011
	Application for the modification of an already authorised food enzyme	Regulation (EC) 1333/2008
Food Flavourings	Application for the authorisation of a new food flavouring	Directive 2001/18/EC
	Application for the modification of an already authorised food flavouring	
Smoke Flavourings	Application for the authorisation of a new smoke flavouring	Regulation (EC) No 2065/2003
	Application for the modification of an already authorised smoke flavouring	
	Application for the renewal of a smoke flavouring authorisation	

Getting started

Create a dossier: Food Additives

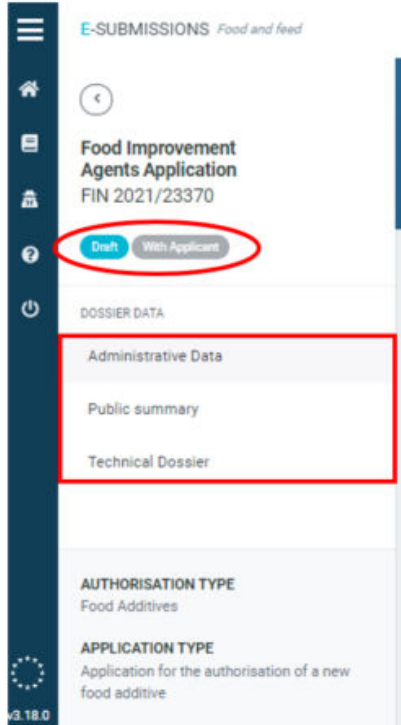
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then choose your Authorisation type. In this example we select **Food Additive**. These practical steps are common to all domains. Select the **Application type**, then press '**Start process**'..



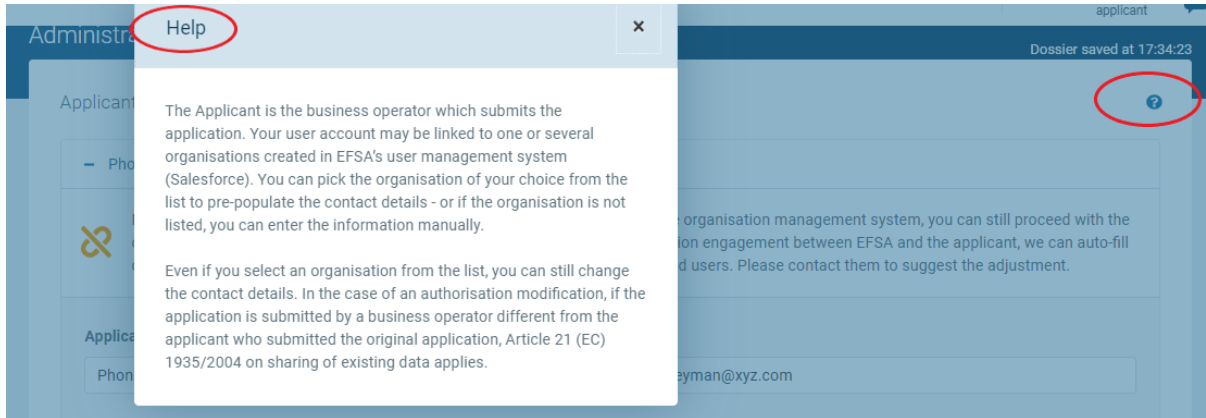
2. Complete the administrative data. Note the mandatory fields (*). If your login email is associated with one or more applicants, a list will appear using the '▼' symbol. From this you can select the appropriate Applicant. The top-left dossier number will remain throughout. The top-right notification bell indicates activity. **Note: The user recognition function is currently disabled. Applicants can still proceed, and input the information manually.**

The screenshot displays the 'Administrative Data' form in the E-Submission Food Chain platform. On the left sidebar, the dossier title 'Food Improvement Agents Application FIN 2021/23370' is circled in red. The main form area features a 'Submit' button in the top right corner. Below a disclaimer, the 'Applicant's contact details' section is visible. It includes a 'New Applicant' link and a note about user recognition. The form contains several fields: 'Applicant/Company name' (with a dropdown arrow highlighted by a red box), 'Email', 'Phone number', and 'Address'. A dropdown menu is open for the 'Applicant/Company name' field, listing 'DLW SIT 07102020-1 Applicant 1' and 'DLW SIT 07102020-1 Applicant 3'. The 'AUTHORISATION TYPE' is 'Food Additives' and the 'APPLICATION TYPE' is 'Application for the authorisation of a new food additive'.

- The column top shows the dossier status and phase. The three dossier sections remain throughout. The bottom section displays the authorisation and application type.



- Click the '?' to see contextual help for the field.



- Click on **'Copy applicant contact details'** to duplicate the Applicants' data inserted in *Step 2*, in case the person responsible is working in the same company as the Applicant. Fields can be manually overwritten.

Contact person/Person responsible for the dossier contact details *

— New responsible

Copy applicant contact details

Name of contact person / Person responsible: Peter Honeyman

Name of the entity/organisation *: application.Name of the entity/organisation

Email *: application.Email

Phone number *: application.Phone number

Website: application.Website

Address *: Address

Post code *: application.Post code

Country *: Select a country

- Enter the **'Subject of the request'**. You may consult the contextual help note '?' for additional information.

Subject of the request *

B I

- If there is authorisation history to the subject of this dossier, click **'Yes'**, then indicate the related Member State. Select the status, then browse to and upload relevant documents with supporting information.

Existing authorisations at MS level

Yes No

Austria Clear Search for a status authorisation Browse

authorisation is mandatory

Add

- Under consideration
- Withdrawn
- Authorised
- Rejected
- Expired

Existing Authorisations in non-EU countries

- Click **'Add'** to detail other Member States where the subject of the dossier has history, and upload documents as before.

Existing authorisations at MS level

Yes No

Country	Status	File Name	Actions
Austria	Authorised	Austria Auth XYZ.png	Refresh Remove
Belgium	Authorised	Belgium Auth XYZ.png	Refresh Remove
Croatia	Search for a status	authorisation	Browse Remove

Add

Existing Authorisations in non-EU countries

- If a data-sharing agreement is available, relating to the entire dossier, click the **'Yes'** radial. Click **'Add document'** for multiple agreements. Note the default 'Non-confidential' badge.

Data sharing agreement in place

Yes No

Files	Type	Status	Date	
- Data sharing Agreement for XYZ-Add.pdf		Non-confidential	24/03/2021 16:44	...

- Metadata

Publicly Available ?

Yes, IPR owned/acquired Yes, IPR NOT owned No

Document type * ?

Select a document type

- Indicate for each document whether it is **'Publicly available'**, or whether there are related IPR considerations. The default setting is **'no'**. For more information on how IPR impacts disclosure, read the chapter on **Intellectual Property Rights (page 94)**.

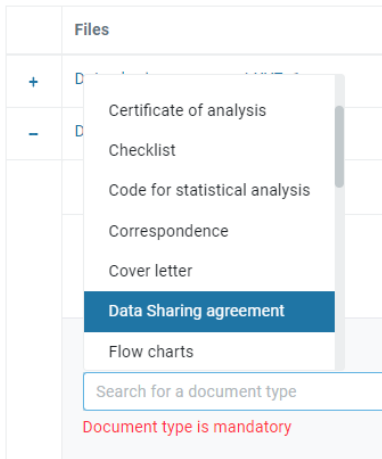
Publicly Available ?

Yes, IPR owned/acquired Yes, IPR NOT owned No ✓

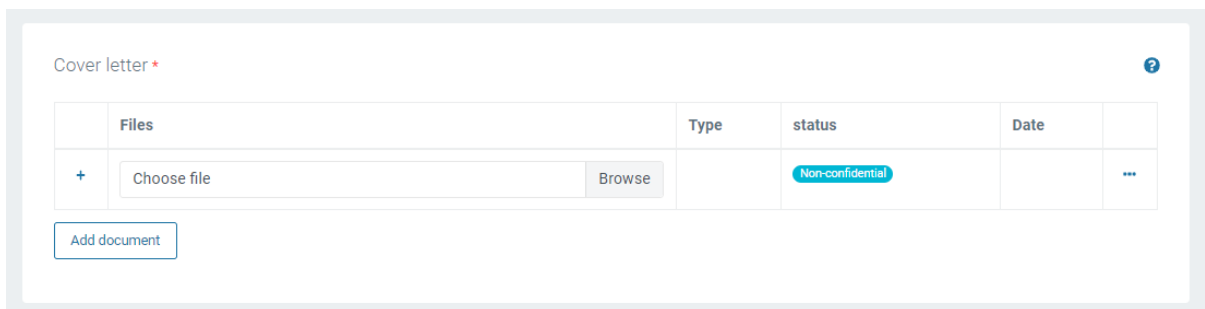
11. Now identify the the '**Document type**' via the metadata dropdown menu (see **Appendix A (page 115)**). In this instance, we select '**Data Sharing agreement**'.

Data sharing agreement in place

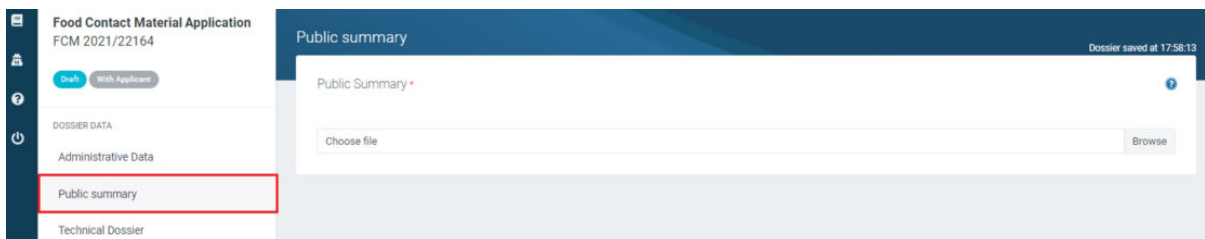
Yes No



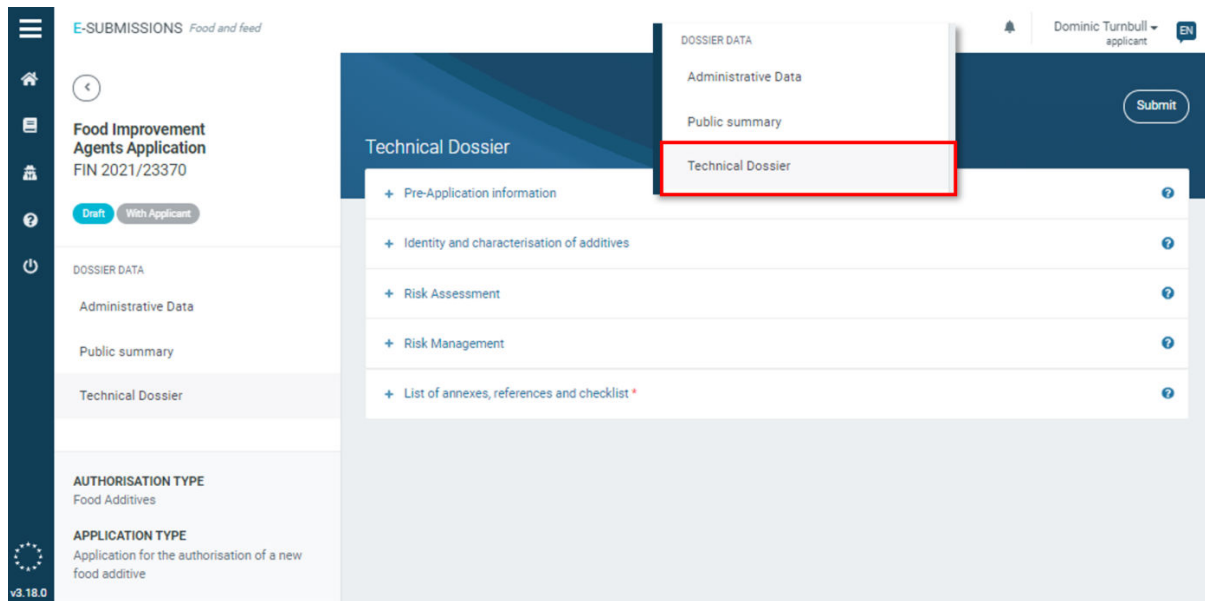
12. Upload the cover letter.



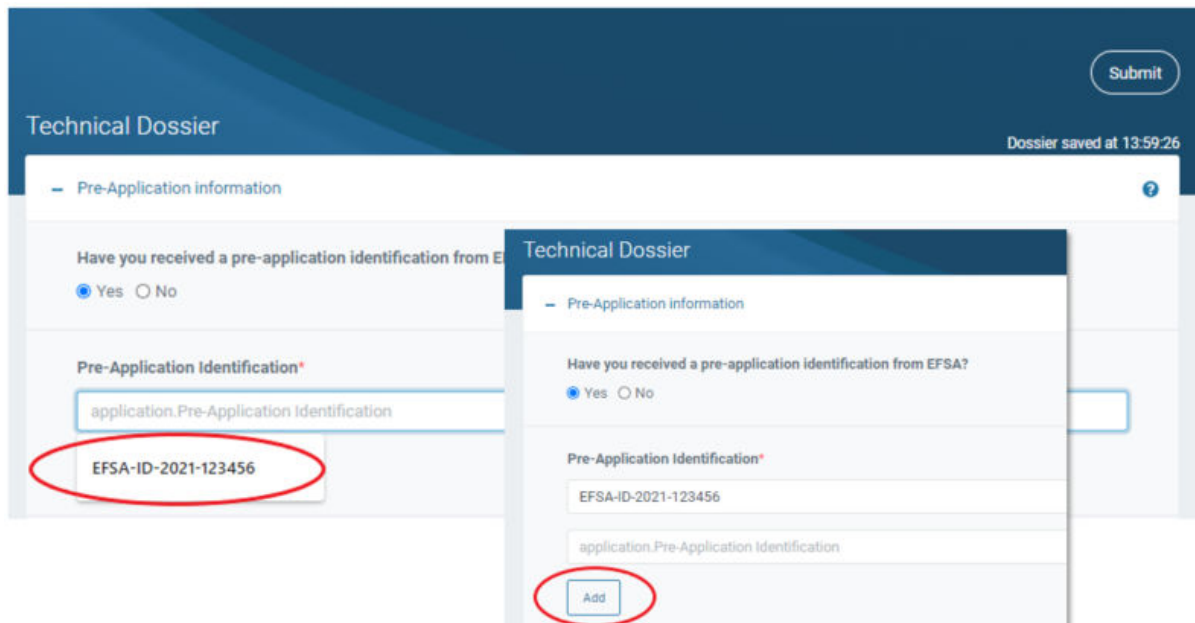
13. Click the '**Public summary**' tab, upload a public summary.



14. Click to the Technical dossier. The full table of contents reflects the sections required by legislation and outlined in EFSA guidance.



15. If you engaged with EFSA during the pre-submission phase, you would have been assigned a Pre-Application Identification number. Please input it here. Note the format. Click 'Add' to include multiple IDs.



16. If you pre-notified any study which was withdrawn or is otherwise not present within this dossier, input its Pre-Notification ID here, including a justification for why it has been omitted. Click '**Add**' if there are multiple study omissions.

If necessary, please provide the study identifications of studies that have been notified in the database of study notifications (established by EFSA) that have not been included in this application and/or have been withdrawn from the database. In addition, please provide justifications explaining the reasons why these studies were not included or withdrawn, respectively.

The justification for the non-inclusion of pre-notified studies is not subject to confidentiality rules and will be disseminated once the dossier is validated. So please consider this to be a public document in terms of personal and confidential information.

EFSA-2021-00001234

Justification ⓘ

Justification is mandatory

Add

17. When you upload a file in any section, you must select the metadata '**Document type**' from the dropdown menu. If you upload a study report, select '**Study Report**'. This will launch some additional fields (e.g. EFSA study ID, Study type, Title, authors etc.)

Used as antimicrobial agent
 Yes No

Adding a file is optional

Files	Type	status	Date
Study Report XYZ.png		Non-confidential	23/02/2021 15:05

— Metadata

Publicly Available
 Yes No

Document type * ⓘ

Select a document type

Document type is mandat

- Operating Procedure
- Other
- Owner- License Information
- Publication
- Raw Data
- Scientific Summary
- Study design
- Study Report**
- Summary report

Add document

18. Input the Study ID assigned by EFSA when the study was notified. The system will present ID prompts based on the studies notified on behalf of the Applicant, if the user is recognised in ConnectEFSA. Then complete the study ID type and identifier

Adding a file is optional

Files	Type	status	Date	
- Study Report XYZ.png	Study Report	Non-confidential	23/02/2021 15:05	...

- Metadata

Publicly Available
 Yes No

Document type [?](#)
 Study Report Clear

STUDY IDENTIFICATION

Have you received a EFSA study identification ?
 Yes No

EFSA study identification
 EFSA-2021-00001235

Study ID type
 Select a study ID type application.Value +

19. Complete the study fields, with related dates and values. Note that these entries will be published.

STUDY DETAILS [?](#)

Study type *
 Select a study type ⓘ
Study type is mandatory

Title
 XYZ study title here

Study completion date *
 Enter a study completion date ⓘ
Study completion date is mandatory

Study quality type *
 Select a study quality type ⓘ
Study quality type is mandatory

Study guidelines
 Search for a study guidelines
 OECD Guidelines
 EFSA Guidelines
 Other Guidelines

Vertebrate study
 Yes No

Add document

20. You can upload non-confidential files. By default the green badge indicates 'Non confidential'. You can also upload files in which you will make one, or multiple, requests for confidentiality. Click the three dots and select '**Request confidentiality treatment**' once each is uploaded. The badge will now indicate 'Confidential'. See [How the request confidentiality \(page 99\)](#) for more details.

Files	Type	Status	Date	
+ Non-confidential data version.png		Non-confidential	23/03/2021 0	Request confidentiality treatment
- Confidential data version.jpg		Non-confidential	06/04/2021 1	Update document
- Metadata		Confidential		Remove document and data

Publicly Available ?

Yes, IRP owned/acquired Yes, IPR NOT owned No

21. When you select from the dropdown menu '▼', type a key word and options will be presented if that word exists in the database. Here we see the free-typing option available for substance selection. But note that in some cases there is a 'closed list' of selections.

Technical Dossier Dossier saved at 14:27:09

Submit

+ Pre-Application information ?

- Identity of Substance ?

- Identification of substance(s) *

- natural

Class type
 substance organism

Name of substance
 natural Clear

Identifiers
 Genus Clear

Natural mixture of talc and chlorite (NTMC) +

Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt

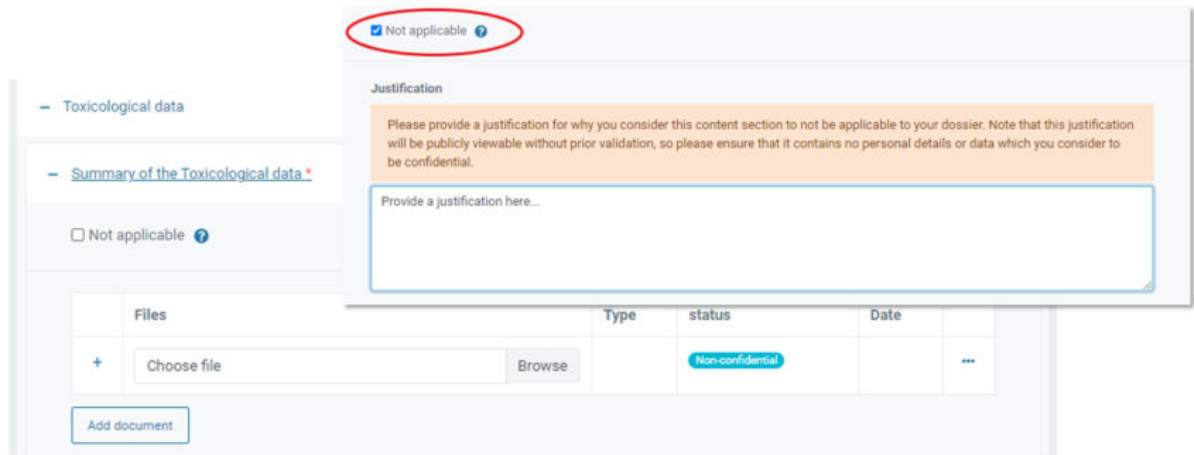
Rosemary extract liquid of natural origin

Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates

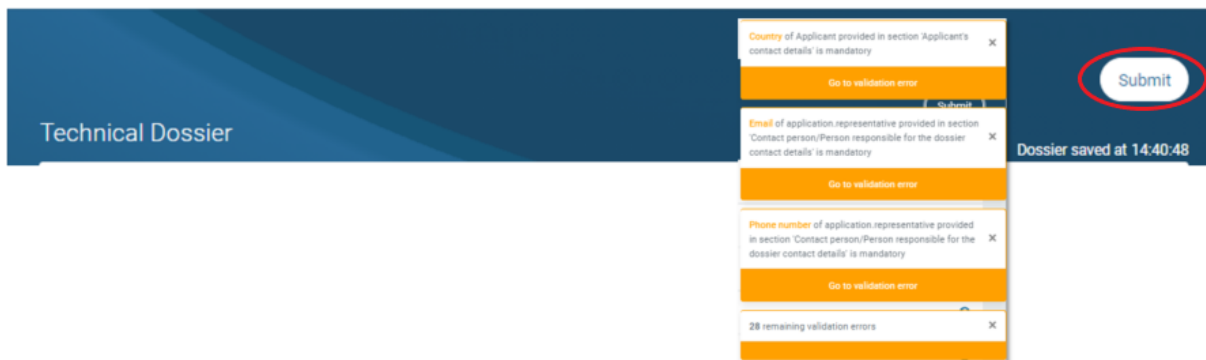
sugar, natural

+ application.additiveOrMonomerHeading *

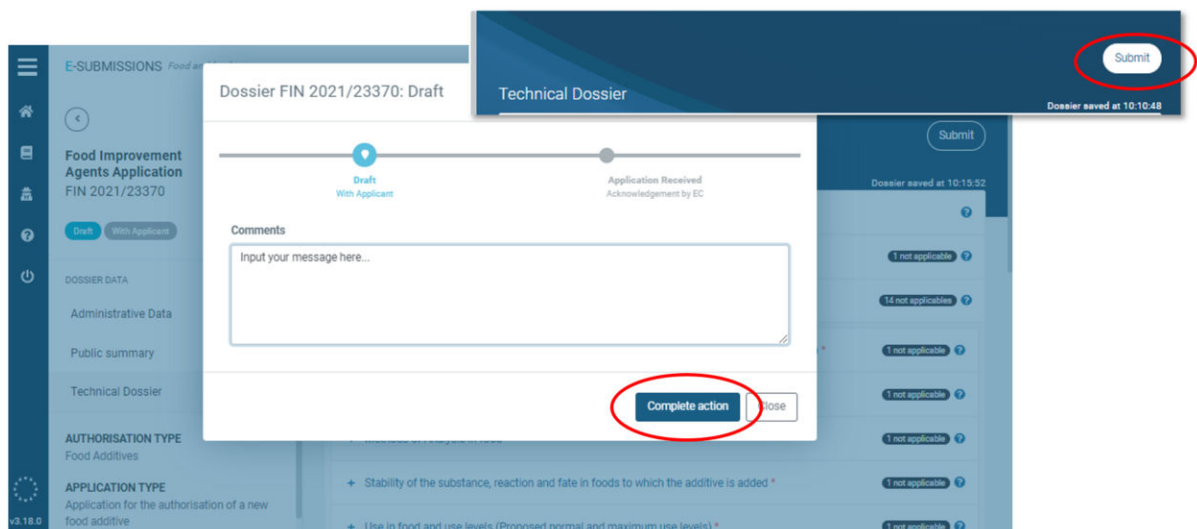
22. Some mandatory fields may not apply to your dossier. Click **'Not applicable'** and provide a justification.



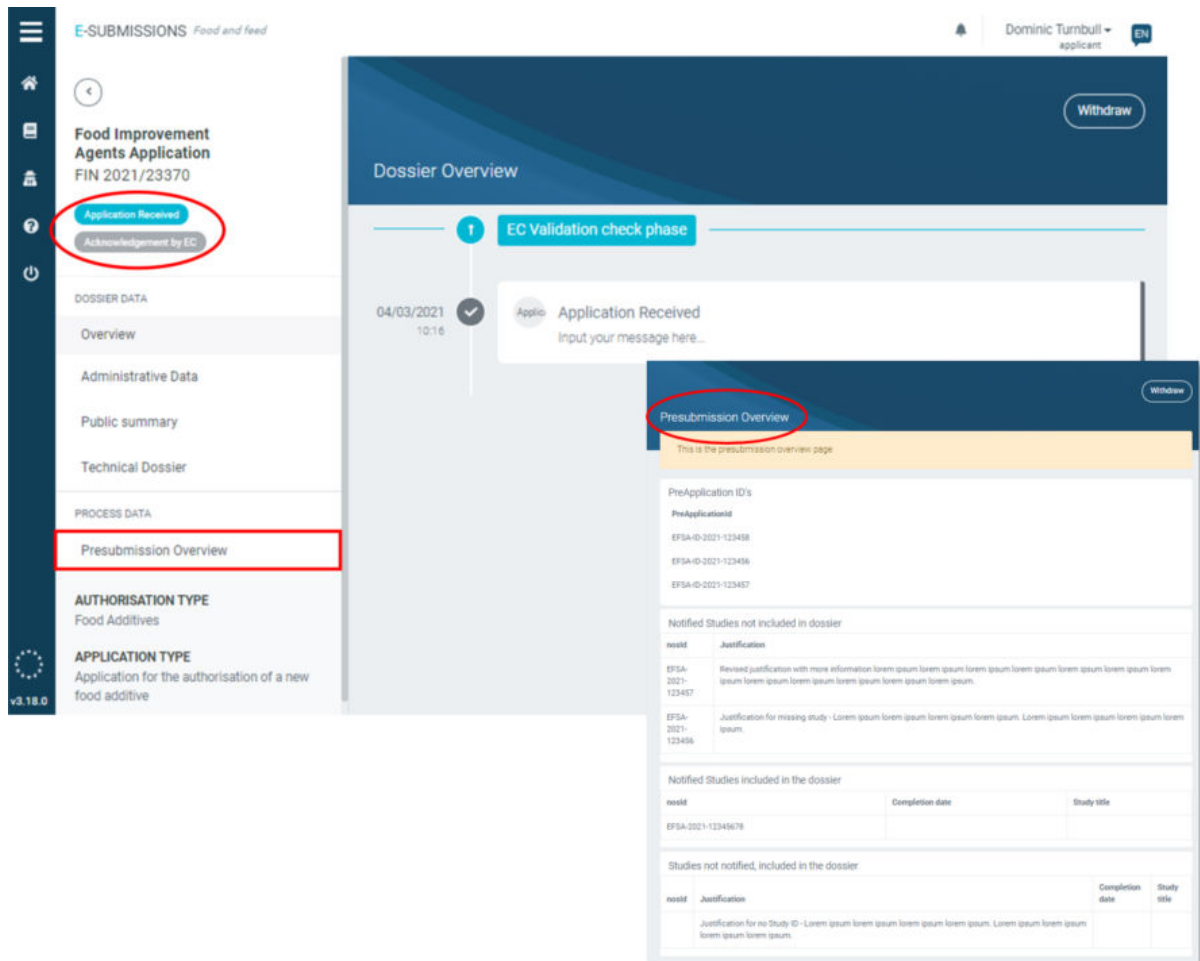
23. When all dossier sections have been completed, click **'Submit'**. If mandatory fields remain incomplete, error messages will appear. These need to be addressed. Click on **'Go to validation error'** to arrive at the blocking section.



24. Click **'Submit'** and input a final message into the box which displays. Click **'Complete action'** to send. The dossier is sent and cannot now be edited without invitation.



25. The dashboard status changes to '**Application received**'. Acknowledgement will follow, then the validation process begins. A 'Pre-submission overview' tab appears, which collates on one screen the data, as input, relating to the pre-submission phase. You now need to wait. For any action taken in relation to your dossier, a relevant entry will appear in your timeline. If an action is required from you, you will receive a notification.



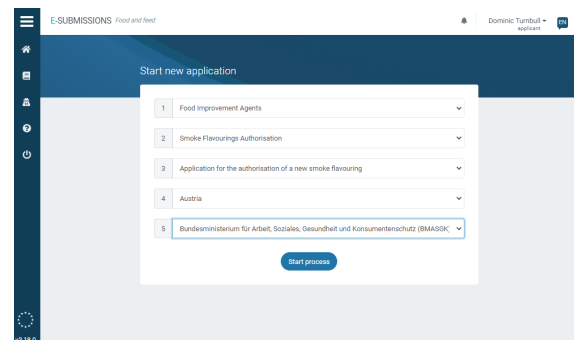
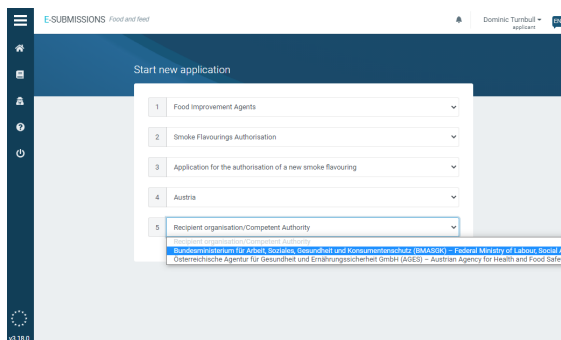
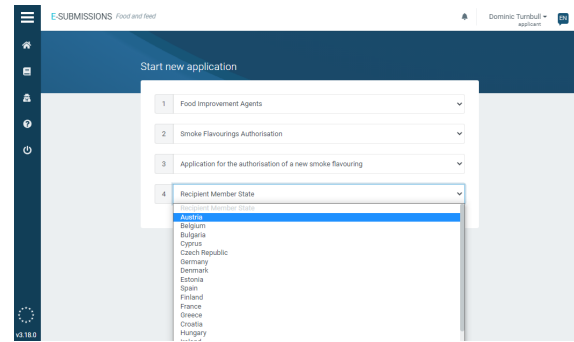
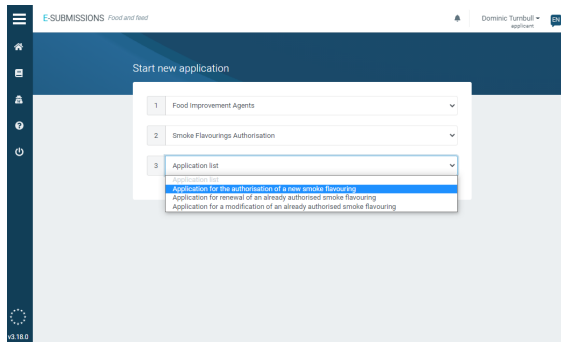
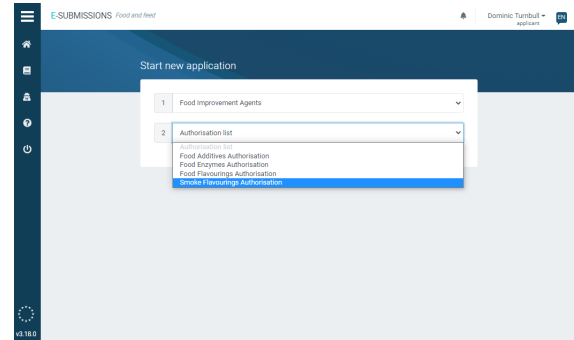
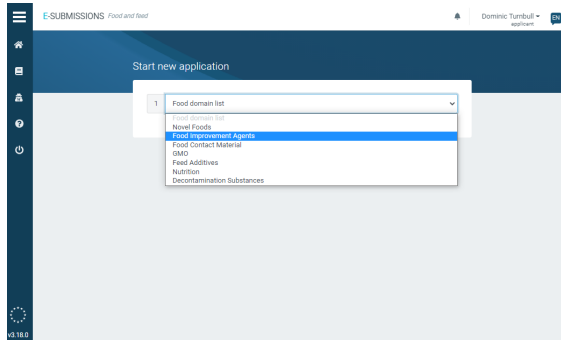
NOTE

EFSA guidance: Guidance on submission for food additive evaluations

EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Smoke Flavourings

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then choose your domain type **Smoke Flavourings**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**, and then click 'Start process'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.

The screenshot shows the E-SUBMISSIONS Food and feed platform interface. The left sidebar contains navigation icons and a list of sections: Home, Drafts, Dossier Data, Administrative Data, Public summary, **Technical Dossier** (highlighted with a red box), Member States / Competent Authorities, and Authorisation Type. The main content area displays the 'Technical Dossier' section with a list of sub-sections: Pre-Application information, Characterisation of the smoke flavouring primary product, Proposed uses and exposure assessment, Safety data, Risk Management, and List of annexes, references and checklist. A 'Submit' button is visible in the top right corner.



NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



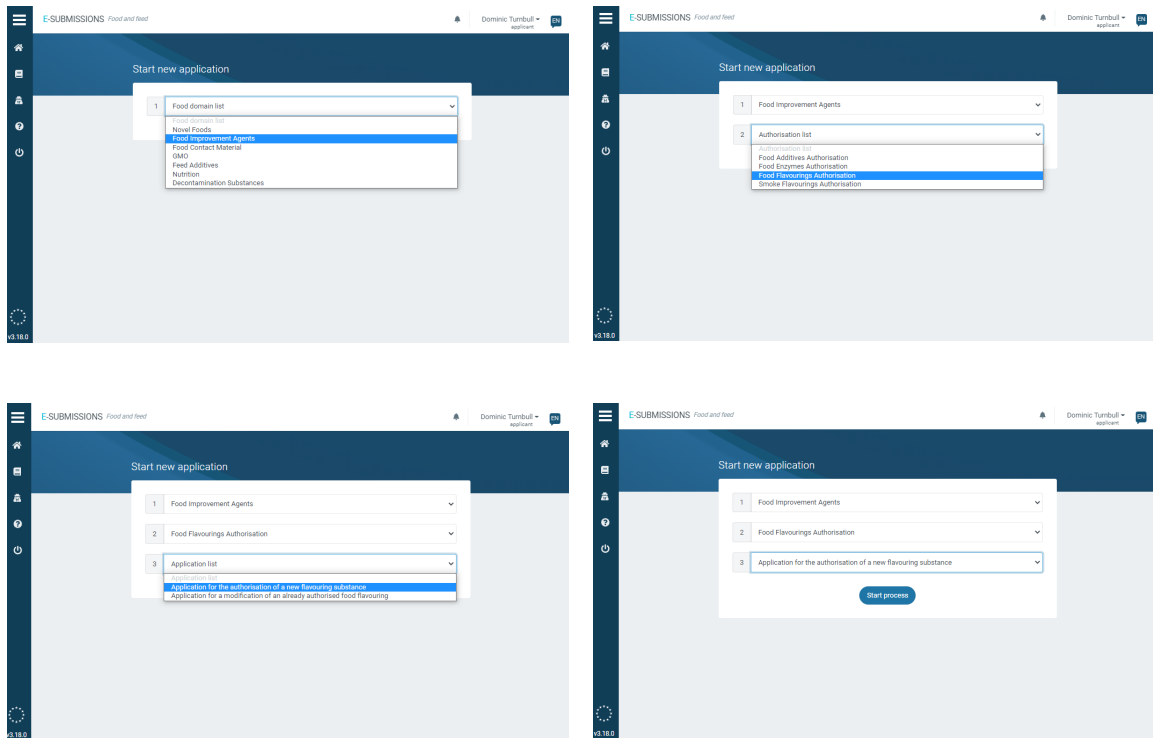
NOTE

EFSA guidance: Guidance on submission of a dossier on a Smoke Flavouring Primary Product for evaluation by EFSA.

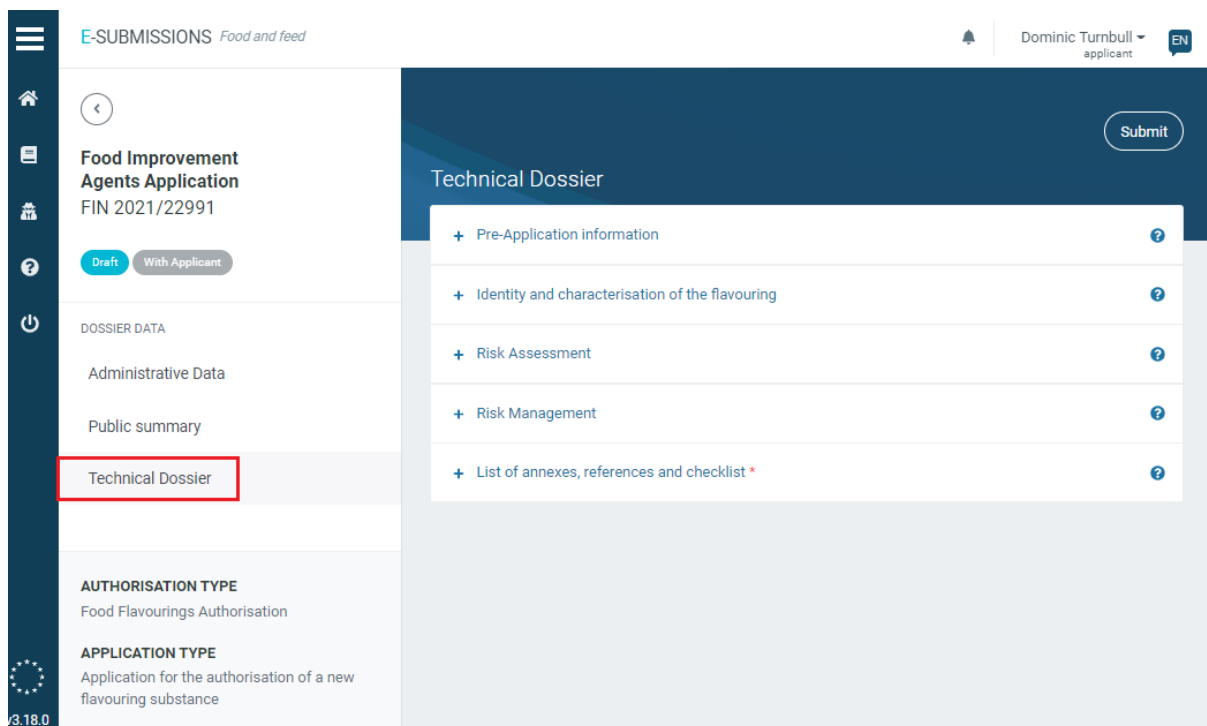
EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Food Flavourings

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then click '**Food Flavourings**' from the Authorisation list. Select the **Application type**, and click '**Start process**'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives** (page 34) submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



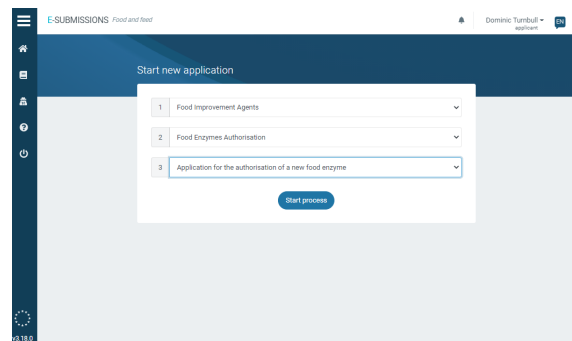
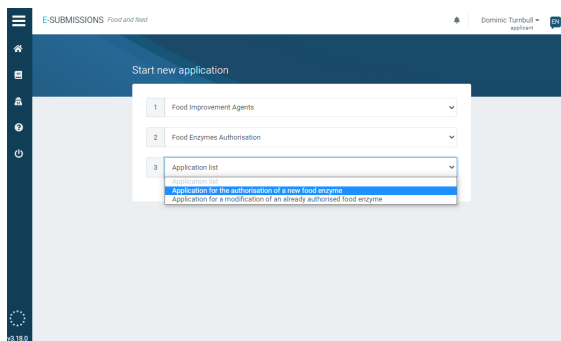
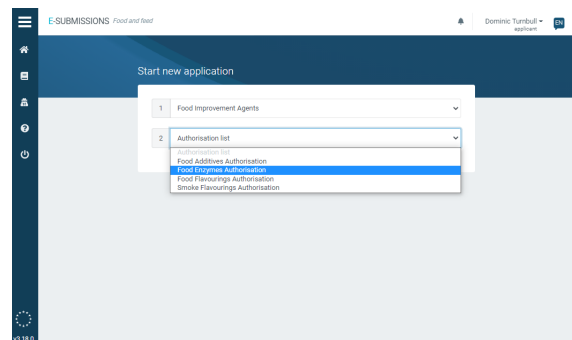
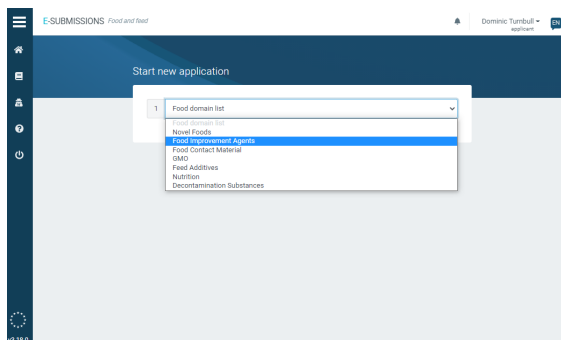
NOTE

EFSA guidance: **Guidance on the data required for the risk assessment of flavourings to be used in or on food**

EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Food Enzymes

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then click '**Food Enzymes**' from the Authorisation list. Select the **Application type**, and click '**Start process**'.



- The Technical Dossier section is structured according to legislation and unique to each domain.

The screenshot displays the E-SUBMISSIONS platform interface. The top navigation bar includes the text 'E-SUBMISSIONS Food and feed', a notification bell, the user name 'Dominic Turnbull applicant', and a language selector 'EN'. A 'Submit' button is visible in the top right corner. The main content area is titled 'Technical Dossier' and contains a list of sections: 'Pre-Application information', 'Identity and characterisation of the enzyme', 'Risk Assessment', 'Risk Management', and 'List of annexes, references and checklist *'. Each section has a plus sign and a question mark icon. On the left side, there is a sidebar with a menu icon, a home icon, and a list of application details: 'Food Improvement Agents Application', 'FIN 2021/22986', 'Draft With Applicant', 'DOSSIER DATA', 'Administrative Data', 'Public summary', and 'Technical Dossier' (which is highlighted with a red box). Below this, there are sections for 'AUTHORISATION TYPE' (Food Enzymes Authorisation) and 'APPLICATION TYPE' (Application for the authorisation of a new food enzyme). The version number 'v3.18.0' is shown at the bottom left.



NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



NOTE

EFSA guidance: Guidance on the submission of a dossier on food enzymes for risk assessment.

EFSA landing page for all **Regulations and Guidance documents.**

Feed Additives

Feed additives are products used in animal nutrition for purposes of improving the quality of feed and the quality of food from animal origin, or to improve the animals' performance and health, e.g. providing enhanced digestibility of the feed materials. Feed additives may not be put on the market unless authorisation has been given following a scientific evaluation demonstrating that the additive has no harmful effects, on human and animal health and on the environment.

Table 4. Submission types and legislation

Authorisation type	Application type	In accordance with
Feed Additives	Application for the authorisation of a new feed additive or a new use of a feed additive	Article 4.1 (EC) 1831/2003
	Application for the modification of an already authorised feed additive	Article 13.3 (EC) 1831/2003
	Application for the renewal of a feed additive authorisation	Article 14 (EC) 1831/2003
	Application for urgent authorisation of a feed additive	Article 15 (EC) 1831/2003



NOTE

EFSA guidance: **Administrative guidance to applicants on the preparation and presentation of applications for authorization of additives for use in animal nutrition.**

EFSA landing page for all **Regulations and Guidance documents.**



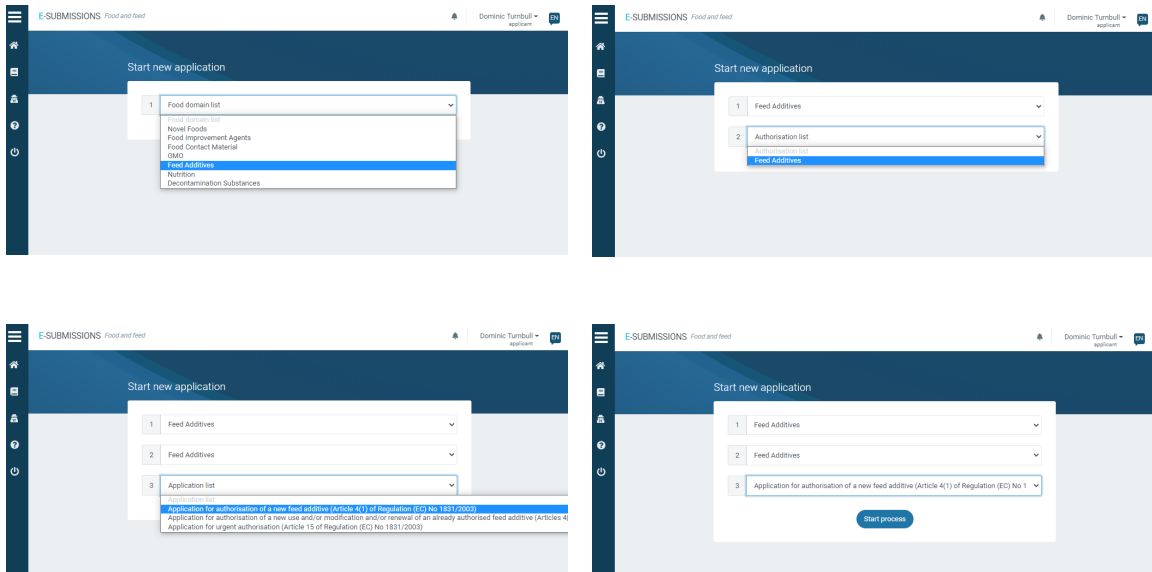
NOTE

The **European Union Reference Laboratory for Feed Additives** has prepared **practical guidance** for applicants regarding their analytical approach and sample-testing fee. See Commission Regulation (EC) 429/2008.

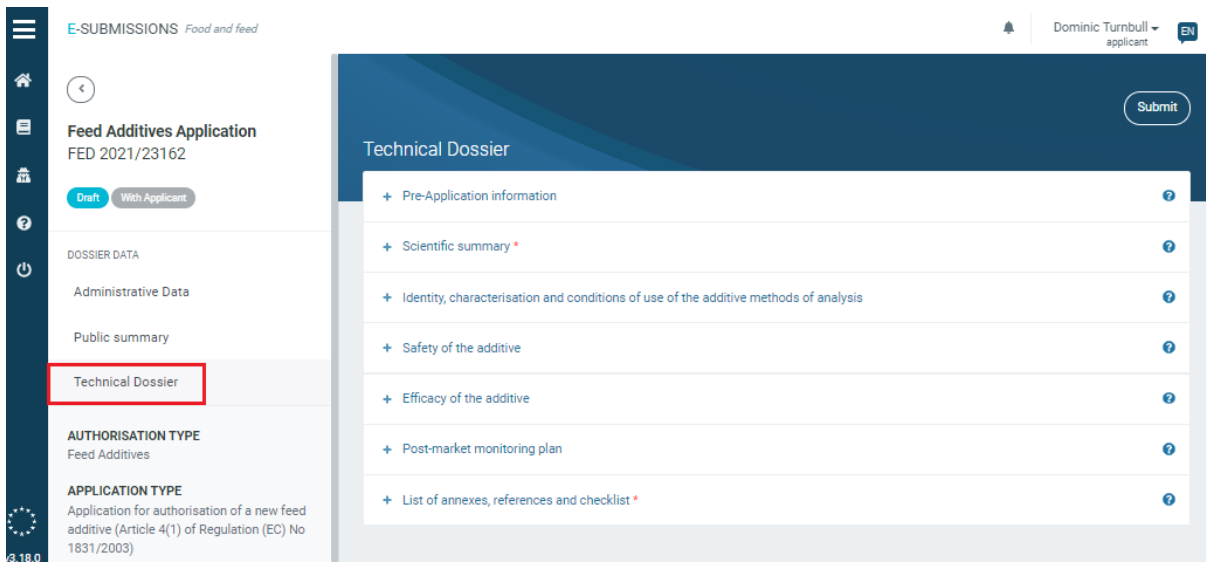
Getting started

Create a dossier: Feed Additives

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Feed Additives** from the Food domain list. Then click '**Feed Additives**' from the Authorisation list. Select the **Application type**, and click '**Start process**'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

Decontamination Substances

In the field of decontamination substances, EFSA evaluates applications for decontamination substances other than potable water.



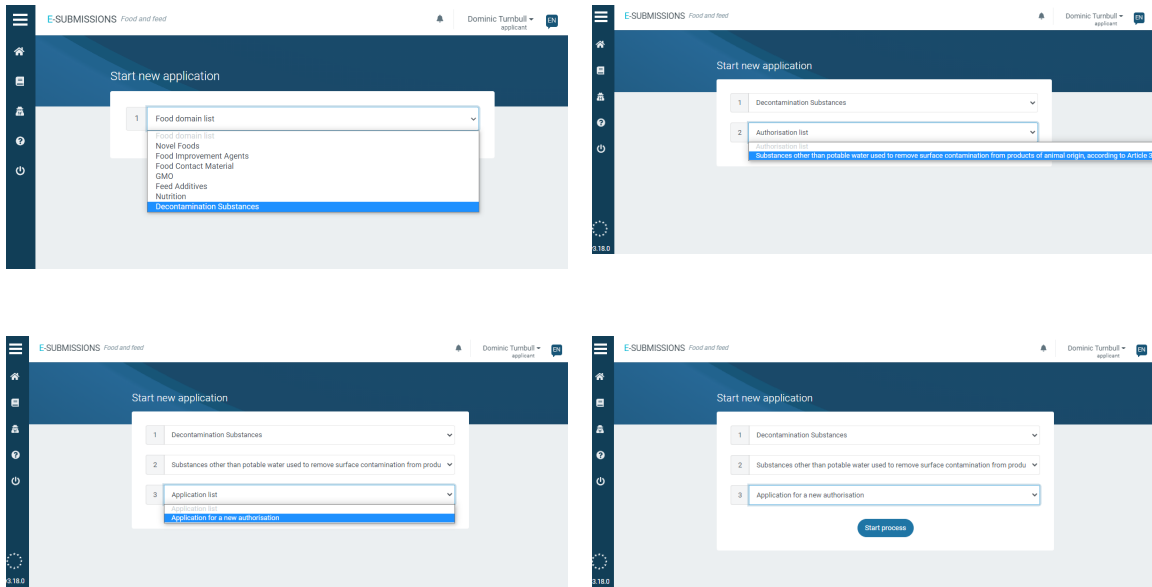
NOTE

See EFSA's overview: [Biological hazard applications: overview and procedure](#)

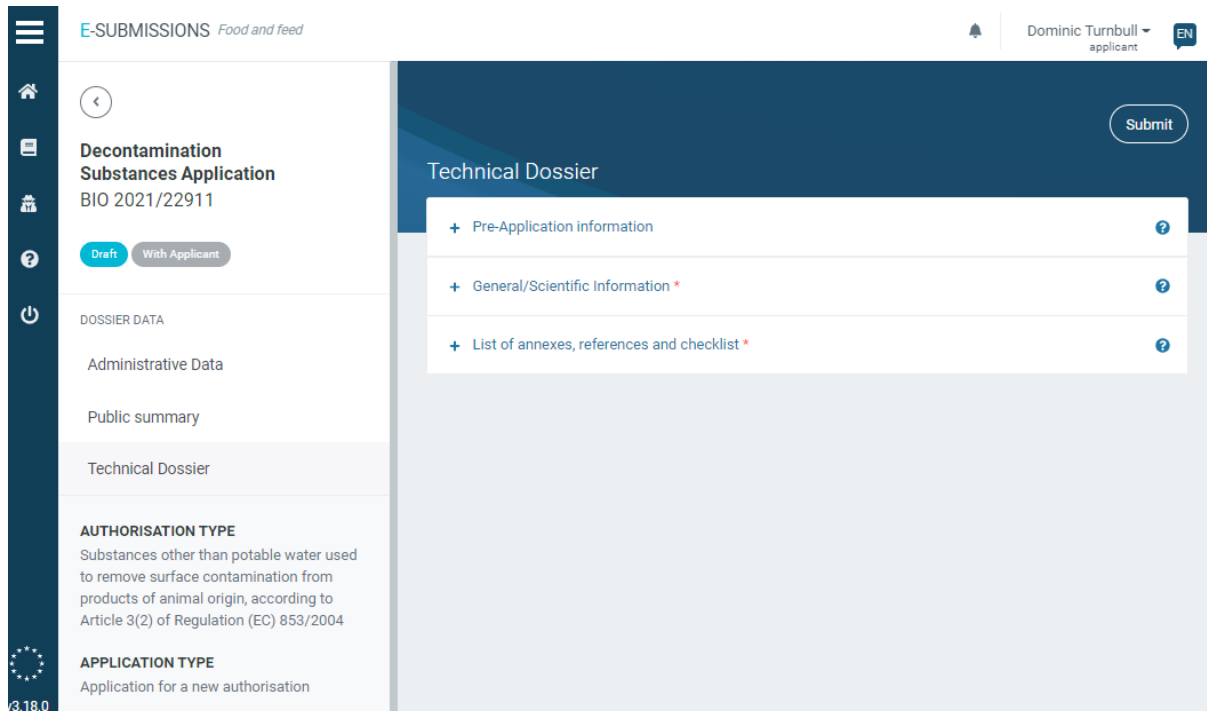
Getting started

Create a dossier: Decontamination Substances

1. According to EFSA guidance and EC regulation, the distinct domain template will be generated via the following steps. Select **Decontamination Substances** from the Food domain list. Then choose the **Application type**.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

Nutrition

EFSA assesses the scientific evidence of health claims applications submitted for an authorisation in the EU. Applications are submitted to Member States [competent authorities] via the e-submission platform.

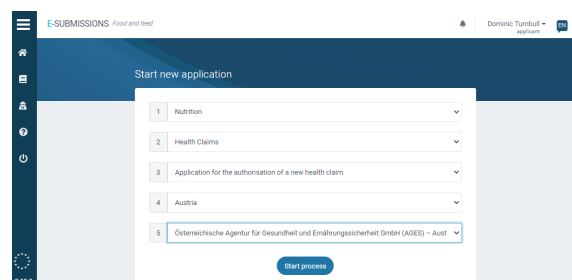
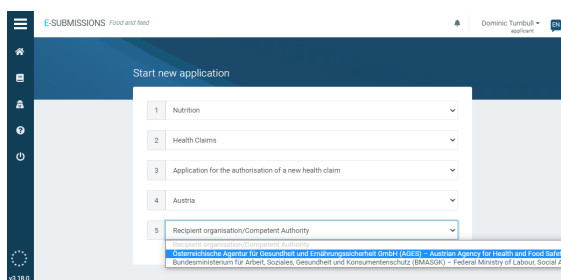
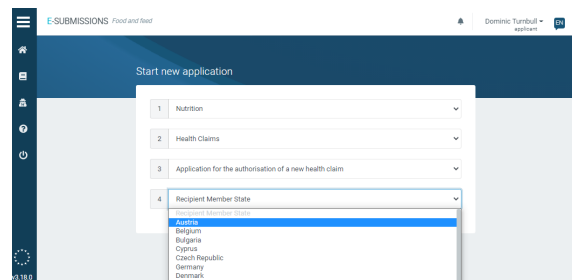
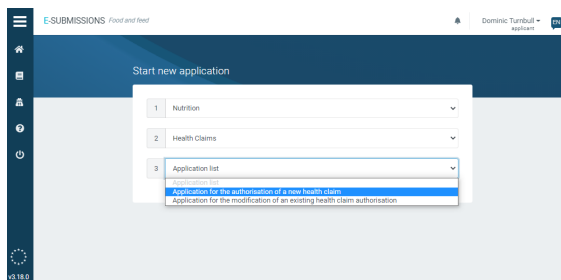
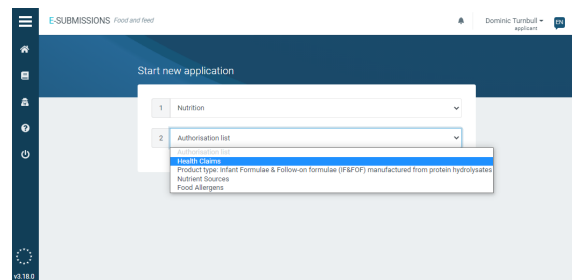
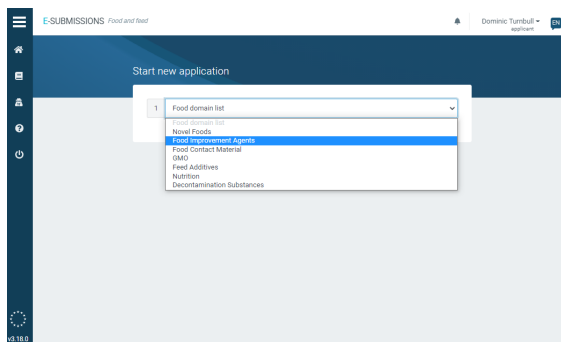
Table 5. Submission types and legislation

Authorisation type	Application type	In accordance with
Health Claims	Application for the authorisation of a new health claim Application for the modification of an existing health claim authorisation	Regulation EC 1924/2006
Infant Formulae & Follow-on formulae (IF&FOF) manufactured from protein hydrolysates	Request for the scientific assessment of an IF and/or a FOF manufactured from protein hydrolysate with a view to amend Regulation (EU) 2016/127	Directive 2006/141/EC Regulation EU 609/2013 Regulation EU 2016/127
Food Allergens	Application/Request for the exception of labelling for a food allergen	Regulation (EU) 1169/2011
Nutrient Sources	Application for the authorisation of new nutrient sources	Regulation EC 1925/2006 Directive 2002/46/EC

Getting started

Create a dossier: Health Claims

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then choose your domain type **Health Claims**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**, and then click '**Start process**'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.



NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



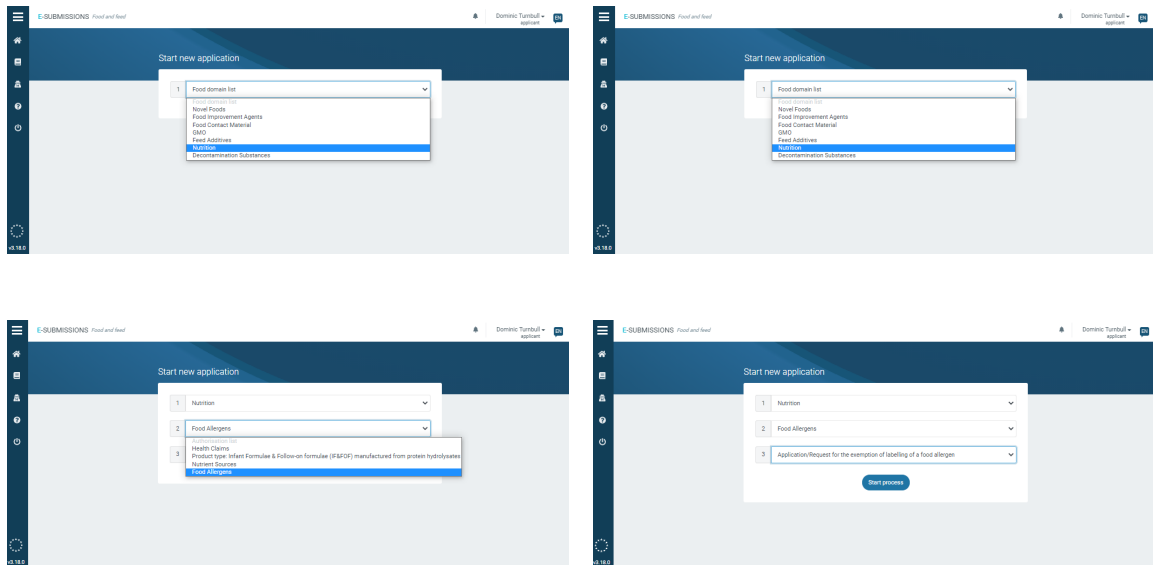
NOTE

EFSA guidance: Scientific and technical guidance for the preparation and presentation of a health claim application.

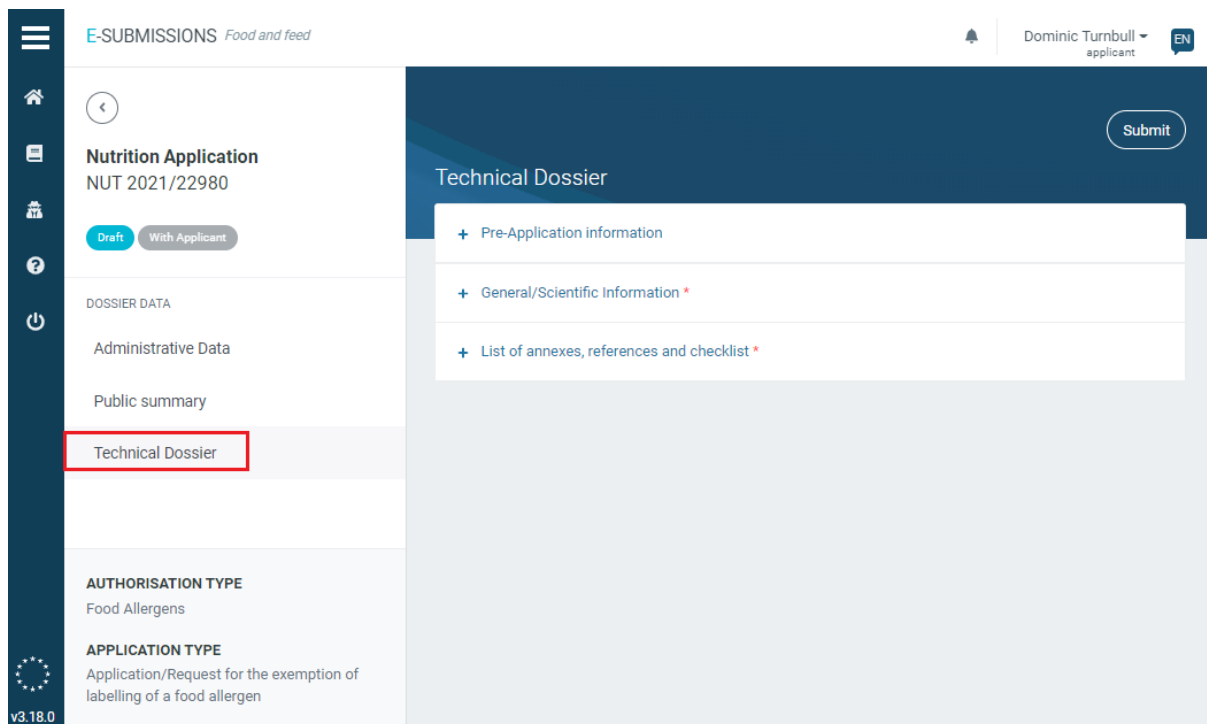
EFSA landing page for all **Regulations and Guidance documents**.

Create a dossier: Food Allergens

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Nutrition** from the Food domain list. Then choose your Authorisation type **Food Allergens** and the **Application type**, then press '**Start process**'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



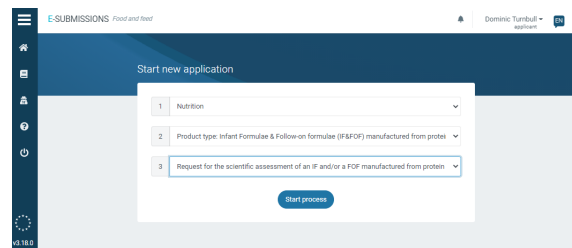
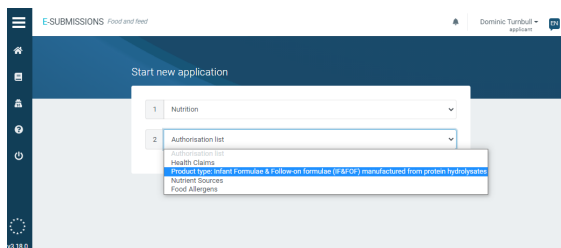
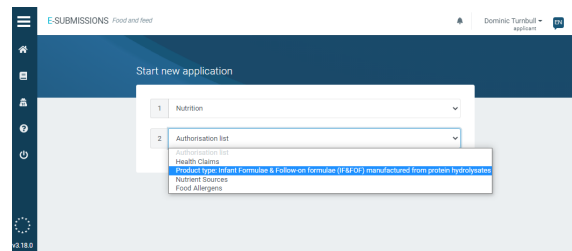
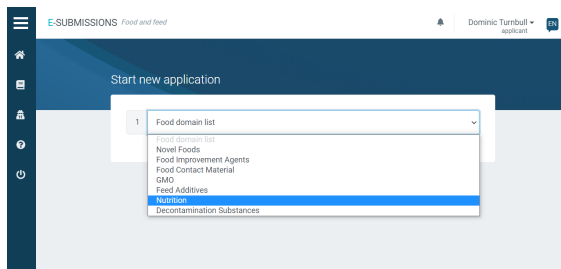
NOTE

EFSA guidance: Guidance on the preparation and presentation of applications pursuant to Article 21 Paragraph 2 of Regulation (EU) No 1169/2011.

[EFSA landing page for all Regulations and Guidance documents.](#)

Create a dossier: Infant Formulae & Follow-on Formulae

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Nutrition** from the Food domain list. Then choose your Authorisation type **Infant Formulae & Follow-on Formulae** and the **Application type**, then press 'Start process'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.

The screenshot displays the E-SUBMISSIONS Food and feed platform interface. The top navigation bar includes a hamburger menu, the text 'E-SUBMISSIONS Food and feed', a notification bell, the user name 'Dominic Turnbull applicant', and a language selector 'EN'. The main content area is divided into a left sidebar and a main panel. The sidebar contains a navigation menu with icons for home, documents, users, help, and power. The 'Technical Dossier' menu item is highlighted with a red box. Below the menu, the 'AUTHORISATION TYPE' is 'Product type: Infant Formulae & Follow-on formulae (IF&FOF) manufactured from protein hydrolysates' and the 'APPLICATION TYPE' is 'Request for the scientific assessment of an IF and/or a FOF manufactured from protein hydrolysate with a view to amend Regulation (EU) 2016/127'. The main panel shows the 'Technical Dossier' section with three expandable items: '+ Pre-Application Information', '+ General/Scientific Information *', and '+ List of annexes, references and checklist *'. A 'Submit' button is located in the top right corner of the main panel.



NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



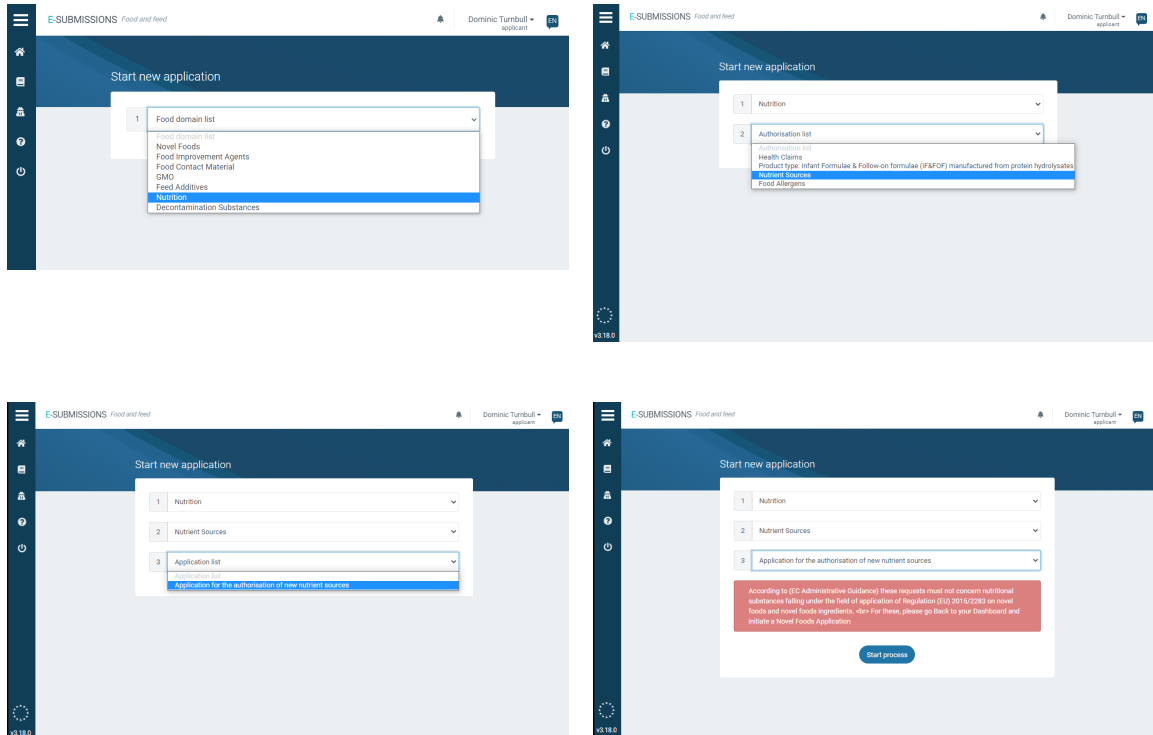
NOTE

EFSA guidance: **Guidance on the preparation and presentation of applications pursuant to Article 21 Paragraph 2 of Regulation (EU) No 1169/2011.**

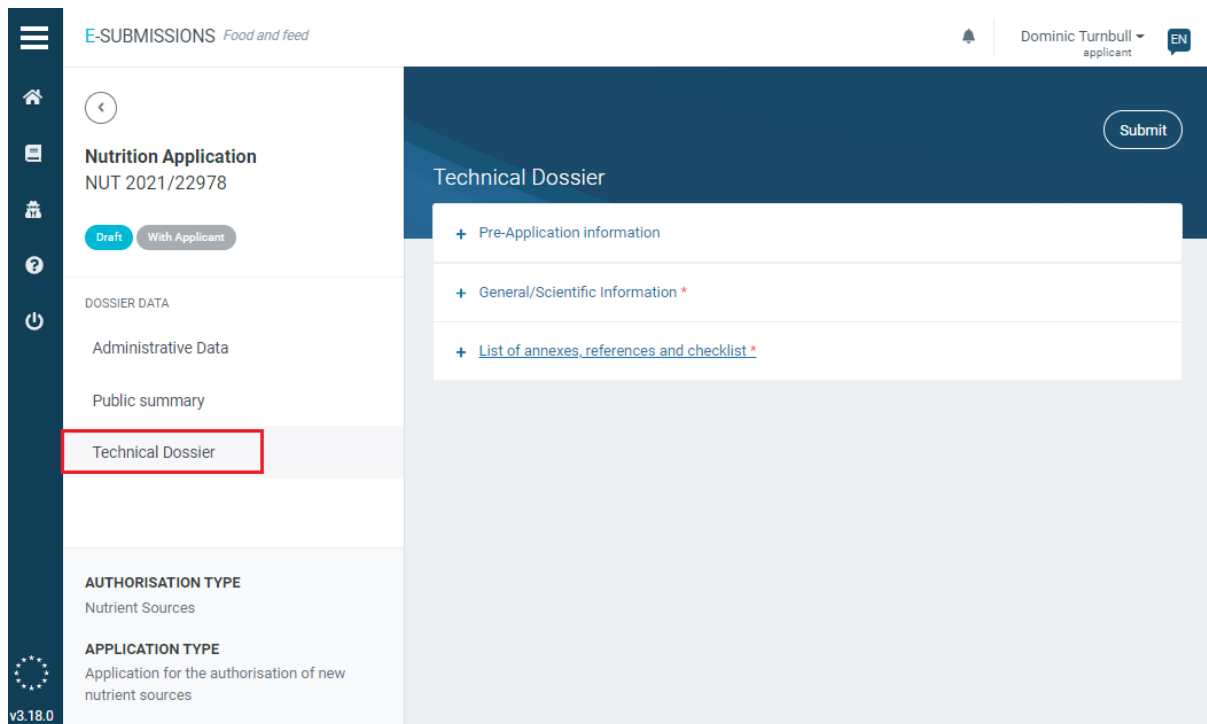
EFSA landing page for all **Regulations and Guidance documents.**

Create a dossier: Nutrient Sources

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Nutrition** from the Food domain list. Then choose your Authorisation type **Nutrient Sources** and the **Application type**, then press 'Start process'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.



NOTE

EFSA guidance: Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources.

EFSA landing page for all **Regulations and Guidance documents**.

Novel Foods

Novel Food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May, 1997, when the first Regulation on novel food came into force. 'Novel Food' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

Table 6. Submission types and legislation

Authorisation type	Application type	In accordance with
Novel Foods	Application for the authorisation of a new novel food	Regulation (EU) 2015/2283
	Application for the modification of an already authorised novel food	
Traditional Foods notification	Notification for the authorisation of a new traditional food	Regulation (EU) 2015/2283
	Notifications for the modification of an already authorised traditional food	
Traditional Foods application	Application for the authorisation of a new traditional food	Regulation (EU) 2015/2283
	Application for the modification of an already authorised traditional food	



NOTE

The **Traditional Food application** will not be visible in the EFSC dropdown menu selection because it only becomes an option if the Traditional Food notification is rejected for safety reasons. In that instance, the Applicant may resubmit an application according to the conditions as outlined in Article 16 of Regulation (EU) 2015/2283.



NOTE

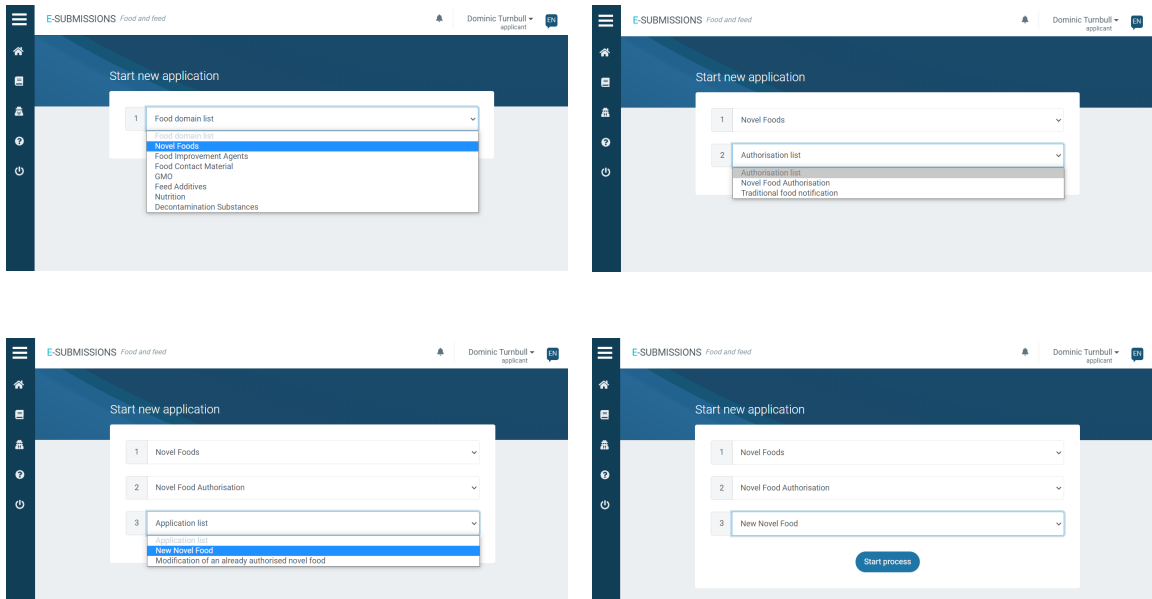
EFSA guidance: [Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation \(EU\) 2015/2283.](#)

[EFSA landing page for all Regulations and Guidance documents.](#)

Getting started

Create a dossier: Novel Foods

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Novel Foods** from the Food domain list. Then choose your Authorisation type **Novel Foods** and the **Application type**, then press 'Start process'.



- The Technical Dossier section is structured according to legislation and unique to each domain.

The screenshot displays the 'E-SUBMISSIONS Food and feed' interface. The top navigation bar includes 'E-SUBMISSIONS Food and feed', a user profile for 'Dominic Turnbull - applicant', and a 'Submit' button. The main content area is titled 'Technical Dossier' and contains a list of sections, each with a plus sign and a question mark icon:

- 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) *
- Bioavailability
- Nutritional information *
- Toxicological information *
- Genotoxicity *
- Subchronic toxicity *
- Chronic toxicity and carcinogenicity *
- Reproductive and developmental toxicity *
- Human data *
- Allergenicity *
- Concluding remarks *
- References *
- Annexes to the dossier *

The left sidebar shows the application details: 'Novel Foods Application NF 2021/23046', 'Draft With Applicant', and a 'DOSSIER DATA' section with sub-items: 'Administrative Data', 'Summary data', and 'Technical Dossier' (highlighted with a red box). At the bottom left, it indicates 'AUTHORISATION TYPE: Novel Food Authorisation' and 'APPLICATION TYPE: New Novel Food'.

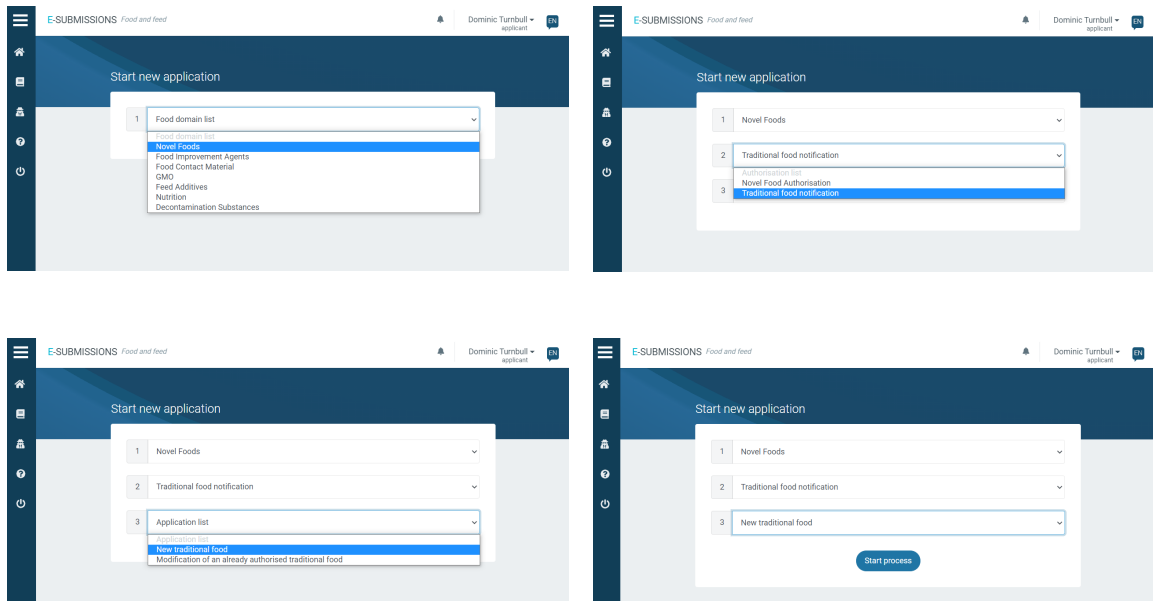


NOTE

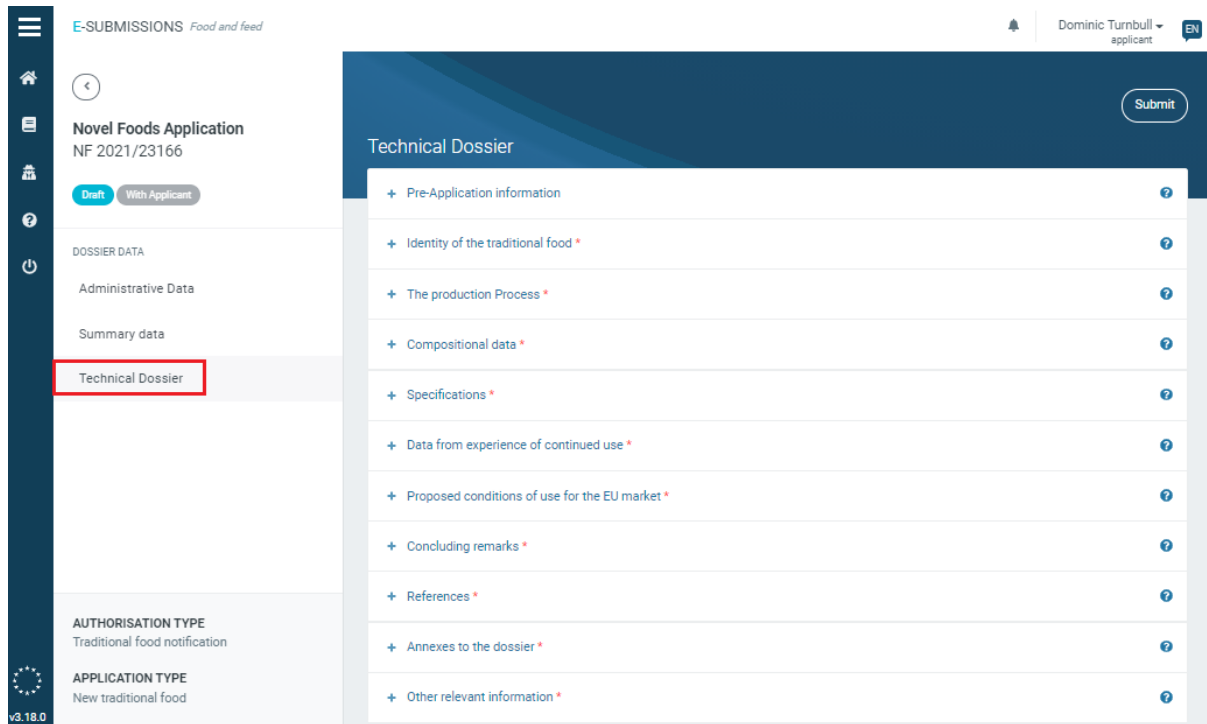
The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

Create a dossier: Traditional Foods

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Novel Foods** from the Food domain list. Then choose your Authorisation type **Traditional Foods** and the **Application type**, then press '**Start process**'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.





NOTE

The submission process is the same for all dossiers which are assessed by EC and EFSA. This **Food Additives (page 34)** submission example illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

Genetically Modified Organisms

Applicants can apply for GMO authorisations by submitting a dossier. Authorisations are valid throughout the EU and may be for:

- Cultivation
- Marketing of food and feed and derived products

If the GMO is to be used in food or feed without cultivation: applying for food and feed purposes is enough. If the GMO is to be used in food or feed with cultivation in the EU: companies need applying both cultivation and food/feed purposes under the same Regulation. If the GMO is not to be used in food or feed: applying for authorisation for cultivation is enough.

Table 7. Submission types and legislation

Authorisation type	Application type	In accordance with
GMO Food and Feed	Application for authorisation of a new genetically modified food and/or feed	Articles 11 and 23 (EC) 1829/2003 Regulation (EC) 1829/2003 Regulation (EU) 503/2013
	Application for renewal of authorisation of genetically modified food and/or feed	
	Application for modification of an existing authorisation of a genetically modified food and/or feed	
Deliberate release into the environment of genetically modified higher plants (GMHPs)	Notification concerning new release of genetically modified higher plants	Directive 2001/18/EC
	Notification concerning renewal of release of genetically modified higher plant	
Deliberate release into the environment of GMO other than higher plants (OTHPs)	Notification concerning new release of GMOs other than higher plants	Directive 2001/18/EC
	Notification concerning renewal of release of GMOs other than higher plants	



TIP

An applicant must submit food and feed samples for evaluation to [European Union Reference Laboratory for GM Food & Feed](#) (EURL GMFF). The EURL's acknowledgment of its reception of samples, reagents and methods should appear within the dossier, as indicated in EFSA's completeness checklist. Therefore, EFSA recommends that the documents and samples are provided before submitting GM plant applications.



NOTE

EFSA landing page for all [Regulations and Guidance documents](#).

2. The Technical Dossier section is structured according to legislation and unique to each domain.

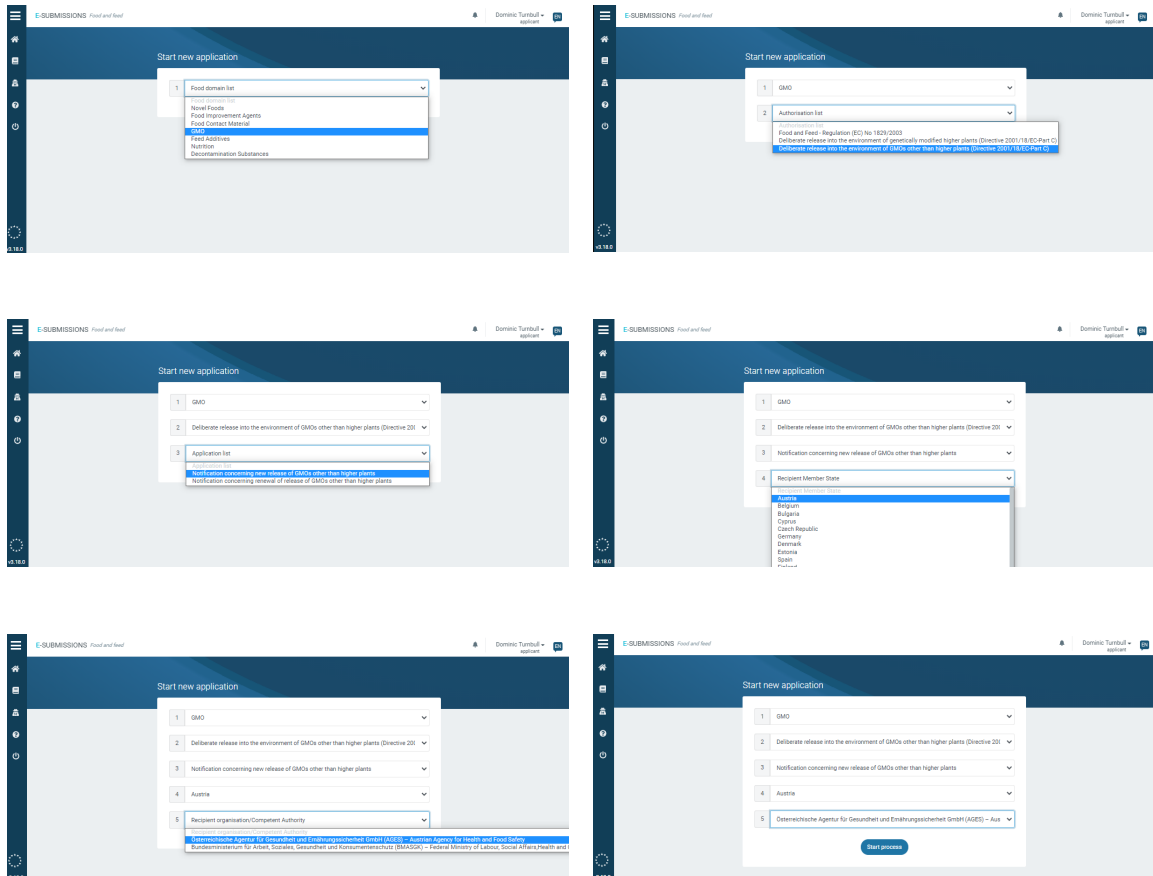


NOTE

The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.


Create a dossier: Deliberate release of Genetically Modified Organisms other than Higher Plants


1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **GMO** from the Food domain list. Then choose your domain type **Deliberate release of Genetically Modified Organisms other than Higher Plants**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**, and then click 'Start process'.



2. The Technical Dossier section is structured according to legislation and unique to each domain.

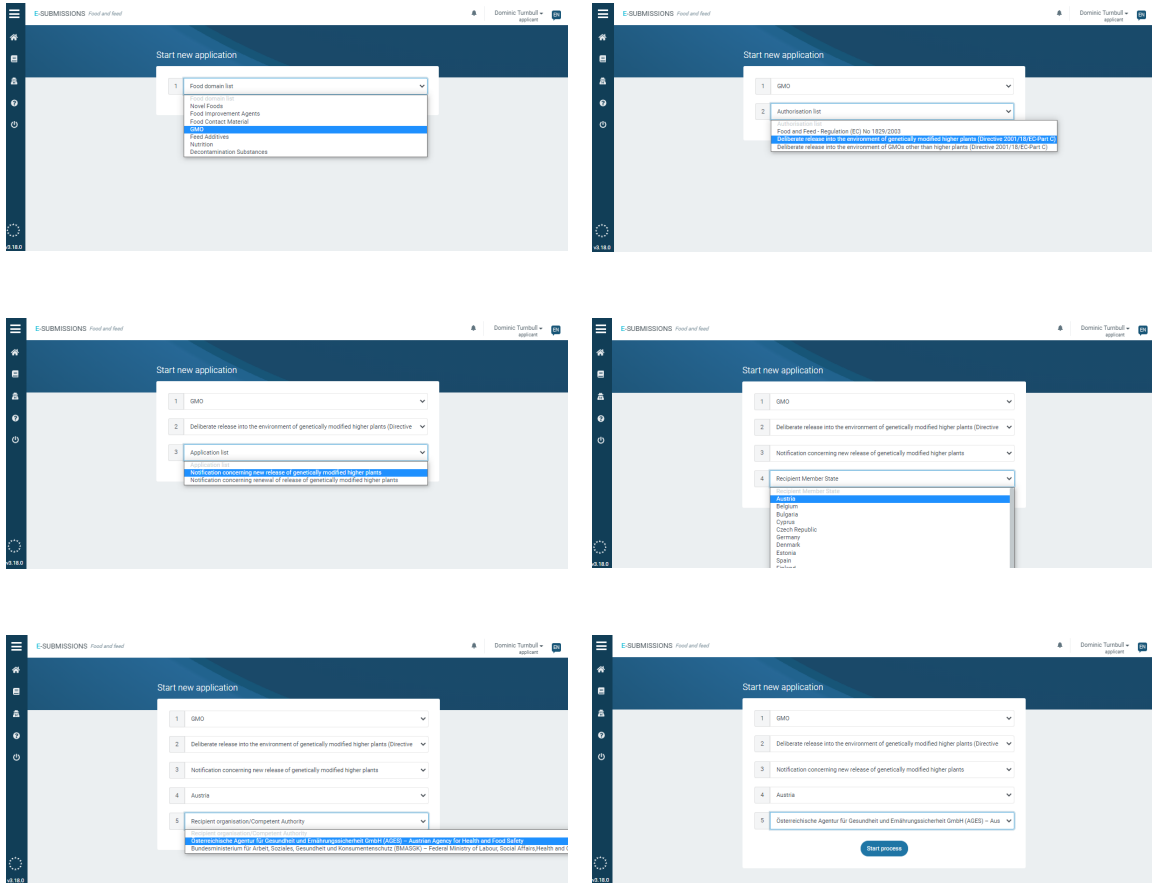
The screenshot shows the 'E-SUBMISSIONS Food and feed' interface. The left sidebar contains navigation icons and a list of sections: 'Draft', 'With Applicant', 'DOSSIER DATA', 'Administrative Data', 'Public summary', and 'Technical Dossier' (highlighted with a red box). Below these are 'MEMBER STATES / COMPETENT AUTHORITIES' (Austria) and 'AUTHORISATION TYPE' (Deliberate release into the environment of GMOs other than higher plants). The main content area is titled 'Technical Dossier' and lists various sections with expandable icons and help links: Pre-Application information, General Information, Information relating to the genetic modification, Information relating to the conditions of release and the receiving environment, Information relating to the interactions between the GMOs and the environment, Information on monitoring, control, waste treatment and emergency response plans, Additional Information, Environmental Risk Assessment - Conclusions, Conditions for the placing on the market of the product, including specific conditions of use and handling - Art. 13 (2)(c) *, Proposed period for the consent - Art. 13 (2)(d) *, Monitoring plan - Art. 13 (2)(e) *, Labelling proposal - Art. 13 (2)(f) *, Packaging proposal - Art. 13 (2)(g) *, Data/Results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier or other notifiers either inside or outside the Community - Art. 13 (3) and Art. 13 (4) *, and List of annexes, references and checklist *. A 'Submit' button is located in the top right corner.

 **NOTE**
 The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.


 **NOTE**
 If requested during the process, the application might be sent to EFSA for opinion. The transparency rules are only applicable as regards the placing on the market of GMOs or in products (Part C) and only where EFSA opinion is requested.


Create a dossier: Deliberate release of Genetically Modified Higher Plants

1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **GMO** from the Food domain list. Then choose your domain type **Deliberate release of Genetically Modified Higher Plants**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**, and then click 'Start process'.

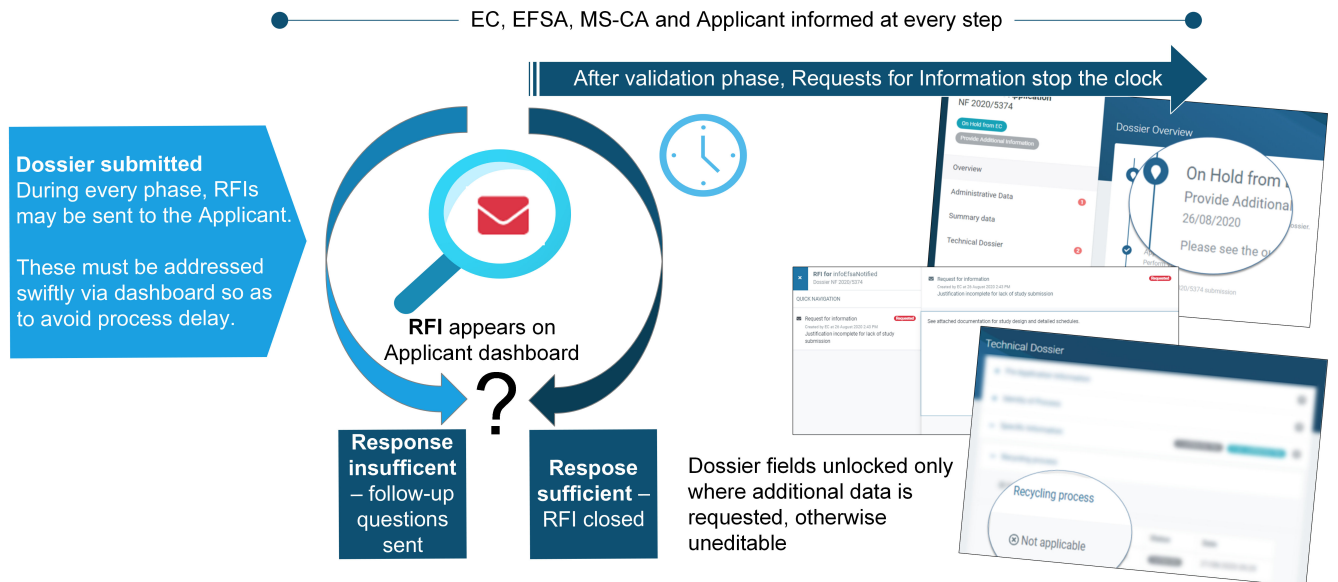


2. The Technical Dossier section is structured according to legislation and unique to each domain.

 **NOTE**
 The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in **Food Contact Materials (page 14)**, illustrates the process, covering: Administrative Data, Public summary, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

 **NOTE**
 If requested during the process, the application might be sent to EFSA for opinion. The transparency rules are only applicable as regards the placing on the market of GMOs or in products (Part C), and only where EFSA opinion is requested.

Requests for information



Following the dossier submission, the MS-CA or EC (depending on regulatory domain) may issue Requests for Information (RFI) before forwarding the dossier to EFSA. On receipt of a dossier and mandate from EC, EFSA then performs the Completeness and/or Suitability check, in accordance with the relevant sectoral legislation. EFSA may also send RFIs, via the ESFC platform, to ensure the dossier is complete and meets the standards for scientific assessment. All RFIs must be suitably responded to.

Once the RFIs are addressed, with Information added to – or uploaded into – the unlocked fields, the Applicant resubmits the updates, and EFSA makes an assessment of the response over a short time period. If questions remain, EFSA may seek further information framed by time limits set out in sector legislation and EFSA guidance.

During risk assessment phase

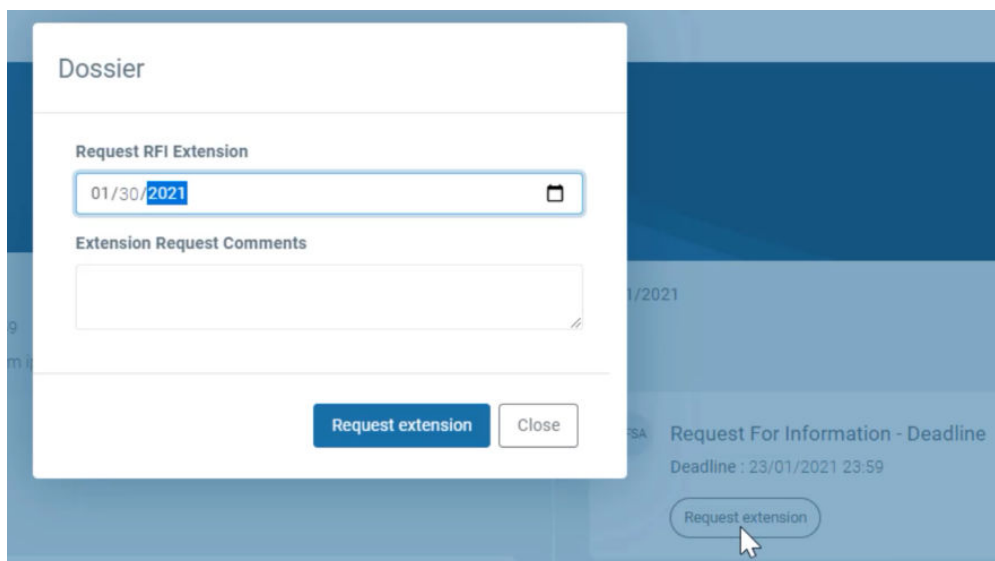
Risk assessment begins after dossier validation. The clock counts down towards the process completion – the timeframes vary by domain and application type. If the assessor finds incomplete, insufficient, unclear or inadequate data, the clock stops and a RFI is sent with a response deadline.



NOTE

While we refer to 'Request for Information' (RFI) on the ESFC platform and in other related documentation, you may see EFSA refer to this interaction as an 'Additional Data Request' (ADR) during the Risk Assessment phase. They are the same, and are addressed in the same way on the platform.

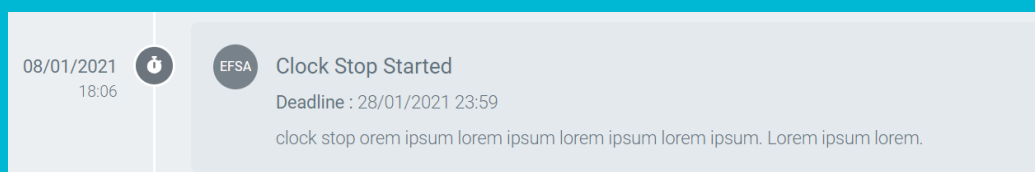
The RFI notification email links to the Applicant's dashboard, with the specific fields unlocked and ready to receive further information. Through the dashboard an applicant can **request a deadline extension**, with an explanation. EFSA will consider the request, and indeed it may set an alternative date.



NOTE

EFSA may choose to initiate its 'Stop Clock' procedure if there's a significant omission from the information provided during Risk Assessment. When this happens, the clock on the regulatory timetable for the risk assessment is paused until the RFI is addressed.

You will see the clock-stop status on the dashboard, as below. It will impact the risk assessment deadline displayed on the top left of the screen. Click [here](#) for more information. Interactions take place through dashboard notifications and by email:



TIP

Swift and complete turnaround for RFIs: Once the Applicant has fully responded and resubmitted the dossier updates, the clock continues. However, if queries remain regarding a particular request, the clock resets for that request until a suitable answer is delivered. Refer to EFSA [Administrative Guidance](#) for more detail on the 'stop-the-clock' procedure and timing.




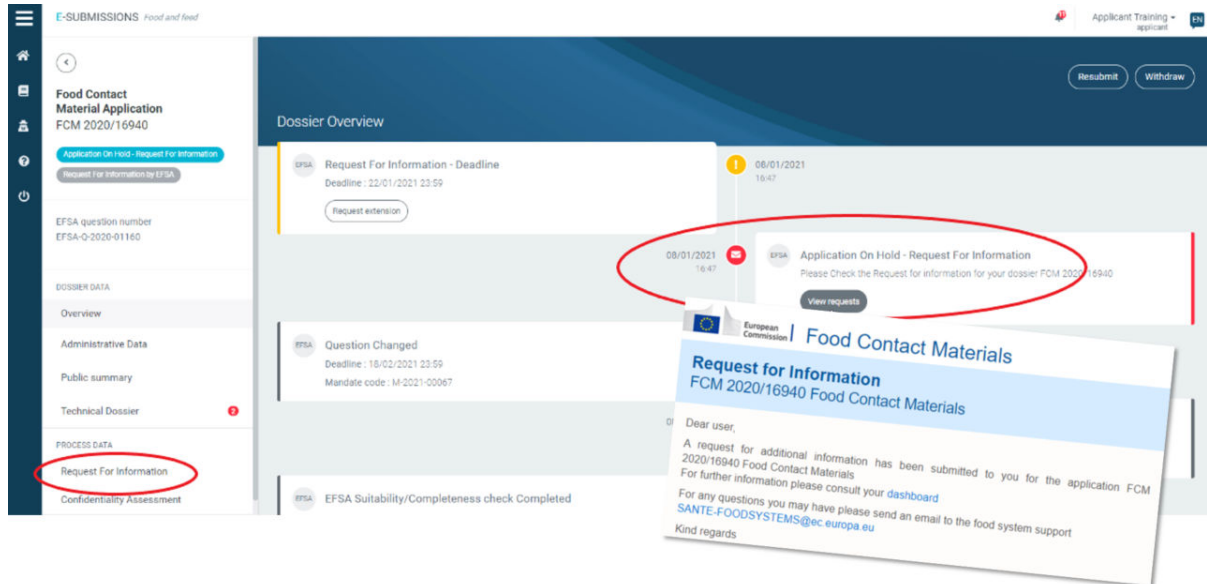
WARNING

The written exchanges which take place during the RFI procedure may be disclosed, so ensure they contain no personal or confidential information.

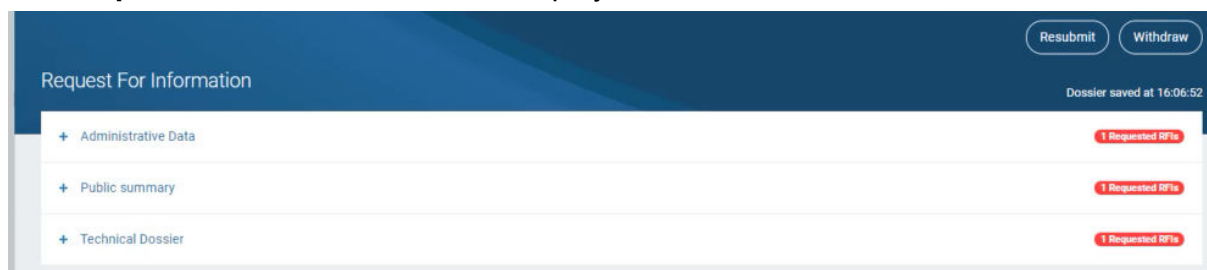


Responding to a Request for Information

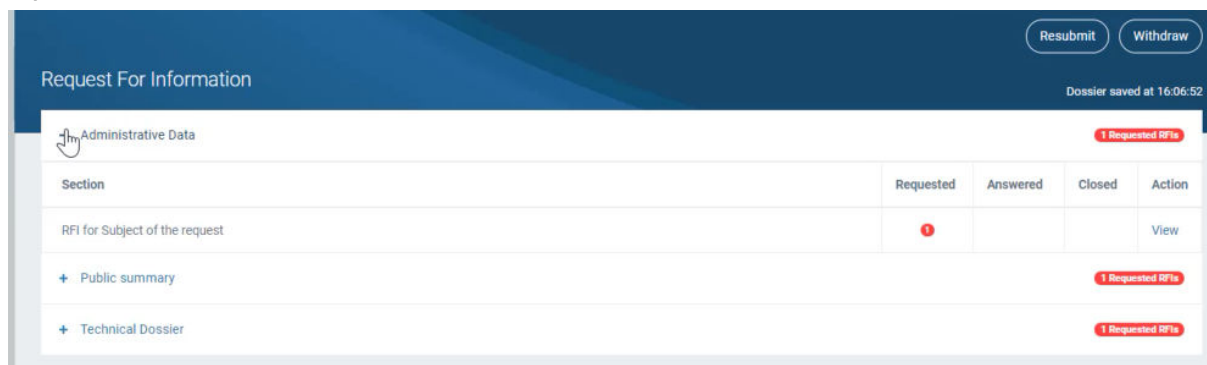
1. The notification bell  on the top right of the screen indicates activity on your dashboard. A **'Request for Information'** (RFI) tab appears on the left, red outstanding RFIs are number-flagged next to their section, and in the dashboard you see the RFI entry.



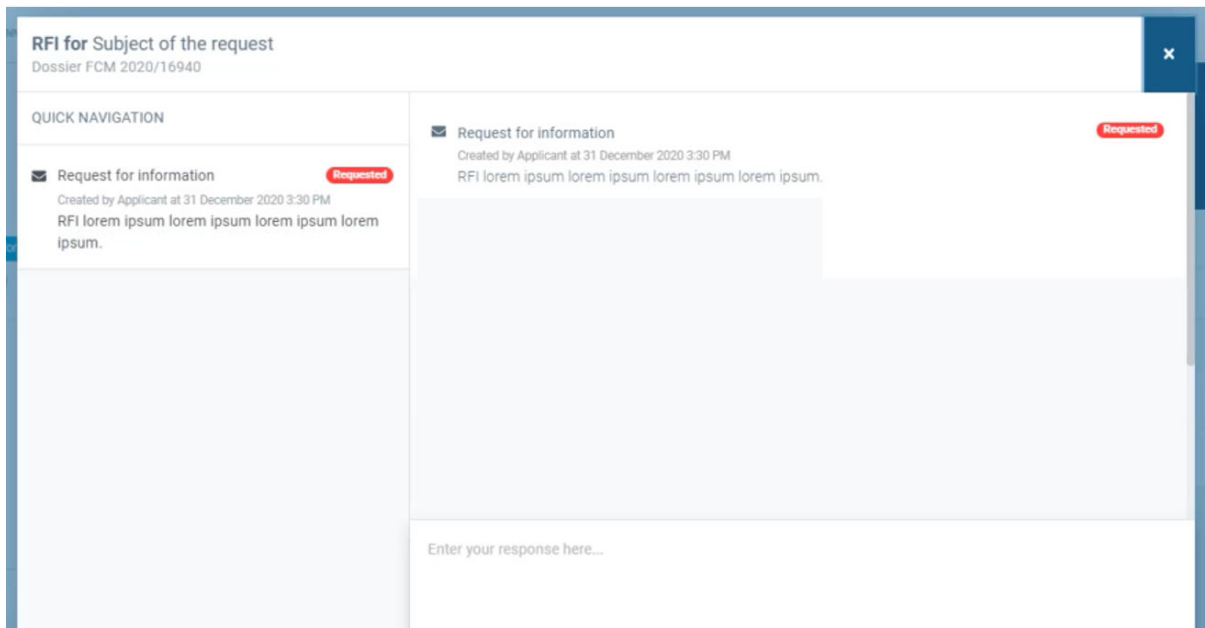
2. RFIs (and Additional Data Requests) can arrive during any assessment phase. Click the **'Request for Information'** tab to display the overview screen.




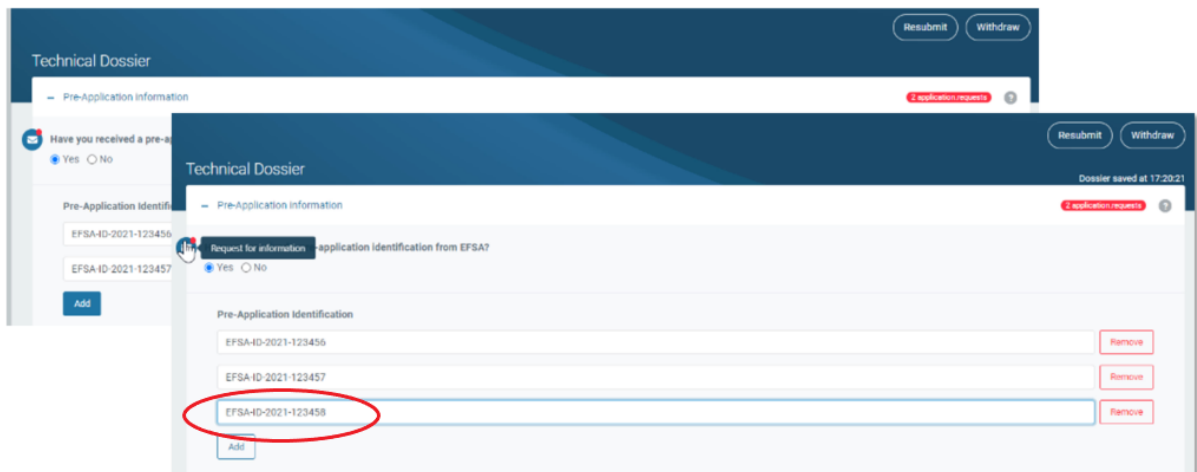
3. Open a section '+' and click on **'View'** to read the RFI.



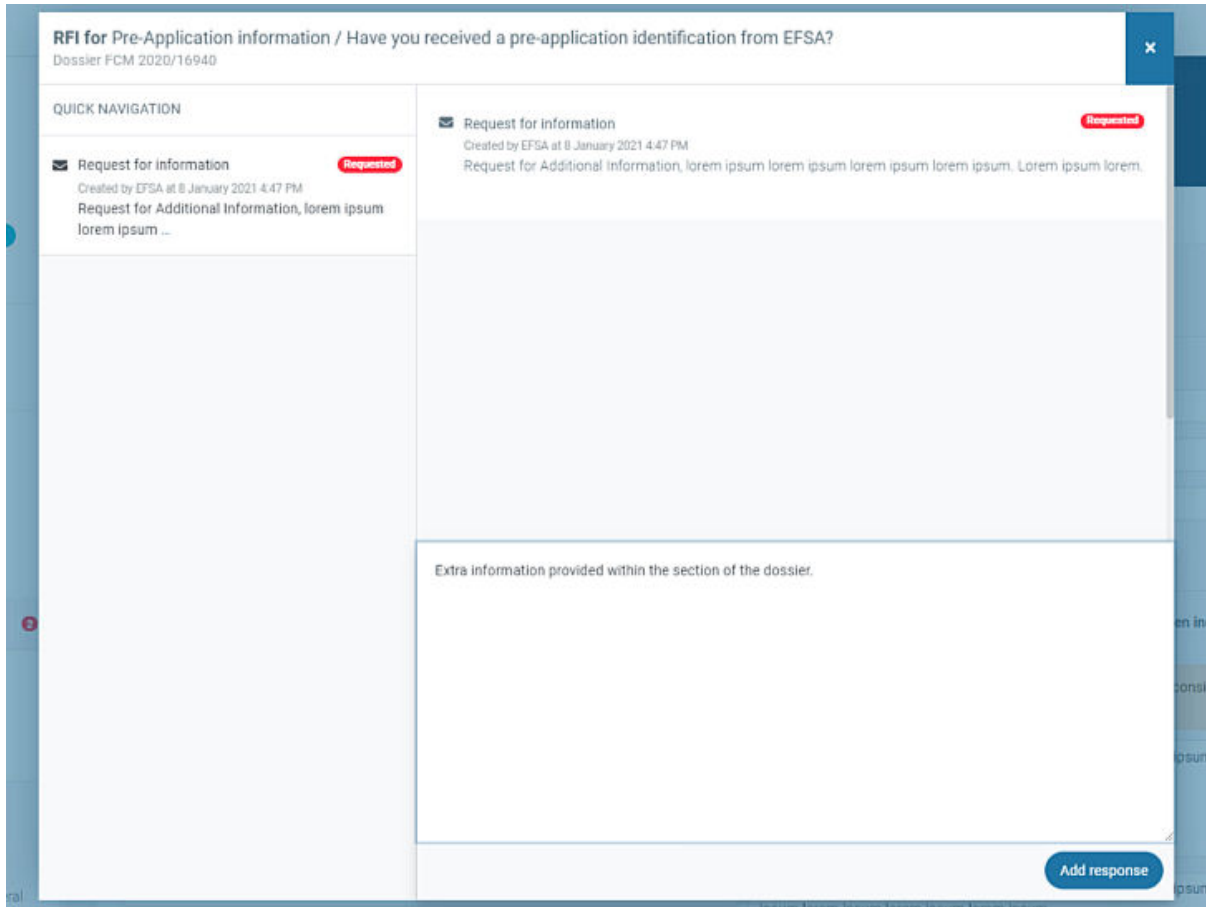
4. Read the question and possible document included.



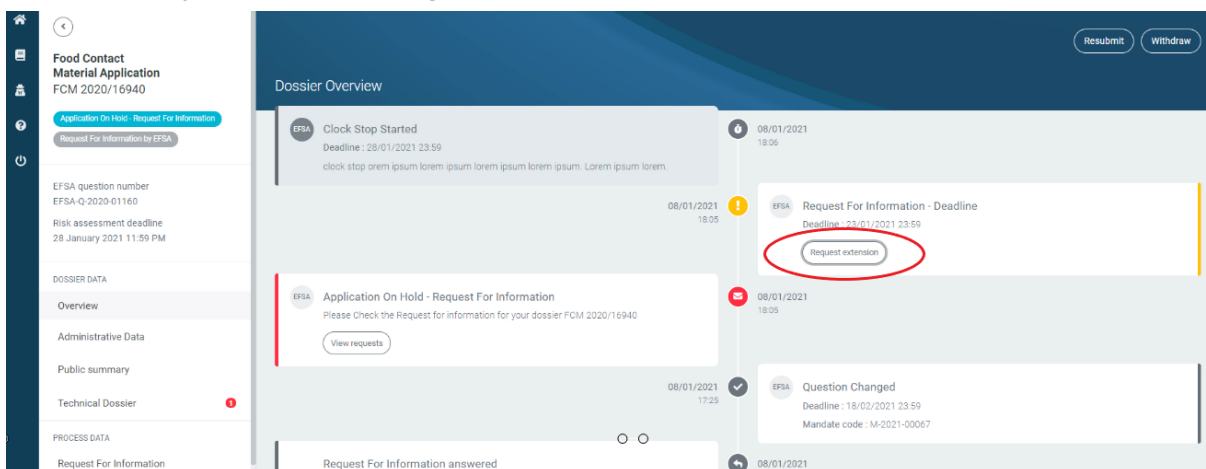
5. Scroll through the section which contains the RFI until you see a red email icon , then supply the extra information in the unlocked field.



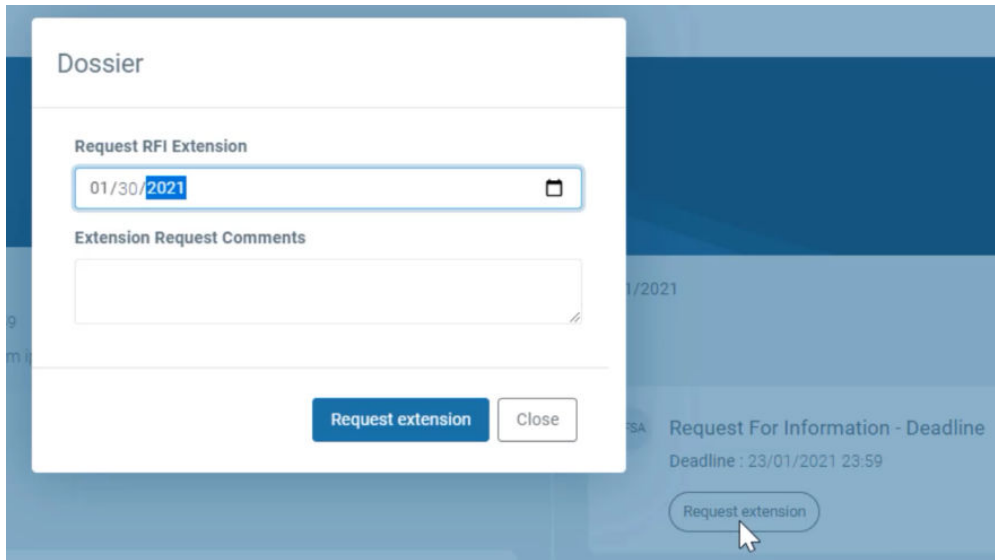
- Write a message to outline how you addressed this request, giving details on files provided or fields changed, or if any of the information requested was not provided, then click **'Add response'**. You will see the red email icon is now green ✓ beside the section. Please, note, you need to respond to all requests before being able to resubmit.



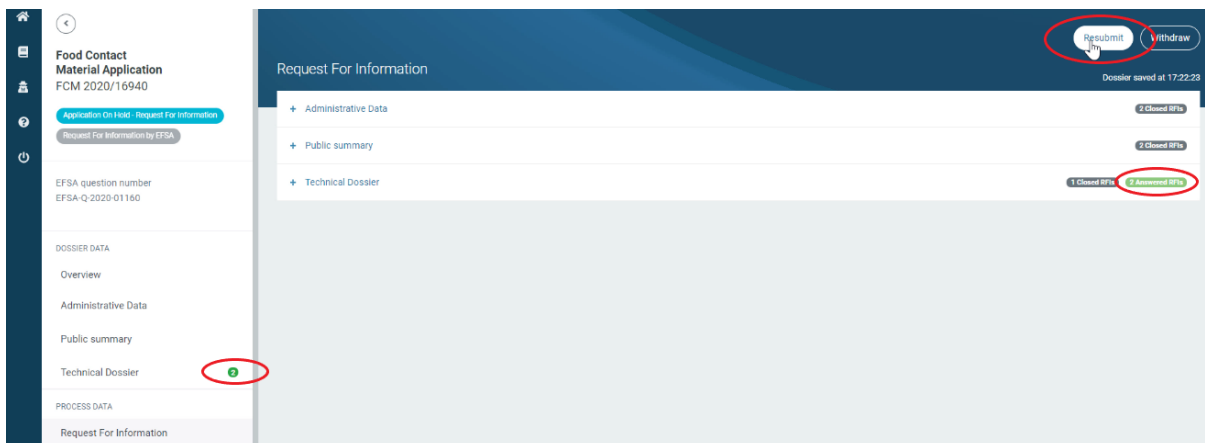
- If an extension is needed for addressing the requests received, the dashboard shows a deadline extension facility for RFIs arriving during the Suitability and Risk Assessment phases. Click **'Request extension'**.



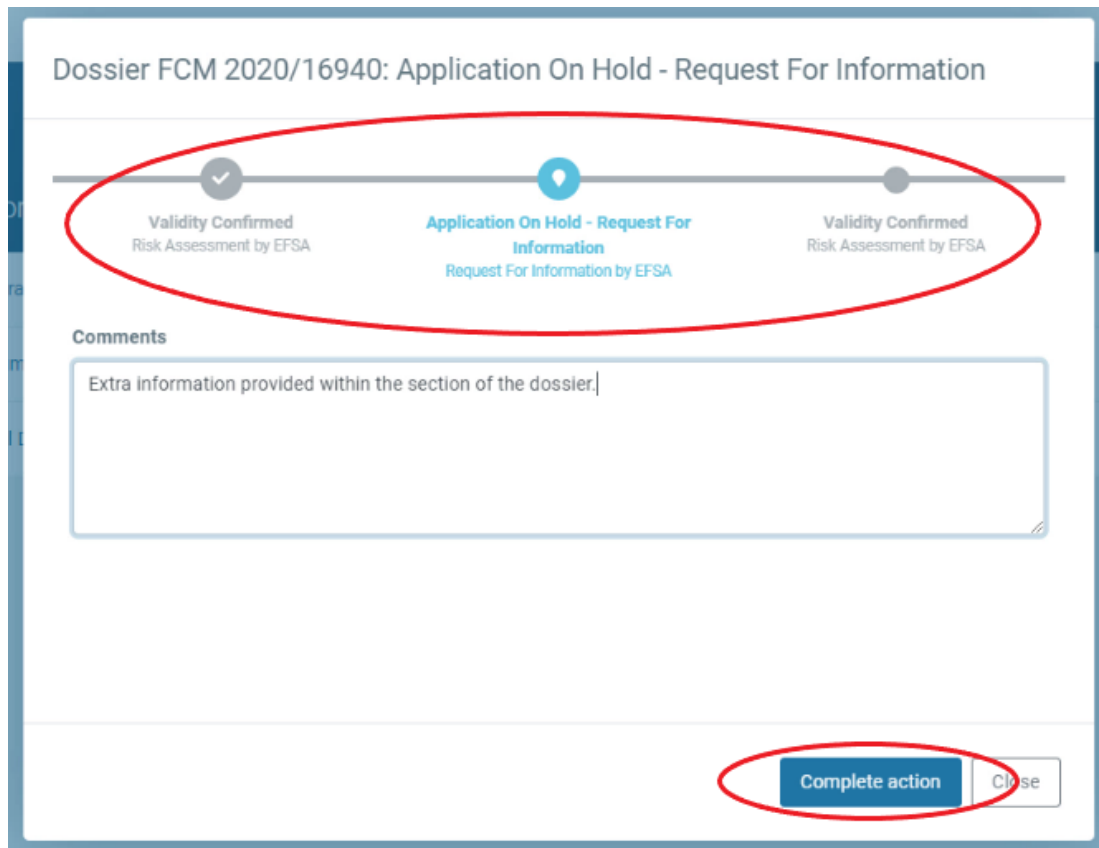
- Set your preferred date for EFSA to consider, with a supporting explanation. Click **'Request extension'**. EFSA will post the deadline (the same or new) on the dashboard following their assessment of the request.



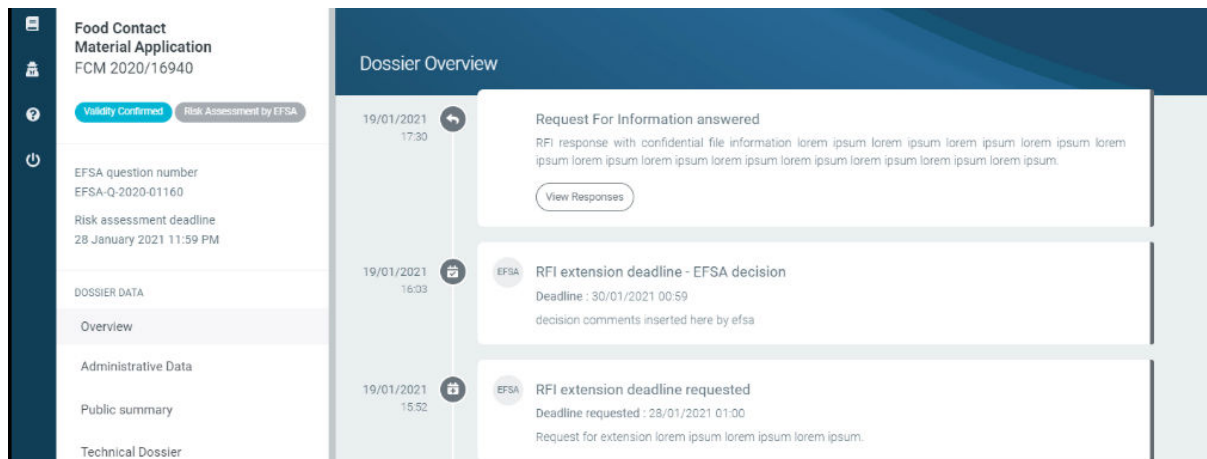
- The RFI overview screen also shows the total number of completed RFIs (in green), as well as those not yet addressed (in red). When all are replied to, click to resubmit your updates. Now again click to **'Resubmit'** your updates.



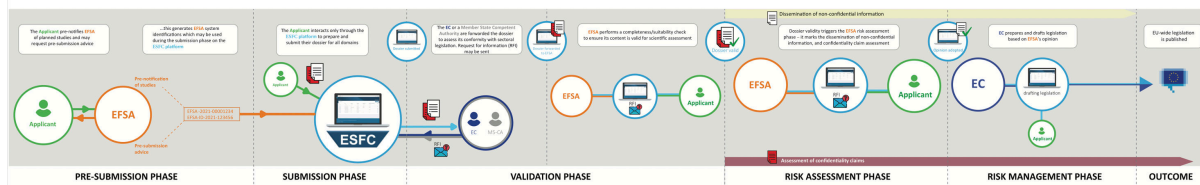
10. You will see a box where you can provide a final message. This also displays the dossier status path.



11. Your response to the RFIs is reflected in the dashboard.



Authorisation process



The ESFC platform requests verifiable detail across a full range of metrics that relate to each dossier, to ensure that all applications and notifications face a rigorous, science-based, and transparent control system. See the above authorisation process flow diagram [here \(page 117\)](#).

Transparency in the process

The platform has been developed to help applicants comply with the Transparency Regulation.

Transparency underpins consumer confidence in EU food safety, and strengthens the reliability, objectivity and independence of the EFSA assessment process. [See more \(page 111\)](#).

Who receives the application?

All dossier content is funneled through the ESFC platform, and immediately routed to the actor designated by legislation.

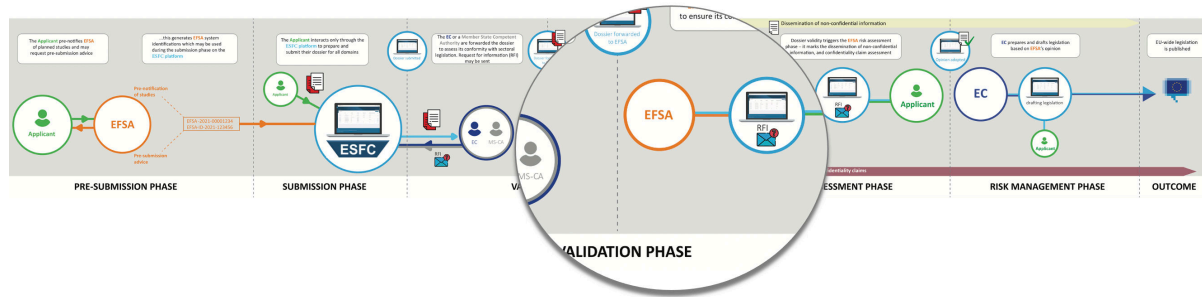
- Dossiers routed to the Member State Competent Authority (MS-CA) for which risk assessment is done by EFSA:** GM Food & Feed (new authorisations and modifications), Smoke Flavourings (new authorisations and modifications), Health Claims (new authorisations and modifications) and all Food Contact Materials.
- Dossiers routed to the MS-CA for which risk assessment may be done by EFSA:** GMO (Part C) is managed by the MS-CA, and transparency rules only apply when they seek EFSA's opinion.
- Dossiers routed to the European Commission:** Food Improvement Agents, Novel/ Traditional Foods, Feed Additives, GM Food & Feed (renewals).

Risk management and ultimate approval or rejection are carried out by EC or Member States, not by EFSA.

Table 8. Food domains and EFSA guidance

Food domain	Guidance
Food Contact Materials	Regulation and guidance
Food Improvement Agents	Regulation and guidance
Genetically Modified Organisms	Regulation and guidance
Feed Additives	Regulation and guidance
Nutrition	Regulation and guidance
Decontamination Substances	Regulation and guidance
Novel Foods	Regulation and guidance

Validation checks



After submission, the Applicant receives acknowledgment by email. The ESFC platform will direct the dossier to the selected MS-CA or EC (depending on the domain), which after an initial administrative or completeness check may request EFSA to proceed. The following validation phase for a dossier determines whether it contains the correct information components and studies, and whether it complies with the Notification of Studies requirements. The Confidentiality assessment process is not carried out during the dossier validation phase, but only after the dossier is found to be valid.

Validation varies by domain. Most validation checks are carried out by EFSA. RFIs are sent through the ESFC platform, see [Request for Information \(page 77\)](#).



NOTE

From an applicant's perspective, all dossier interactions focus on the **ESFC timeline** irrespective of which body is assessing validation, confidentiality or risk assessment.



TIP

Close adherence to the available EFSA guidance documents – containing templates, formatting requirements and detail expectations – will facilitate the progress of a dossier.

Application 'valid'

When validated, the dossier moves to scientific risk assessment. Its content makeup is complete and the detail meets the requirements for scientific risk assessment. At this point, non-confidential information is disseminated EFSA, EC, or MS-CA (depending the regulatory framework) may begin the assessment of the confidentiality requests.

The screenshot displays the 'Dossier Overview' for a 'Food Contact Material Application' (FCM 2020/13145). The interface is divided into a sidebar and a main content area. The sidebar contains navigation options such as 'Validity Confirmed', 'Risk Assessment by EFSA', and 'EFSa question number'. The main content area shows a timeline of events: 'Validity Confirmed' (11/11/2020 09:09), 'EFSa Suitability/Completeness check Completed' (10/11/2020 14:59), 'Application Acknowledged by EFSA' (10/11/2020 14:59), and 'EFSa Suitability/Completeness Check' (10/11/2020 14:58). A large green 'Valid' stamp is overlaid on the 'Validity Confirmed' event.

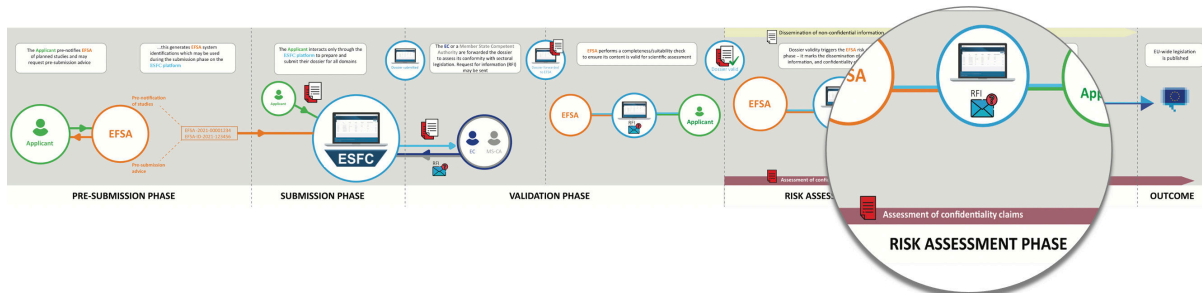


WARNING

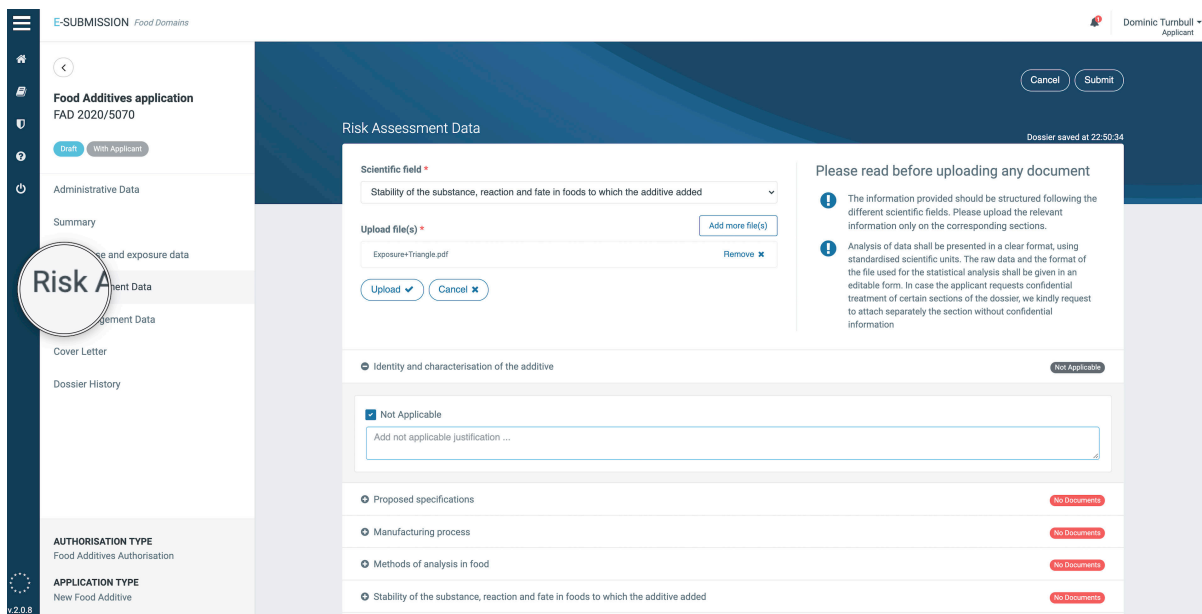
Validation triggers public dissemination: Information included in the submitted files that is not requested to be treated as confidential by the Applicant will be automatically disclosed after the dossier is considered 'valid' by the assessor.

Please note that content provided directly into fields (i.e., not held within uploaded files) cannot be included in a request for confidentiality treatment. Therefore the Applicant is required to ensure no confidential or personal data is included.

Risk assessment



EFSA analyses dossier data, any supporting studies or existing research, and it conducts public consultations to identify whether other relevant scientific data or studies are available on the subject matter concerned by the dossier. Interactions with the Applicant take place through dashboard notifications and by email:



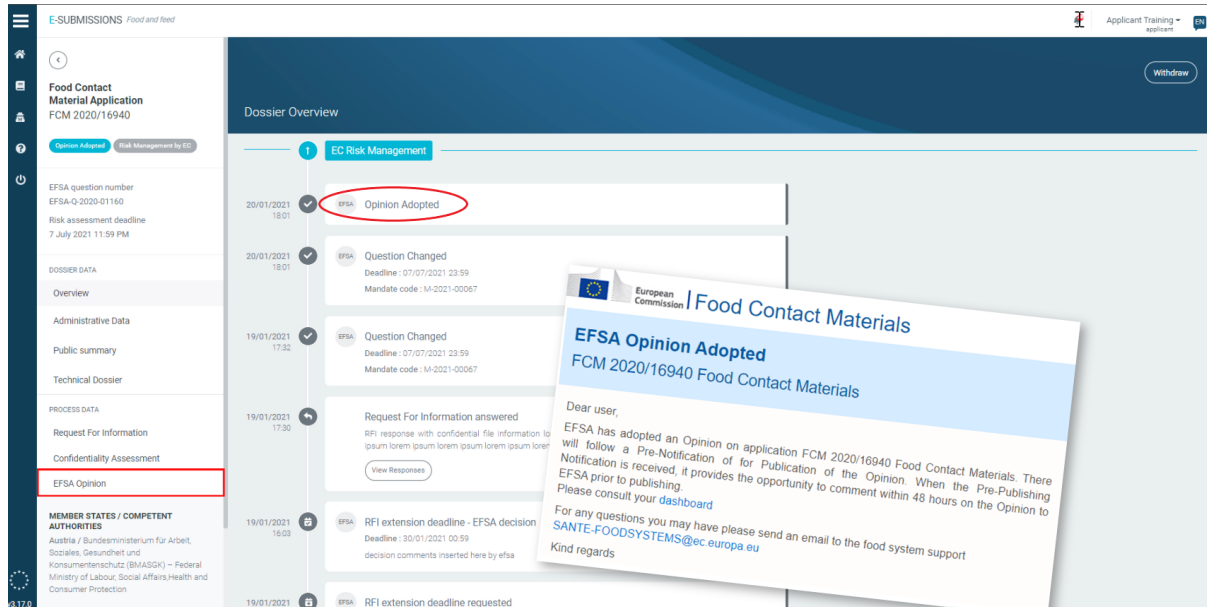
Timeframe for risk assessment

From the moment of dossier's validity, EFSA requires between four to nine months, depending on the domain, to conduct its risk assessment. The timeframe set out in legislation includes a 'clock-stop' procedure when extra information is requested which may extend the process. Deadline and dossier status are displayed in the ESFC dashboard.

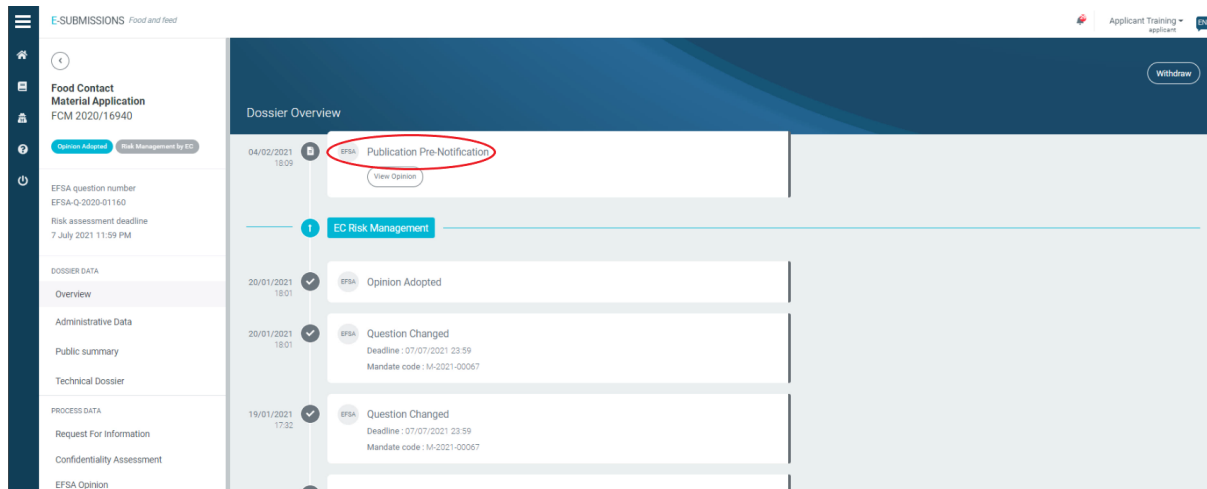
For more information, go to the [Administrative guidance for the processing of applications for regulated products \(update 2021\)](#).

Opinion outcome

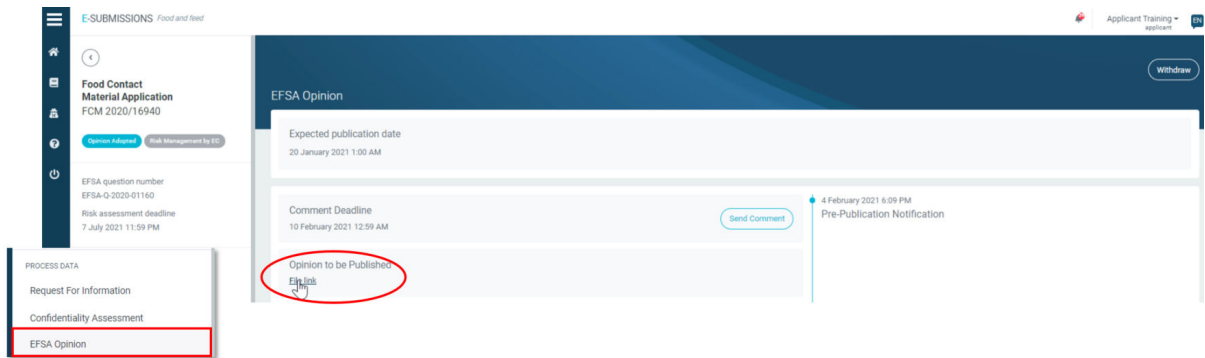
1. An email arrives to inform the user that EFSA has adopted an opinion. The dashboard displays a new 'EFSA Opinion' tab in the lower left pane.



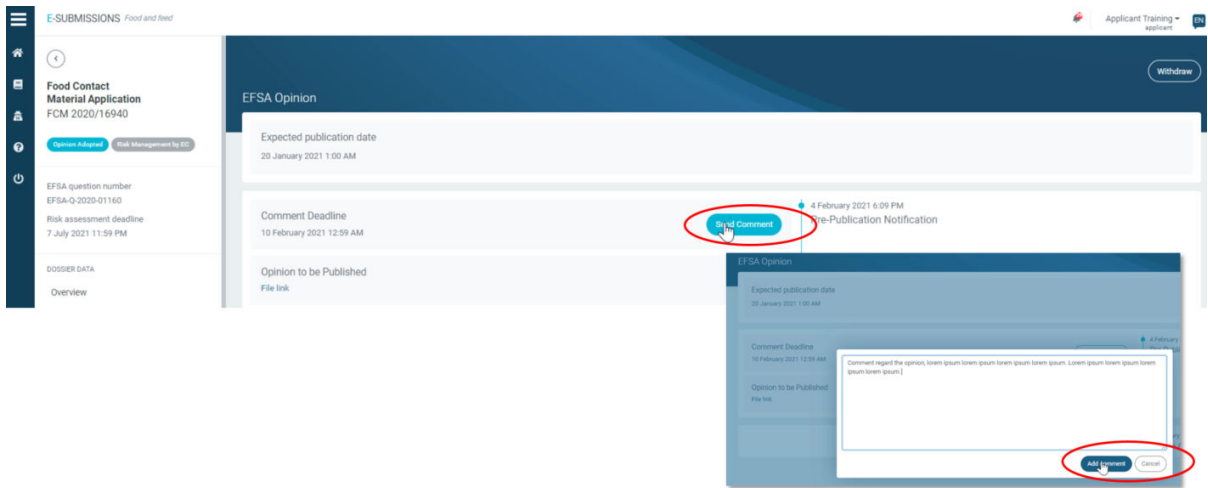
2. A pre-publication notification arrives, offering the Applicant a preview of the EFSA position and its exact wording.



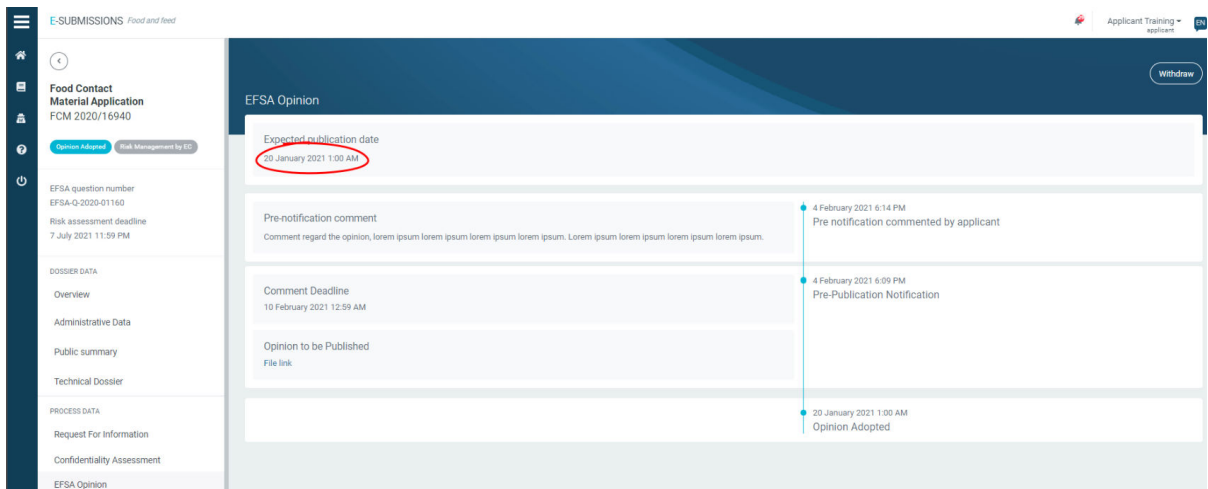
- By clicking the '**EFSA Opinion**' tab, the platform provides a read-only view. Click on the '**Opinion link**' to access the wording. Note the comment deadline above.



- You have an option to comment on the general wording of the Opinion, prior to the deadline. Click '**Send comment**', type your comment and click '**Add comment**'. It is sent and EFSA is informed. Note that once the deadline has passed, the Comment button disappears.



- Your comment appears on the dashboard. Now wait for EFSA's reaction.



- The opinion is published. You are informed, and Risk Management begins. Now wait for the next step.

The screenshot displays the 'Dossier Overview' for 'Food Contact Material Application FCM 2020/16940'. The interface includes a left-hand navigation menu with sections for 'DOSSIER DATA', 'PROCESS DATA', and 'MEMBER STATES / COMPETENT AUTHORITIES'. The main content area shows a timeline of events:

- 08/02/2021 09:43**: EFSA Output Published (highlighted with a red circle). Includes a 'View Opinion' button.
- 08/02/2021 09:43**: EFSA response on Pre-Publication comment. Response to applicant. Includes a 'View Opinion' button.
- 04/02/2021 18:14**: EFSA Pre-Publication Applicant Comment. Comment regard the opinion, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Includes a 'View Opinion' button.
- 04/02/2021 18:09**: EFSA Publication Pre-Notification. Includes a 'View Opinion' button.
- 20/01/2021 18:01**: EFSA Opinion published (partially obscured by a banner).
- 20/01/2021 18:01**: EFSA QM (partially obscured by a banner).
- 19/01/2021 17:32**: EFSA (partially obscured by a banner).

A large blue banner in the foreground reads: **Opinion published FCM 2020/16940 Food Contact Materials**. Below the banner, a message is visible: 'Dear user, EFSA has published their Opinion on the Dossier FCM 2020/16940 Food Contact Materials. Please consult your dashboard. For any questions you may have please send an email to the food system support SANTE-FOODSYSTEMS@ec.europa.eu. Kind regards. Deadline : 07/07/2021 23:59. Mandate code : M-2021-00067'.

Authorisation procedure result

The risk management conclusion will be:

- Authorisation (modification/renewal) granted. You will be informed.
- Authorisation rejected. You will be informed with an explanation. A generic reason will also be published.

Withdraw dossier

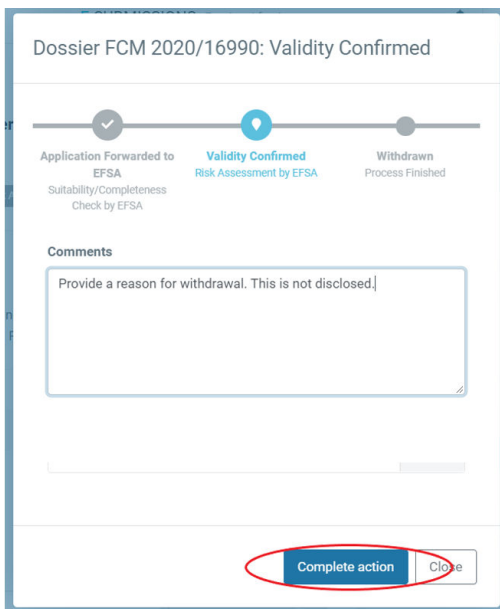
You can withdraw at any time, and you will need to provide an explanation for the action which will be seen by EFSA. EC will be informed. Your dossier information will be removed from the dissemination portal immediately. See EFSA's [Practical Arrangements](#).

How to withdraw your dossier

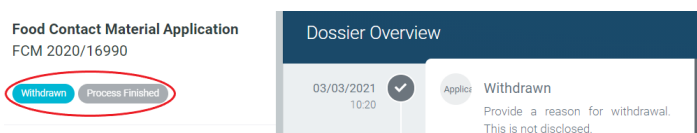
1. At any phase the Applicant can click **'Withdraw'** to end the process.



2. An explanation dialogue appears, showing the current phase and following phase. Input an explanation. Click **'Complete action'**.



3. The badges and dashboard confirm that your decision has been implemented. The process has ended.



Intellectual Property Rights

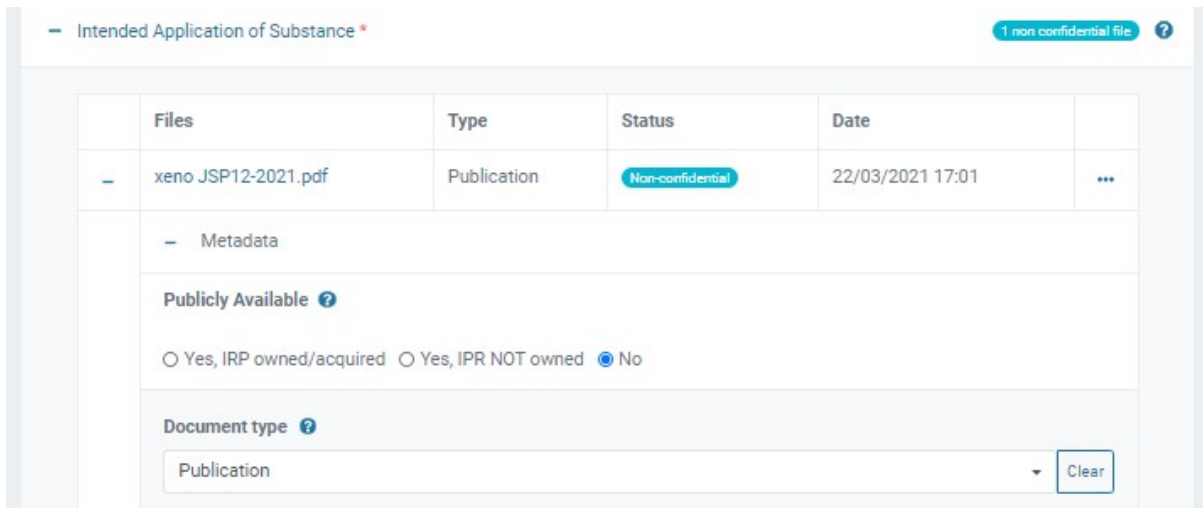
How to accommodate IPR not owned by the Applicant

The new provisions of the Transparency Regulation, amending among others the General Food Law Regulation, provide for the proactive public disclosure by EFSA on its website of all scientific studies that support any request addressed to the European Food Safety Authority (EFSA) for scientific output, including applications for authorisations/approvals.

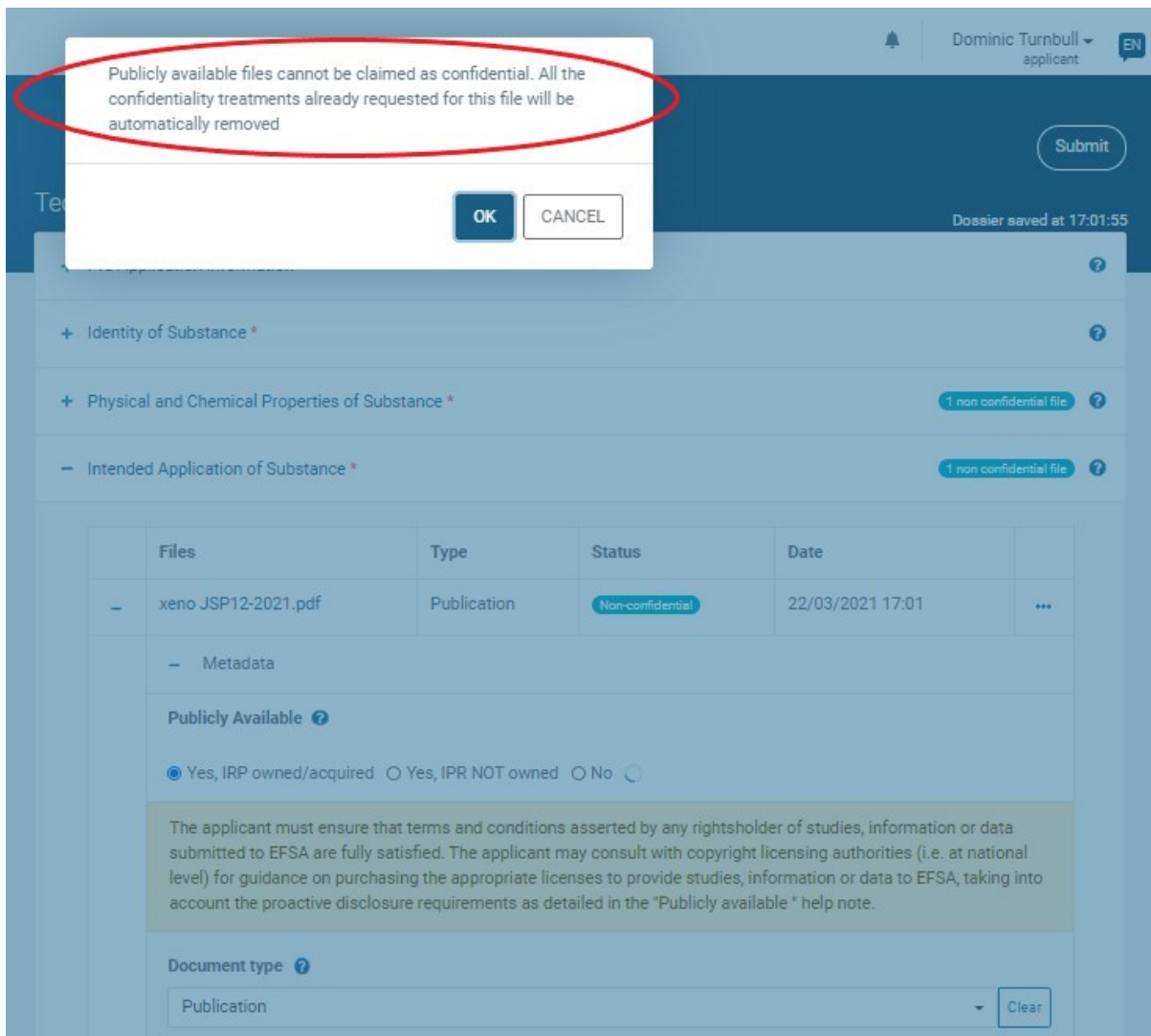
There may be instances however, where applications may be supported by published studies for which the applicant **does not own** or **cannot obtain** the relevant Intellectual Property Rights (IPRs) – i.e. copyright – for the reproduction of those published studies on EFSA's website by EFSA. In those cases only, the Applicant needs to take notice of the following:

- Where the Applicant supports its applications by invoking published studies, the Applicant would need to provide risk assessors with the copies of those studies for the purposes of the risk assessment, namely to facilitate the scientific assessment. For the submission of these copies for EFSA risk assessment purposes, the Applicant would need to ensure that any rights' holder of these published studies are fully satisfied, e.g. payment of any applicable fees to obtain a copy of the relevant published scientific study for the sole purpose of submitting for EFSA risk assessment purposes. The proactive dissemination of the published studies will only occur if the Applicant is in possession of the relevant IPRs (copyright) for such reproduction on EFSA's website. Applicants are not expected to purchase the reproduction rights of studies already publicly available (e.g. studies published in scientific journals) in order to meet the transparency requirements of Article 38(1)(c) of the General Food Law Regulation, as amended by the Transparency Regulation.
- If the Applicant does not own or cannot obtain the relevant IPRs (copyright) of published studies for the purposes of reproduction on EFSA's website, the Applicant would be required for public disclosure purposes to submit the relevant bibliographic references/citations to these published studies indicating where these publications are available to the public and, where available, their web links for public dissemination.

1. By default, 'Publicly Available' is set to 'No'.



2. Clicking 'Yes, IPR owned/acquired' shows a reminder that publicly available documents cannot accept confidentiality treatment requests, therefore this file will be made public. Please read the disclaimer presented.




- Clicking **'Yes, IPR NOT owned'** will open a new field for free text, intended for direct citations and references to the source publication. The 'IPR protected' badge appears. This citation text will appear on the dissemination portal. The publication file itself will only be available as part of the scientific assessment.

The screenshot shows the 'Technical Dossier' interface. At the top right, the user is identified as 'Dominic Turnbull applicant' with a language selector 'EN'. A 'Submit' button is visible. The dossier is saved at 17:29:55. The interface lists several sections: 'Pre-Application information', 'Identity of Substance *', 'Physical and Chemical Properties of Substance *' (with 1 non-confidential file), and 'Intended Application of Substance *' (with 1 non-confidential file). Below these is a table of files:

Files	Type	Status	Date
- xeno JSP12-2021.pdf	Publication	Non-confidential IPR Protected	22/03/2021 17:01

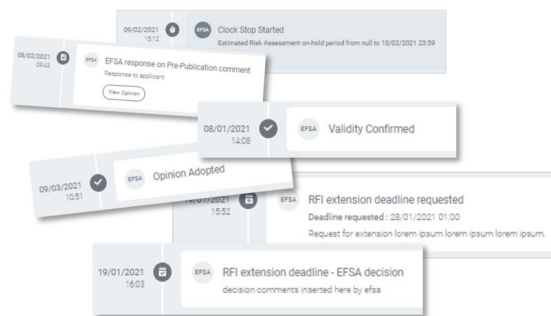
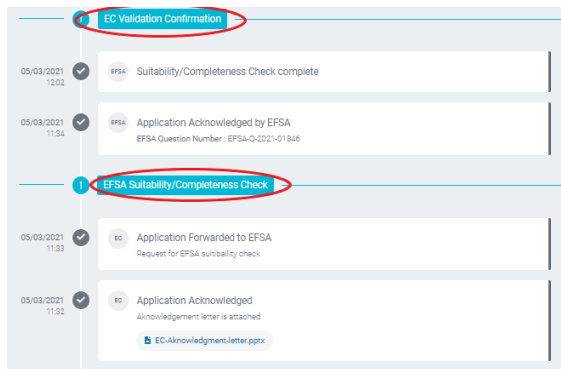
The 'IPR Protected' badge is circled in red. Below the table, there is a 'Metadata' section with a 'Publicly Available' toggle. The 'IPR Reference *' section contains instructions for providing bibliographic references for publications available to the public. A text input field is provided for entering these references.

ESFC dossier tracking

Throughout the submission process, users who are connected to a dossier receive notification emails indicating activity. The emails link back to the platform dashboard. Any activity is also flagged by the notification bell , in date order, for all your ongoing dossiers.

Such interactions could relate to: *Completeness or Suitability checks, Requests for Information during all phases, confidentiality clarifications, draft opinions, intentions to disclose, sanitised file uploads, pre-publication notifications of the outcome, status changes, stop-clocks, and simple acknowledgments of document receipts.*

The status badges denote the current and next phase for the dossier Validity Confirmed Risk Assessment by EFSA. The dashboard timeline will update as the dossier proceeds through each stage.

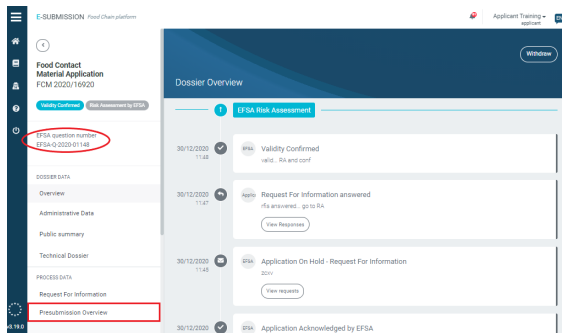


WARNING

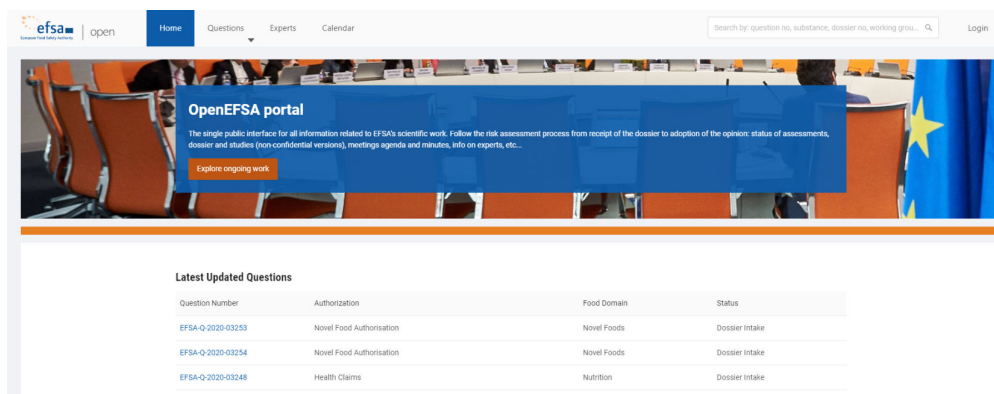
As the Applicant/Notifier, you should be aware that once an actor (i.e., EC, MS-CA and EFSA) is logged into the platform, they will see the activity timeline showing the history and current phase of any dossier. If the dossier phase is with them, that actor can interact via RFI. The content will also be viewable, but always in read-only mode.

EFSA Question Number

When EC or MS-CA send the dossier to EFSA for Risk Assessment, it allocates the dossier a Question Number (e.g. EFSA-Q-2009-12345). This appears top left of the dashboard. If you have dossier questions, refer to that number when you contact EFSA. Dossiers which do not require Risk Assessment by EFSA (i.e. never forwarded to EFSA) – for example, those Novel Foods dossiers which pass directly to Risk Management – there will be no Question Number provided.



Through the **OpenEFSA** portal, the Applicant or the general public can track dossier progress.



Dossier confidentiality

The Applicant needs to provide scientific data and other supplementary information in a confidential version (full and unedited), necessary to support his or her dossier. However, according to the Transparency Regulation, the Applicant can request confidentiality treatment at a line-by-line level. This requires a verifiable justification for each request, demonstrating how making the information public would potentially harm the Applicant's interests to a significant degree, in accordance with Article 39.2 and 39.3 (EC) 178/2002.

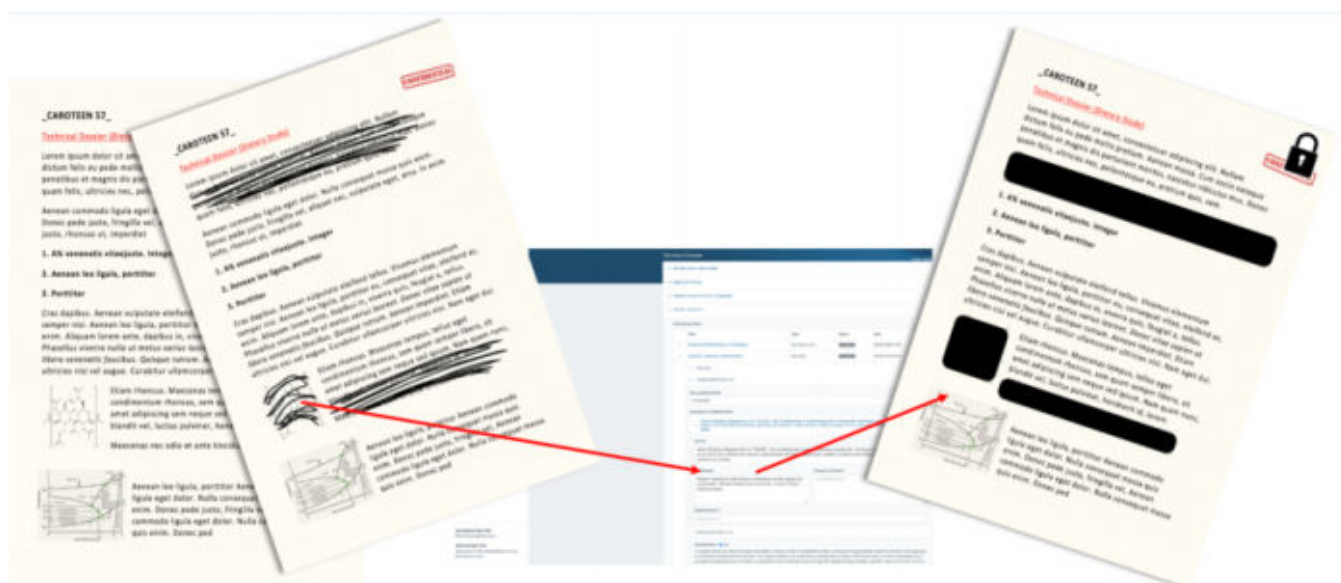
The confidentiality assessment is generally carried out by EFSA, but there are some exceptions in which EC or MS-CA carry out the assessments. A blanket request for confidentiality will not be accepted.

- **EC:** Novel Foods and Traditional Foods, Food Additives, Enzymes and Food Flavourings when they do not require risk assessment.
- **MS-CA:** GMO Part C dossiers, per Article 25, 2001/18/EC, when an EFSA opinion is not sought.

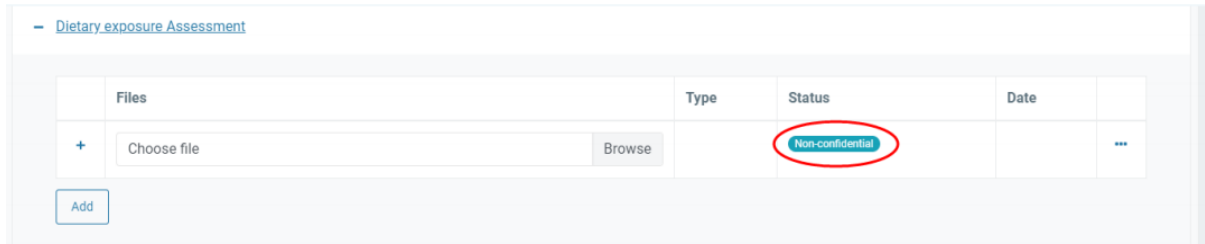
The following pages offer a practical guide to requesting confidentiality, and responding to clarification requests from assessors.

How to request confidentiality

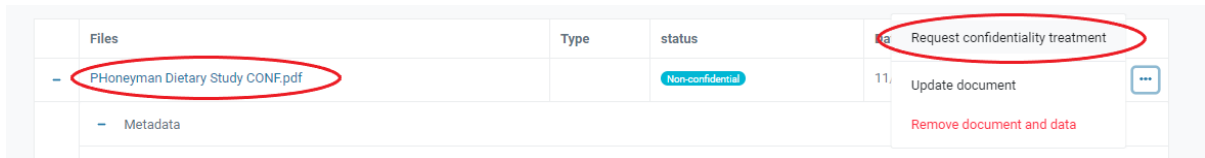
Identify all confidential elements within your content files, then establish which legal ground underpins each request and prepare its justification. Redact a duplicate file to create the 'non-confidential version' – digitally black out content for which you will request confidentiality.



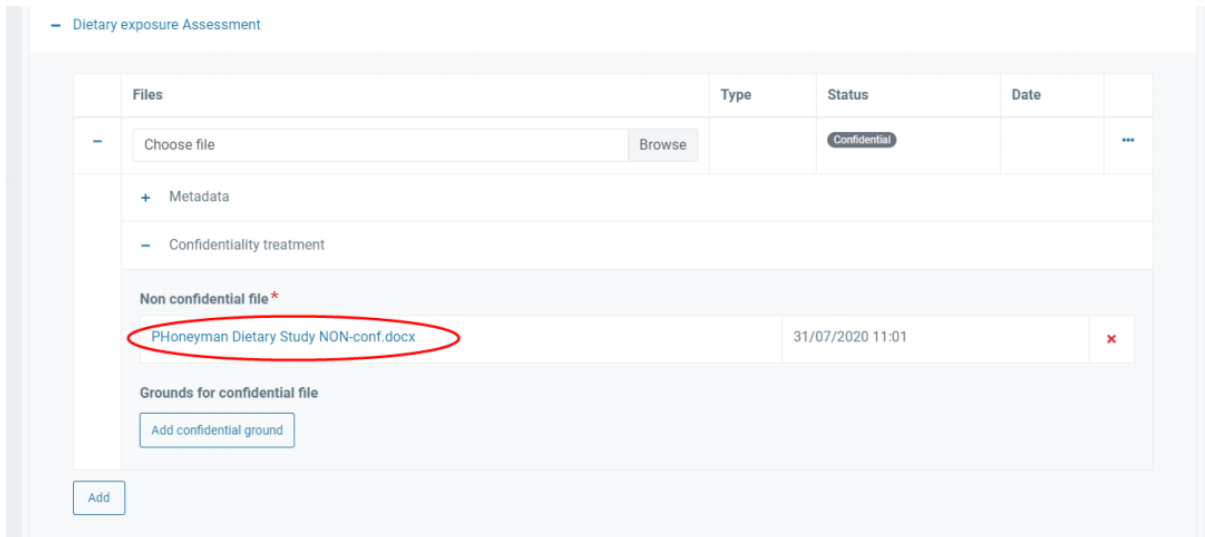
1. In the file upload fields, notice the badge by default invites **non-confidential** files. You can browse to and upload a non-confidential file, i.e. one containing no confidentiality requests, and proceed to identify the file type using the metadata '**Document type**' – see [Appendix A \(page 115\)](#).



2. If you have a file which will contain at least one confidentiality request, upload it here, unredacted, and click the three dots to select '**Request confidentiality treatment**'. The badge will change to '**Confidential**'. Note that if you choose to '**Update document**' and browse/upload a new version, all the metadata and confidentiality treatment information will disappear.



3. Upload its non-confidential file version. This will be proactively disseminated once your dossier has been validated. You can carry out this step at any point – but note that it is mandatory as a follow-up to *step 2*.



- Define your confidential file from the '**Document type**' list, see **Appendix A (page 115)**. Please note that if the document type selected is 'Study report', then additional metadata elements apply, as illustrated here in **step 19 (page 34)**.

The screenshot shows a table with columns: Files, Type, status, and Date. The first row contains 'PHoneyman Dietary Study CONF.pdf', 'Study Report', 'Confidential', and '11/02/2021 16:27'. Below the table, there is a 'Metadata' section with a 'Publicly Available' toggle set to 'No'. A 'Document type' dropdown menu is open, showing options: Owner- License Information, Publication, Raw Data, Scientific Summary, Study design, **Study Report** (highlighted with a red circle), and Summary report. A red circle also highlights the 'Study Report' option in the dropdown. A warning message is visible at the bottom of the dropdown menu.

- Select one ground for each confidentiality request. There may be multiple requests for the same content and document.

The screenshot shows the 'Confidentiality treatment' section. It includes a table with columns: Files, Type, status, and Date. The first row contains 'Phoneyman non-CONF study.png', 'Study design', 'Confidential', and '11/02/2021 17:29'. Below the table, there is a 'Grounds for confidential file' section with a '+ New Ground' button highlighted by a red circle. There is also an 'Add confidential ground' button.

- The pull-down offers general legal grounds for confidentiality, and additional grounds based on your food domain. Now add your justification for requesting confidentiality for this specific information, and paste the exact wording in question. This is a text-only field, so any graphic/table should be referred to by its title and position in the file.

Files	Type	status	Date
- PHoneyman Dietary Study CONF.pdf	Study design	Confidential	11/02/2021 16:27

Metadata

Publicly Available
 Yes No

Document type
 Study design clear

Article 39(2)(a) of Regulation EC No 178/2002 - the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;

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;

Article 39(2)(c) of Regulation EC No 178/2002 - commercial information revealing sourcing, market shares or business strategy of the applicant

Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety

Article 39(e)(1) of Regulation (EC) No 178/2002 - names and addresses of natural persons authoring unpublished studies any other personal data except for a. the name and address of the applicant; b. the names of authors of published or publicly available studies supporting such requests; and c. the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.

Article 39(e)(2) of Regulation (EC) No 178/2002 - personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies and in toxicological information and personal data of individuals involved or contained in human studies, as well as the name of authors of any unpublished studies

Ground is mandatory

Justification

Excerpt of the text

- In the '**Related section**' box, identify the exact position of the content for which you are requesting confidentiality treatment – by page/section number, column, paragraph, line, or word if necessary. Provide this document position in a sufficiently precise manner to exclude any information that is not subject to the confidentiality request.

Related section * ?

Related section

- Now you may select one or multiple applicable conditions that explain the disclosure risks for each selected legal ground.

The screenshot shows a form titled 'Related section' with a text input field containing 'Part 2, b4 - page 21'. Below this is a section titled 'CONDITIONS CHECK LIST' which contains several questions with checkboxes:

- Potential harm** 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 at least to 5% of their total turnover for legal persons, or earnings for natural persons. If the harm is quantified as not reaching this percentage, 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 legal of protection** Yes: The document, information or data for which confidentiality treatment is requested is worthy of legal protection in the form of the award of the confidentiality status;
- Environmental information** Yes: The document, information or data for which confidentiality status is requested does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation. [LINK to eurlax ?]
- Novelty** Yes: The document, information or data for which confidentiality status is requested has not been finalised more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason in the form of a free text in the respective Justification on why public disclosure of that information would still potentially harm its interests to a significant degree.

At the bottom of the form, there is a button labeled 'Add confidential ground' and an 'Add' button at the very bottom left.

- If you have multiple requests per file, a new request can be created by clicking 'Add confidential ground'. The new request may refer to the same ground or the same excerpt, but they have to be introduced separately.

The screenshot shows a file management interface with a table of files:

Files	Type	Status	Date
PHoneyman Dietary Study CONF.pdf		Confidential	01/04/2021 11:42
+ Metadata			
- Confidentiality treatment			
Non confidential file			
PHoneyman Dietary Study Non-conf.pdf			01/04/2021 11:42

Below the table, there is a section for 'Grounds for confidential file' with several options:

- + Article 39(2)(b) of Regulation EC No 178/2002 - commercial li
- + Article 39(2)(d) of Regulation EC No 178/2002 - quantitative cc
- + Article 12(3)(b) of Regulation (EC) No 1331/2008 - where appli information which is relevant to the assessment of safety
- Article 39(2)(b) of Regulation EC No 178/2002 - commercial li

The 'Ground' section is currently set to 'Article 39(2)(b) of Regulation EC No 178/2002 - commercial links'. Below this, there is a 'Justification' field with the text 'Enter a justification for not providing an EFSA study identification'. A 'Related section' field is also present, currently empty. At the bottom of this form, there is a 'CONDITIONS CHECK LIST' section with the same questions as in the first screenshot, and an 'Add confidential ground' button.



NOTE

For more details on the confidentiality process, visit EFSA's '[Transparency Regulation: Practical Arrangements](#)' page.



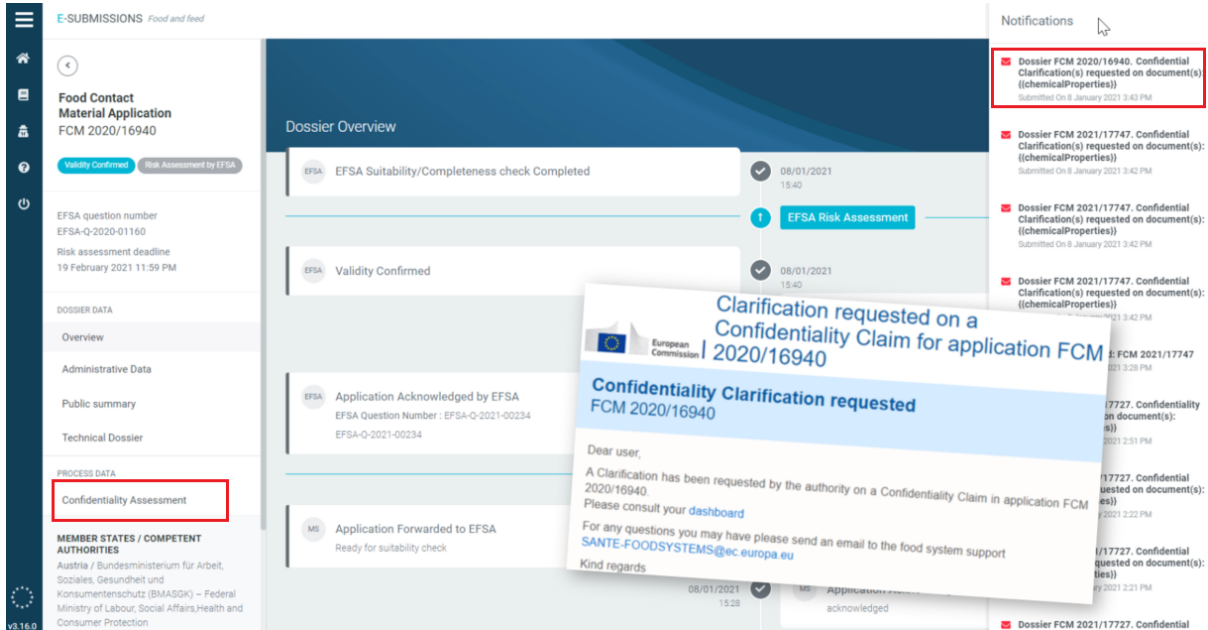
WARNING

Future confidentiality assessments may be triggered by the availability of new information or new scientific understanding.

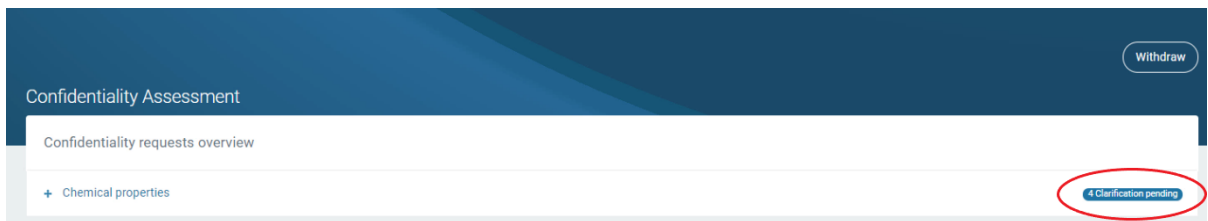
Responding to confidentiality clarifications

You need to respond to clarifications as soon as possible, because the process continues with or without your input.

1. After dossier validation, you will notice the new **Confidentiality Assessment** tab on the left pane. If there are clarification requests, you will receive an email and the notification bell will indicate activity.



2. Click the **'Confidentiality Assessment'** tab. This shows the section and number of clarification requests in 'pending' state.



- Click the '+' to open the relevant section. You will see the file, the confidentiality request ground, and the assessor question. Click **'Reply'** to read it in full and respond.

Confidentiality Assessment

Confidentiality requests overview

— Chemical properties 4 Clarification pending

Documents	Confidentiality requests	Clarification	Draft decision	Final decision	Sanitised	Action
Chemical props - CONF.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Pending			Reply
	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Pending			Reply

- Read the clarification, and respond with free-text in the box below. No files can be uploaded. Click **'Reply to clarification'**. The screen will display your reply - it has now been sent.

REQUEST AND DECISION / Chemical props - CONF.pdf

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
12.4

Request for clarification
Submitted by on 8 January 2021 3:42 PM
Clarification, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem

[Reply](#)

Clarification response, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem.]

REQUEST AND DECISION / Chemical props - CONF.pdf

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
12.4

Response to request for clarification
Submitted by on 8 January 2021 3:54 PM
Clarification response, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem.

[Reply to clarification](#) [Cancel](#)

5. The 'pending' badge is replaced by 'Replied'.

Confidentiality Assessment

Confidentiality requests overview

- Chemical properties 3 Clarification pending

Documents	Confidentiality requests	Clarification	Draft decision	Final decision	Sanitised	Action
Chemical props - CONF.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Replied			None
	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Pending			Reply

6. A draft decision for each confidentiality request arrives.

Confidentiality Assessment

Confidentiality requests overview

+ Chemical properties 2 Comment pending

7. The badges indicate the status. If the assessor does 'Not agree' with your confidentiality request, click 'Comment' to share your opinion.

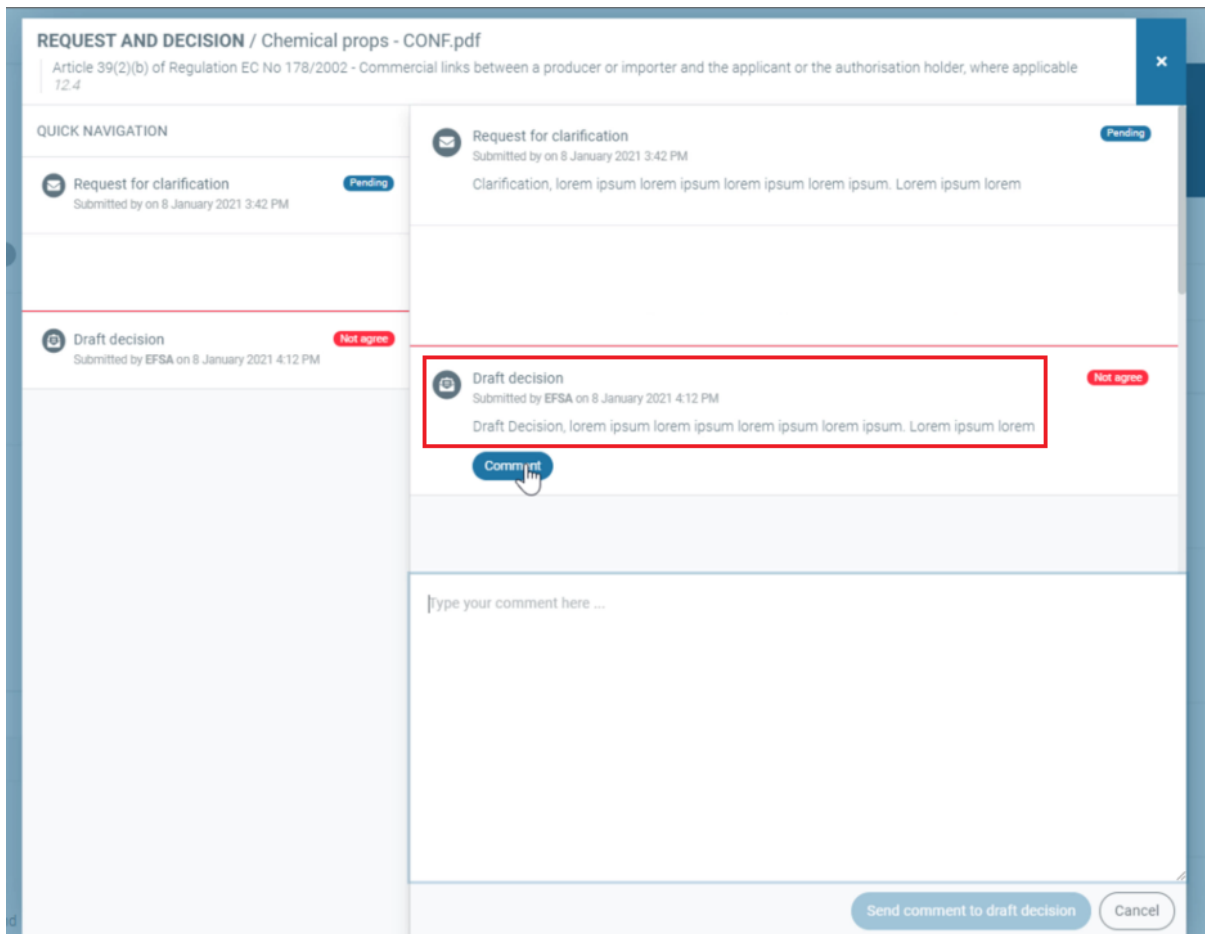
Confidentiality Assessment

Confidentiality requests overview

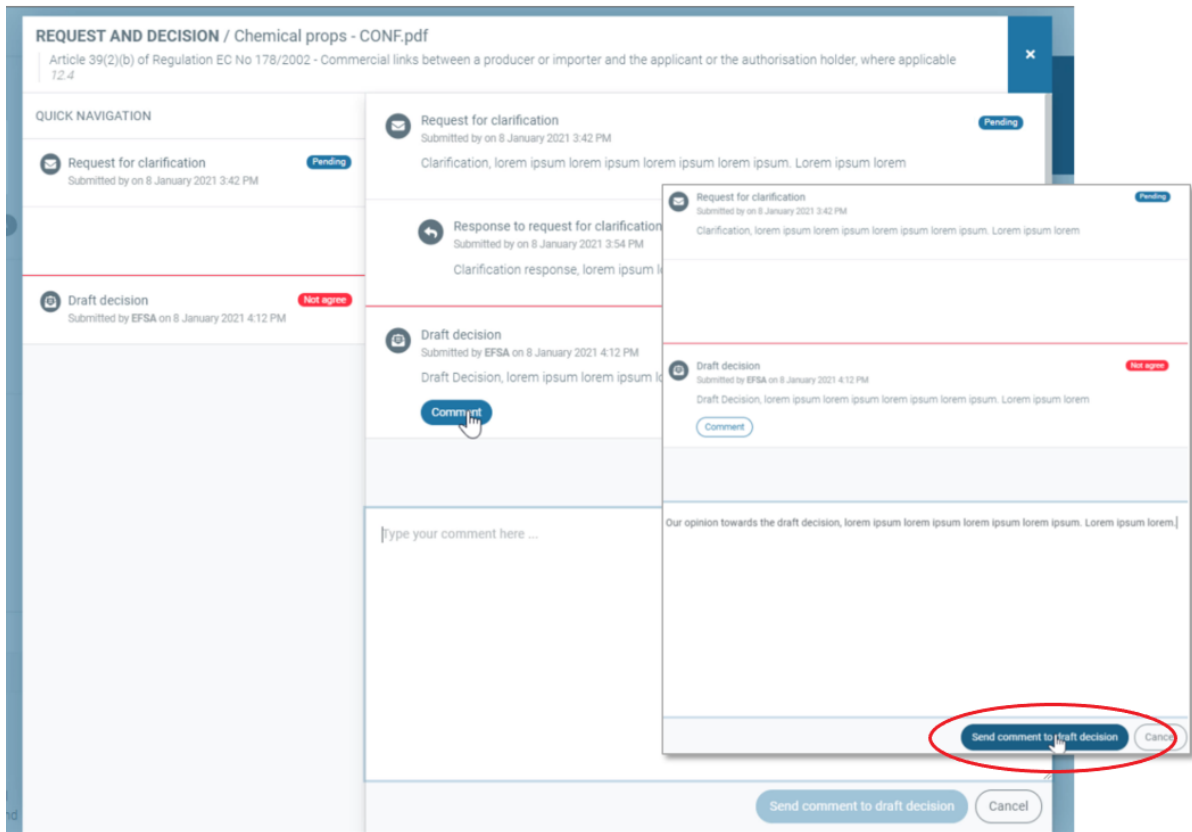
- Chemical properties 2 Comment pending

Documents	Confidentiality requests	Clarification	Draft decision	Final decision	Sanitised	Action	
Chemical props - CONF.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Replied	Draft Decision, lorem ipsum lorem ipsum lorem ipsum lorem ipsum lorem ipsum. lorem ipsum. Lorem ipsum lorem Submitted by EFSA		Accepted	Comment (Deadline: 28 Jan 2021 16:12)
	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by	Pending	Draft Decision, lorem ipsum lorem ipsum lorem ipsum lorem ipsum. Lorem ipsum lorem Submitted by EFSA		Not agree	Comment (Deadline: 28 Jan 2021 16:12)

8. Read the full draft decision. Click '**Comment**' to open the free-text field.



9. When you are ready, click 'Send comment to draft decision'.



10. The final decision arrives. You can check this by clicking the box.

Confidentiality Assessment Withdraw

Confidentiality requests overview

[Chemical properties](#)

Documents	Confidentiality requests	Clarification	Draft decision	Final decision	Sanitised	Action		
Chemical props - CONF.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 12.4	Clarification, lorem ipsum lorem ipsum Submitted by	Replied	Draft Decision, lorem ipsum lorem ipsum Submitted by EFSA	Agree	Decision, lorem ipsum lorem ipsum Submitted by EFSA	Accepted	None
	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ... 12.4	Clarification, lorem ipsum lorem ipsum Submitted by	Pending	Draft Decision, lorem ipsum lorem ipsum Submitted by EFSA	Not agree	Decision, lorem ipsum lorem ipsum Submitted by EFSA	Rejected	None

11. You receive the pre-publication notification by email, and you can read the 'sanitised' versions of your non-confidential files, reflecting the assessment decisions.

The screenshot shows the 'Confidentiality Assessment' overview page. On the left, there is a sidebar with navigation options and application details for 'Food Contact Material Application FCM 2020/16940'. The main area displays a table with the following structure:

Documents	Confidentiality requests	Clarification	Draft decision	Final decision	Sanitised	Action
Chemical props - CONF.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 12.4	Clarification, lorem ipsum lorem ipsum lorem ipsum. Submitted by	Draft Decision, lorem ipsum lorem ipsum. Submitted by EFSA	Decision, lorem ipsum lorem ipsum. Submitted by EFSA		None
	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ... 12.4	Clarification, lorem ipsum lorem ipsum. Submitted by	Draft Decision, lorem ipsum lorem ipsum. Submitted by EFSA	Decision, lorem ipsum lorem ipsum. Submitted by EFSA		None
XYZ ABC study - NOT notified.pdf	Article 39(2)(b) of Regulation EC No 178/2002 - Commercial links between a producer or importer and ... 3	Clarification, lorem ipsum lorem ipsum. Submitted by	Draft Decision, lorem ipsum lorem ipsum. Submitted by EFSA	Decision, lorem ipsum lorem ipsum. Submitted by EFSA		None
XYZ CDE Study_CONF notified ID 00001234.pdf	Article 39(2)(d) of Regulation EC No 178/2002 - quantitative composition of the subject matter of th ...	Clarification, lorem ipsum lorem ipsum. Submitted by	Draft Decision, lorem ipsum lorem ipsum. Submitted by EFSA	Decision, lorem ipsum lorem ipsum. Submitted by EFSA		None



IMPORTANT

If the Applicant disagrees with a decision, pursuant to Article 39b of Regulation (EC) 178/2002, they may submit a Confirmatory Application directly to EFSA. There is a dedicated email address to initiate this process: confidentialityconfirmatoryapplication@efsa.europa.eu



WARNING

If an applicant disagrees with a single confidentiality request disclosure opinion, the top-of-page **Withdraw** button applies to the entire dossier, not just that particular document or request. After withdrawal, all non-confidential content submitted will be removed immediately from the dissemination portal. See more on [Withdrawal \(page 93\)](#) and [process ending \(page 93\)](#).

Transparency

The provisions for the transparency and sustainability of EU risk assessment (the ‘Transparency Regulation’) are laid out in law, Regulation (EU) 2019/1381, and are integrated into the e-submission system, which enables legal compliance when submitting a dossier. The Transparency Regulation enters into application from 27 March 2021.

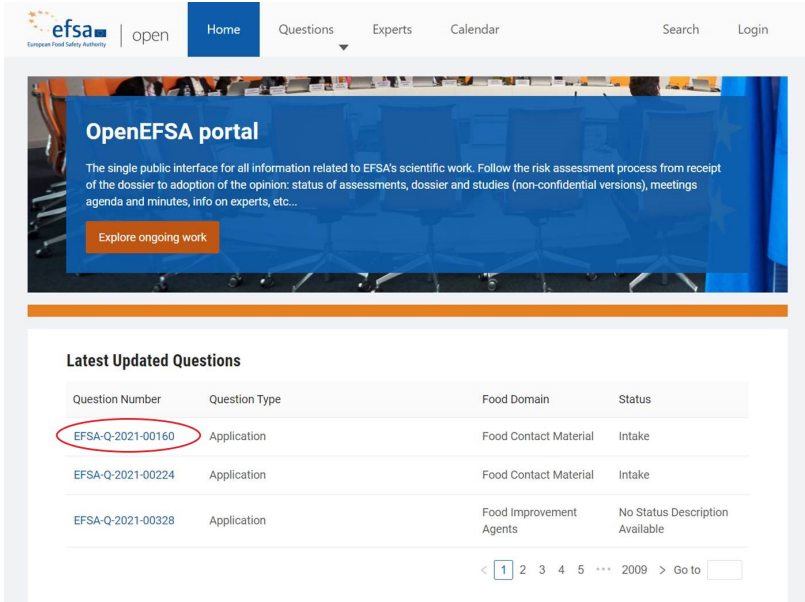
Upon validity of an application or notification, the non-confidential version of the dossier as submitted by the applicant or notifier will be disseminated on the OpenEFSA portal. After confidentiality assessment, the revised (‘sanitised’) version of these files will be disseminated as well. Data accepted as confidential will not be disclosed.

The general public will have access to the non-confidential versions of dossiers which inform the risk-assessment process. Third parties (stakeholders and the general public) will be consulted on these.

Public dissemination

The ESFC platform integrates the transparency regulation requirements for each domain during the input of dossier information. The platform has been developed so that information that is not considered to be confidential by the Applicant will be automatically disclosed after application validation on the [OpenEFSA](#) portal.

Accessing disclosed information



The screenshot shows the OpenEFSA portal interface. At the top, there is a navigation bar with the EFSA logo, 'open', and menu items: Home, Questions, Experts, Calendar, Search, and Login. Below the navigation bar is a banner for the 'OpenEFSA portal' with a description: 'The single public interface for all information related to EFSA's scientific work. Follow the risk assessment process from receipt of the dossier to adoption of the opinion: status of assessments, dossier and studies (non-confidential versions), meetings agenda and minutes, info on experts, etc...'. There is a button labeled 'Explore ongoing work'.

Below the banner is a section titled 'Latest Updated Questions' containing a table with the following data:

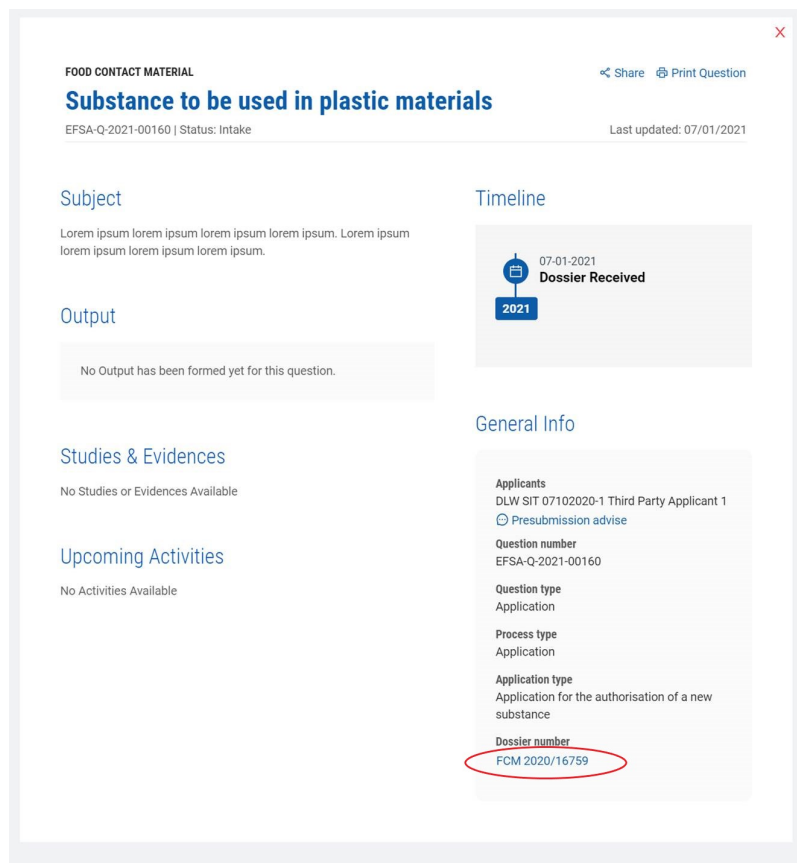
Question Number	Question Type	Food Domain	Status
EFSA-Q-2021-00160	Application	Food Contact Material	Intake
EFSA-Q-2021-00224	Application	Food Contact Material	Intake
EFSA-Q-2021-00328	Application	Food Improvement Agents	No Status Description Available

At the bottom of the table, there is a pagination control showing page 1 of 5, with a 'Go to' input field.

The OpenEFSA dissemination portal lists ongoing and previous submissions. Click on the Question Number to access the overview page.

The EFSA Question overview page contains the follow features:

- The **'Subject'** is the subject of the assessment as it was input through the 'Subject of request' field of the ESFC platform (shown in *step 6 here (page 14)*).
- The **'Output'** section provides a link to the respective EFSA Scientific Output, when this is available.
- The **'Studies and Evidence'** section displays the details related to the Notification of Studies linked to that dossiers, as well as some additional documents produced during the Risk Assessment.
- The **'Upcoming activities'** section will inform you on upcoming events like Panel or Working Group meetings, related to this application.
- The **'Timeline'** box reflects the dossier's status in the authorisation process. This mirrors the ESFC overview timeline.
- **'General Information'** collates the dossier's essential identifiers.



Click the dossier number to display the dossier's structure, data, and access non-confidential supporting information.

The screenshot displays the 'Question details' page for dossier number FCM 2020/16759. The interface includes a navigation menu with 'Home', 'Questions', 'Experts', and 'Calendar'. A search bar is located at the top right. The main content area is divided into two columns. The left column contains a tree view of dossier nodes, with 'Node C.9 - List of annexes, references and checklist' selected. The right column displays 'General info' for the dossier, including 'Regulated Domain', 'Food Contact Material', 'Receivers', 'Product', and 'Components'. The 'Receivers' section shows two entries, each with a name, address, and website. The 'Product' section contains placeholder text. The 'Components' section shows 'No name specified' with class type 'SUBSTANCE' and identifiers.



IMPORTANT

The dossier is publicly disseminated only when it is considered 'valid'. You will be informed through email notification, and this significant point in the process will display in the dossier timeline.

30/12/2020
13:22



Validity Confirmed

Video tutorials and support

Are you a new user and looking for a better understanding of how the ESFC platform works? Watch our hands-on tutorial videos by clicking the link above each icon, or visit EFSA's '[Applicant Toolkit](#)' webpage for more details on their support and activities. This [EC support page](#) outlines the Implementation of the Transparency Regulation.

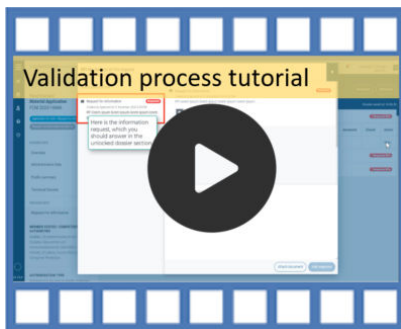
[Introduction to the process](#)



[Preparing your dossier](#)



[The validation process](#)



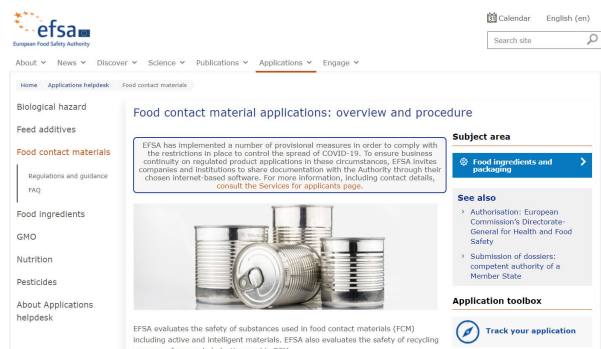
[Interactions and confidentiality](#)



[Opinion adopted and publication](#)



[EFSA range of guidance documents](#)



If you did not find what you were looking for, contact us directly: sante-e-submission-food-chain@ec.europa.eu

Appendix A. Metadata

The Applicant must categorise each uploaded file using the '**Document type**' dropdown menu, based on the following:

Certificate of analysis

This refers to the Certificates of Analyses that confirm that a product meets its product specifications, often required in different dossiers.

Checklist

This refers to the EFSA Checklist for the dossier requirements. If this is needed for your sector, the respective EFSA Administrative Guidance documents will give you instructions for its format.

Code for statistical analysis

This document type can be used for files containing the code used for statistical computing and graphics (e.g. R code, SAS, Python etc.).

Copyright licence

This refers to the licences by which the copyright holder grants permission for others to use material protected by copyright (e.g. published peer-reviewed studies).

Cover letter

This is used for the Cover Letter to the dossier, if required by the specific sector template.

Data sharing agreement/access letter

This refers to the written agreements between current and previous applicants that allow EFSA to access previously submitted data on the subject matter of the current application.

Flow chart

This refers to the graphical representation of flows or processes, often used to describe the manufacturing/production process, if required.

Graph/Image

This document type can be used for graphs and images provided in the technical dossier.

Laboratory accreditation certificate

This refers to the Certification given to laboratories confirming that it complies with certain quality standards, and can be used to support the application.

List of annexes

This refers to the detailed index (List) of all non-previously published files provided in the dossier. If this is needed for your sector, the respective EFSA Administrative Guidance documents will give you instructions for its format.

List of references

This refers to the detailed index (List) of all published studies or other publications provided in the dossier. If this is needed for your sector, the respective EFSA Administrative Guidance documents will give you instructions for its format.

Literature search

This refers to document describing the methodology (strategy, inclusion-exclusion criteria etc.) and results of the literature search performed in support of the application.

Other supporting documents

This document type can be used if the already available document type options cannot describe the submitted file.

Publication

This refers to the published studies, peer-reviewed articles or other publications and references provided in the dossier, used to support the application.

Raw data

This document type can be used for files containing raw, unprocessed, and non-aggregated data collected as a result of an original investigation.

Scientific summary

This refers to the detailed/scientific summary of the dossier, to be used if required by the specific sector template (this summary may contain confidential information); to be distinguished from Public Summary which cannot contain confidential information.

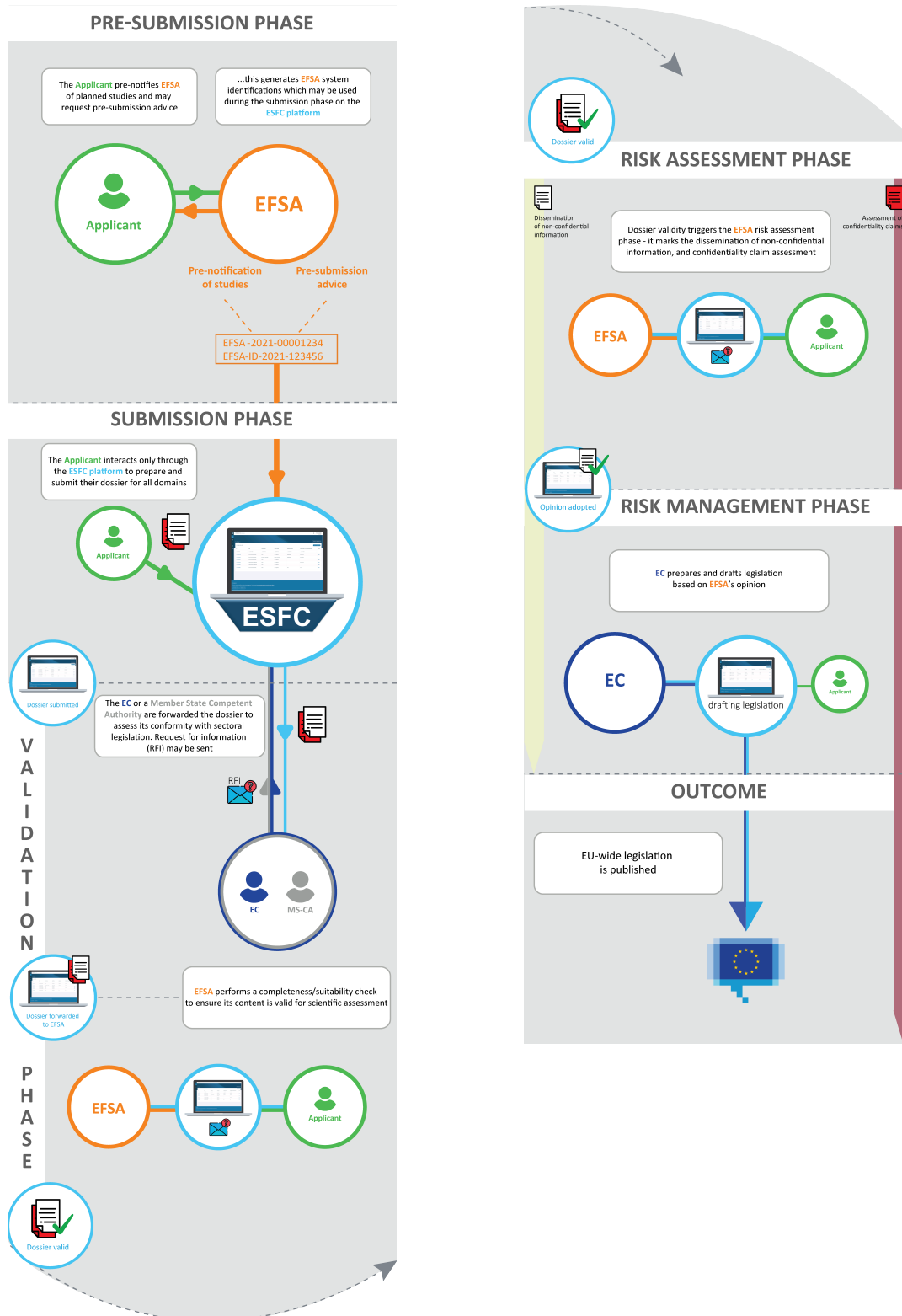
Study report

This refers to the unpublished study reports used to support the application. This document type will trigger some additional data requirements (e.g. notification IDs, Study type, Guideline, Authors etc.) and will support the applicant in complying with the Practical Arrangements on the Notification of Studies.

Technical dossier text

This refers to the Technical Dossier main text, summarising the information required in each one of the respective sections. It is usually accompanied by various annexes and references cited therein.

Appendix B. Authorisation





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