How to submit a dossier for EU authorisation

E-Submission Food Chain (ESFC) platform

User Guide v 9.5.0
April 2024

***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.

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** of this user manual 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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1 Welcome to the ESFC

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. On 27 March, 2021 that system ended. The **ESFC** platform operates for all food domains, excluding plant protection products and MRLs, which 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 the progress of their applications, and assessors can perform their tasks with trackable applicant interactions – i.e. Requests for Information (RFI) and via the communications channel for some domains.
- The system 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.

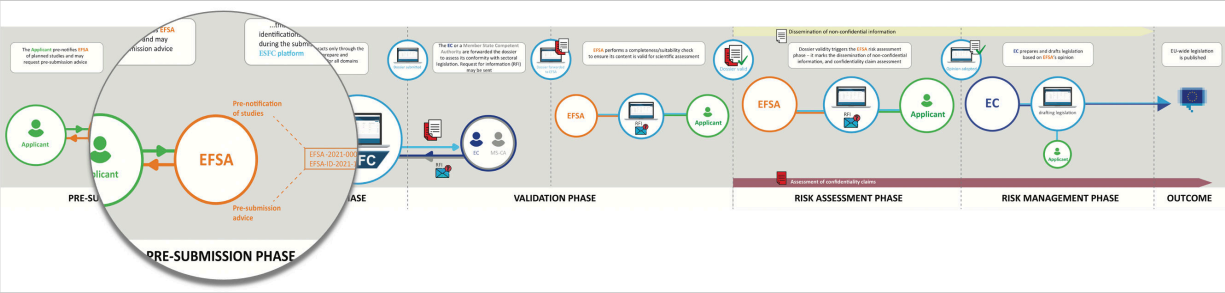
NOTE
Please note that applicants should use **IUCLID** plant protection products and MRL submissions. You will find more information about the IUCLID system in the EFSA Toolkit.

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).

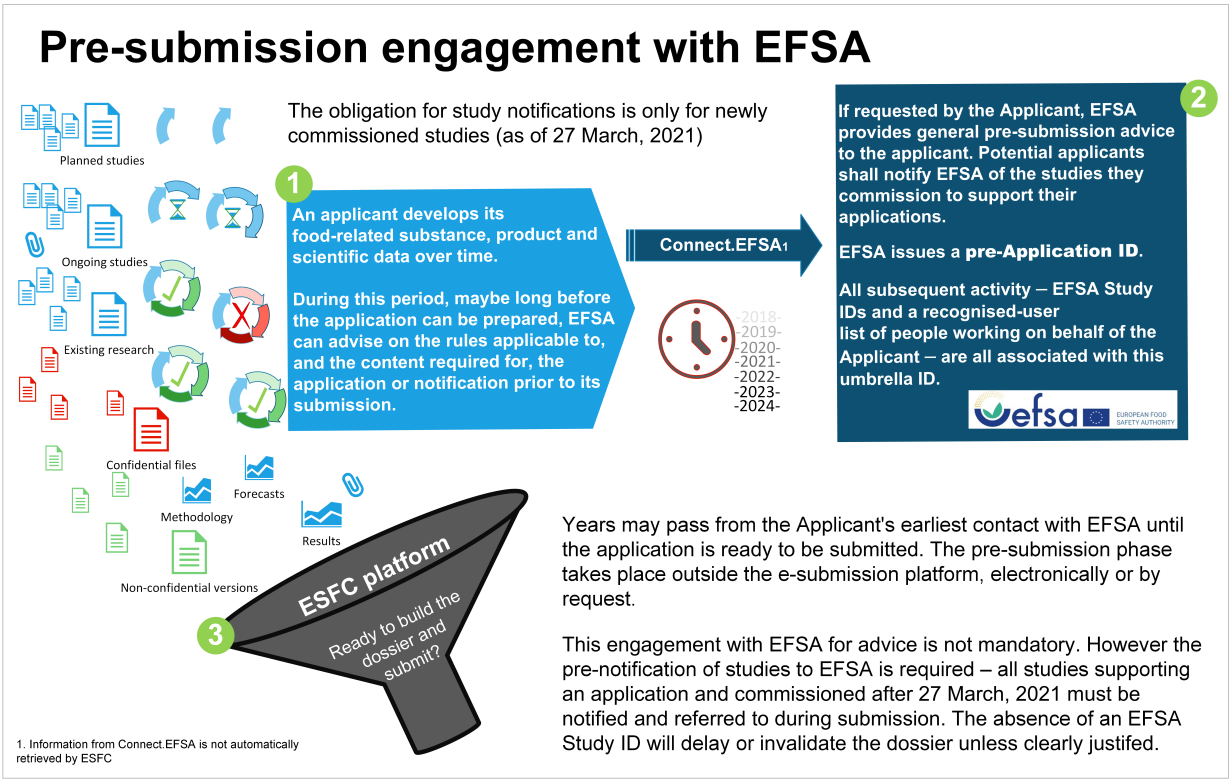
Be aware that after you click on a notification appearing under the bell icon  , it disappears from the drop-down list.

2 Pre-submission phase



Applicants can benefit prior to submitting their application by receiving pre-submission advice for renewals, 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.

Currently the integration with **Connect.EFSA** is not implemented, so the up-to-date information held on Connect.EFSA needs to be manually added in ESFC.



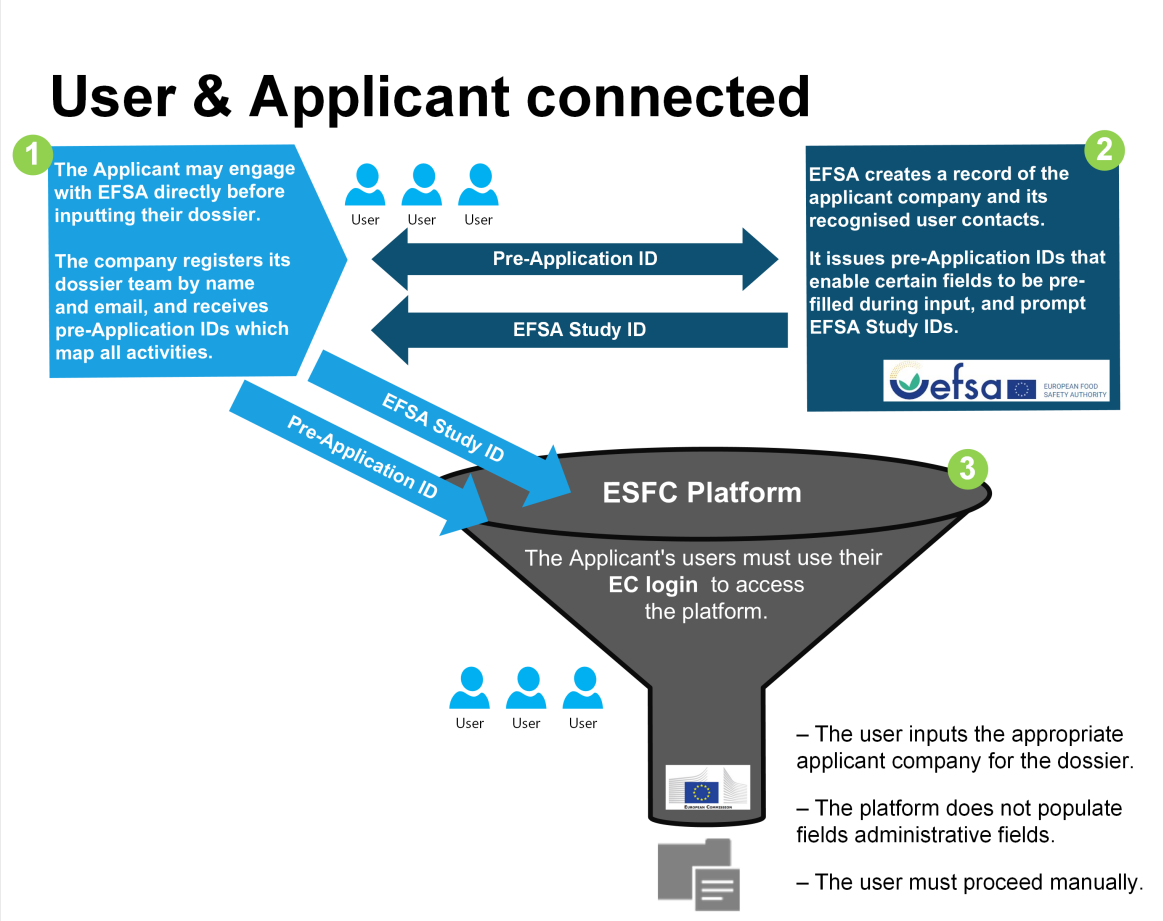
Wider insights and resources

Practical arrangements on pre-submission phase and public consultations
Applications Toolkit
Ask EFSA a question & FAQs
Connect.EFSA portal

2.1 User recognition in EFSA

If an applicant company sought pre-submission advice from EFSA and/or has notified studies, 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 **Connect.EFSA** portal. These contact people would later create and input the dossier and should be kept up to date in the portal.

Note that this information is not retrieved by ESFC automatically.

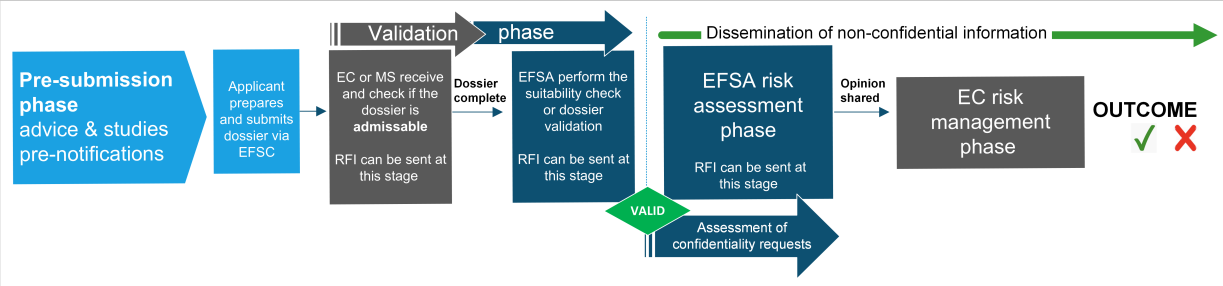


The ESFC platform will require each user to have a personal **EU login** to access and create a dossier. That is the only prerequisite.

NOTE
There can be multiple users for one dossier, see Manage dossier access [10].

IMPORTANT
The user recognition function is currently disabled. Applicants can still proceed and input the information manually.

3 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

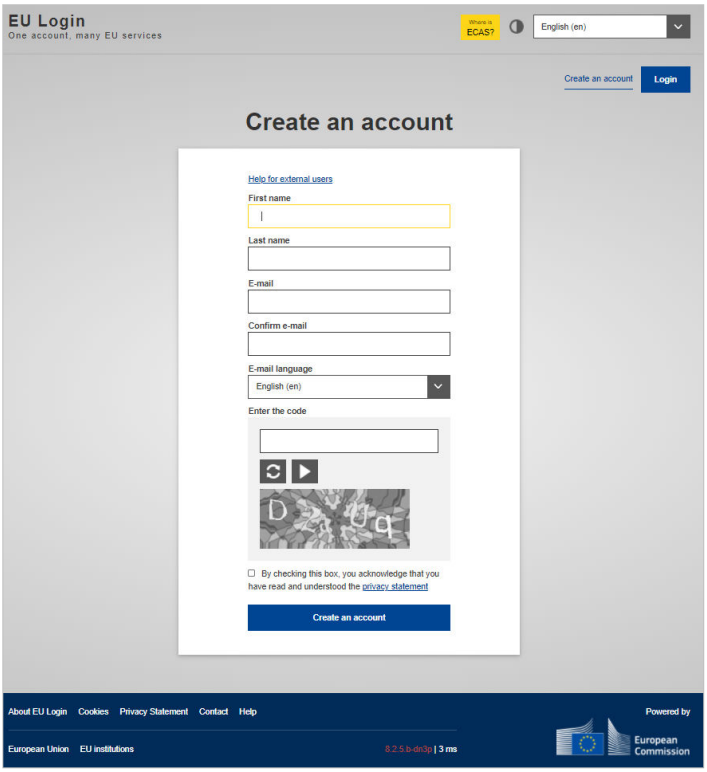
NOTE
The Autosave function ensures that the encoded content is saved automatically. There is no 'Save' button on the platform. Dossier saved at 20:18:19

TIP
To access the platform, you need an EU Authentication Login account [8].

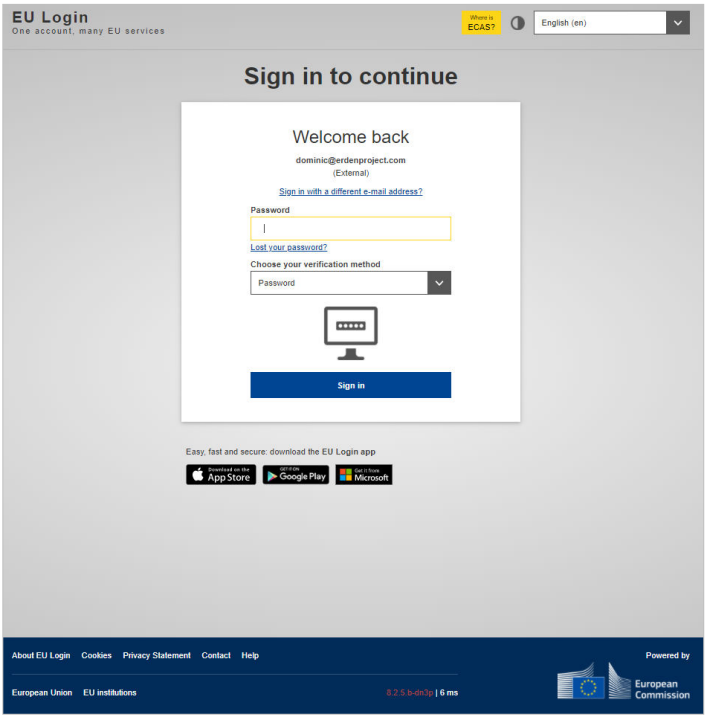
3.1 How to log in

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

If you don't have an EU Login account, please use this link:

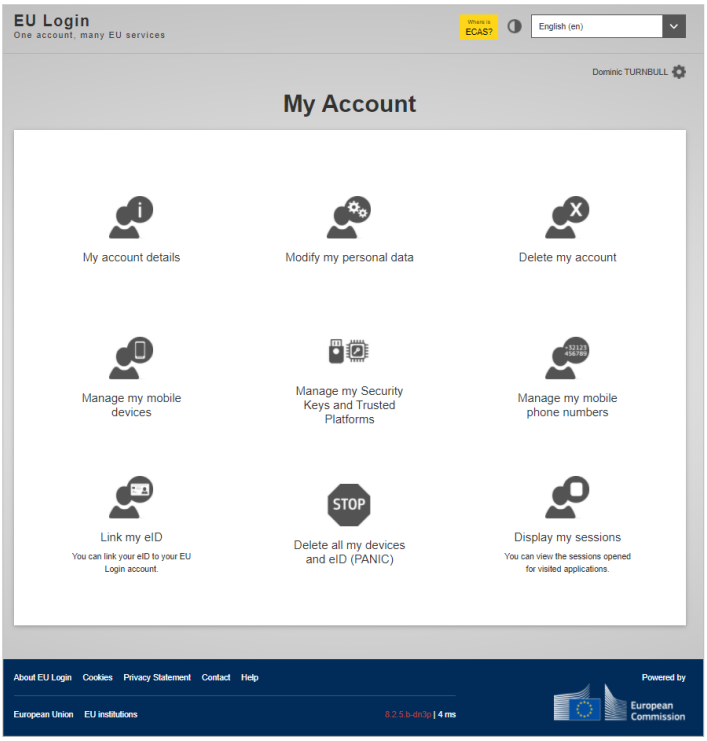


If you already have a user account for EU Login, you can log directly into the ESFC platform via this link:



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

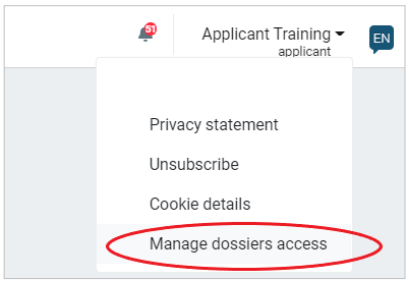
If you want to change your EU Login password, or edit your EU authentication login account, click here.



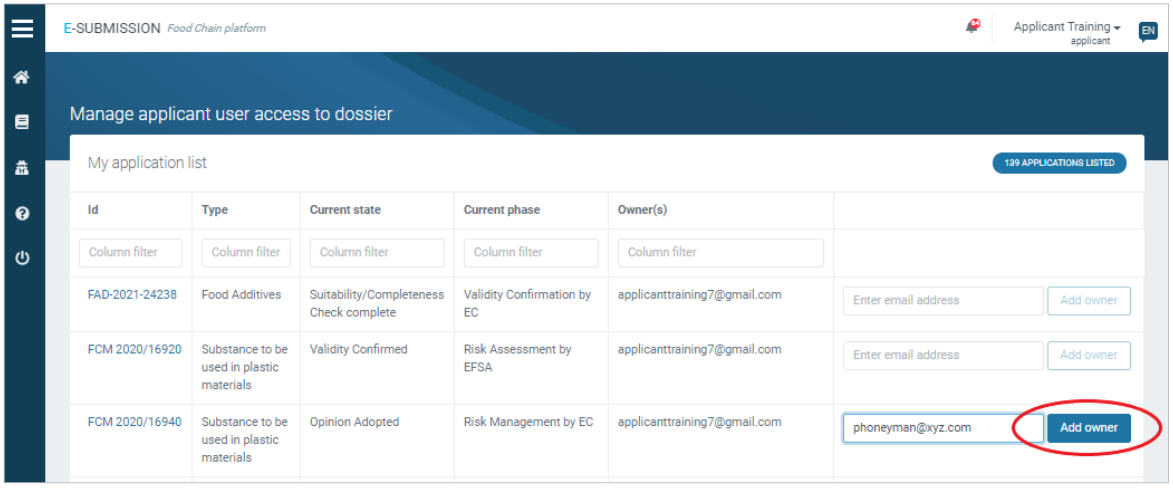
3.2 Dossier access management

The ESFC dashboard presents 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.

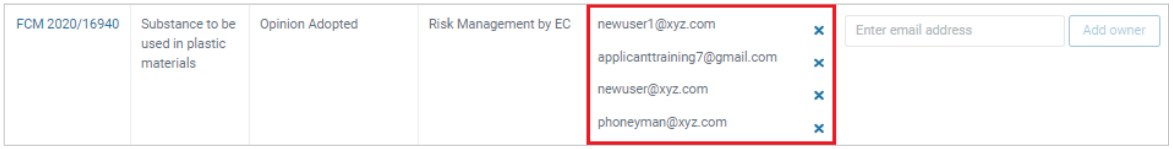
1. Provide access to other users by clicking the '**Manage dossiers access**' option in the top-right dropdown menu ' ▼ '.



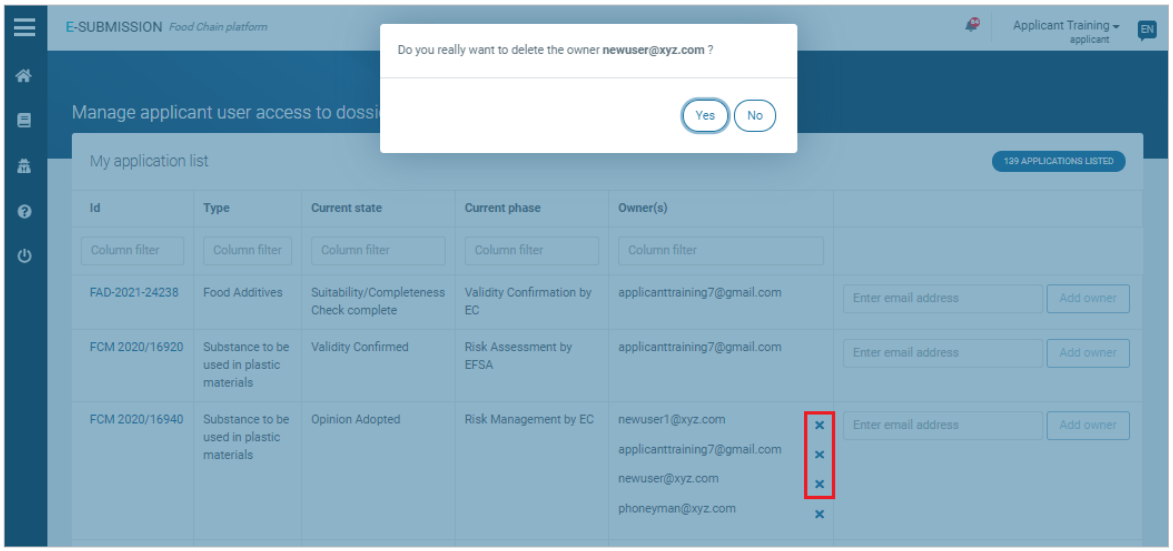
2. Click '**Add owner**' and input their email address. This must be the same as that used to perform their EU login.



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



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



NOTE

Around 90% of users who 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.

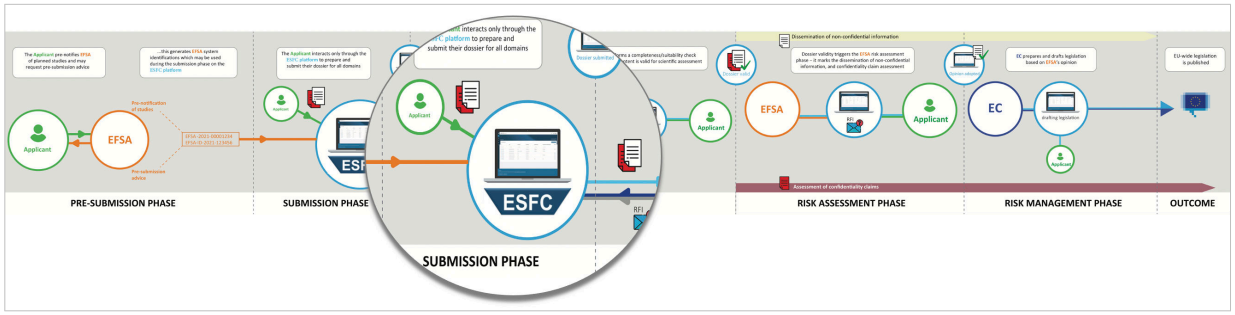
TIP

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

4 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.

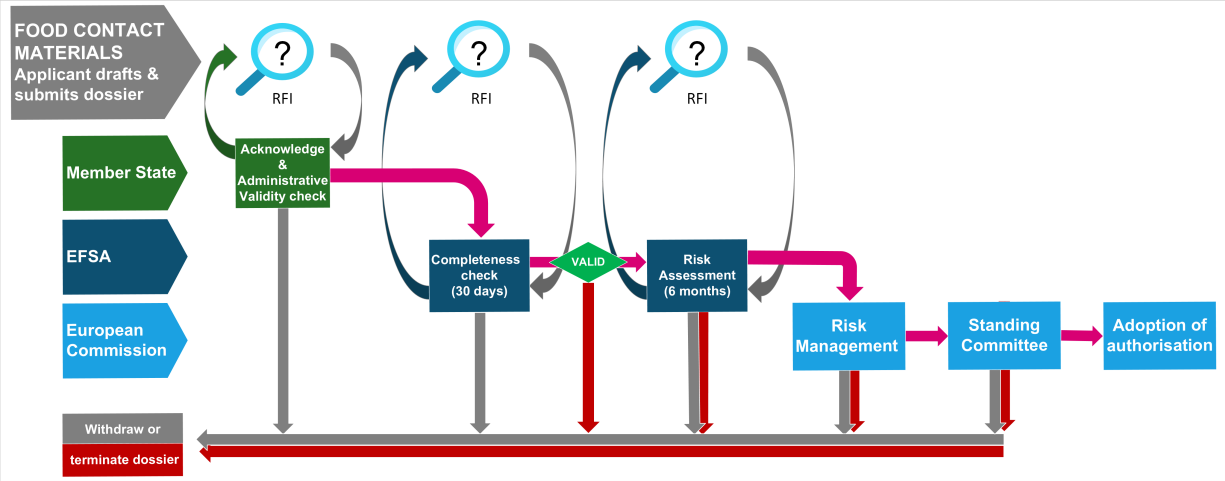
TIP
If certain fields do not apply in the context of your dossier, for example in the case of a submission supporting a modification or extension of an already existing authorisation, you can check the '**Not applicable**' box, then provide a suitable explanation in the text field that appears. You will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

The 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 [5] to better understand how to simplify the input process.

4.1 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.

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

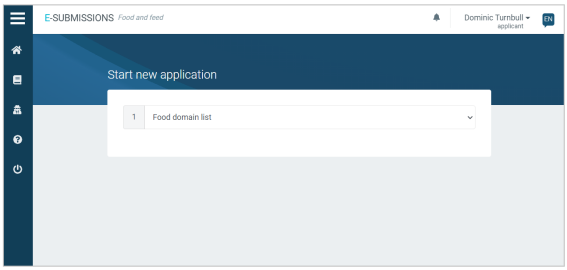
All dossier types selected in this category will generate a template built according to EFSA guidance and legislation. We use the sub-domain **'Substance to be used in plastic'** to demonstrate the submission process. Other FCM application types follow the same input procedures.

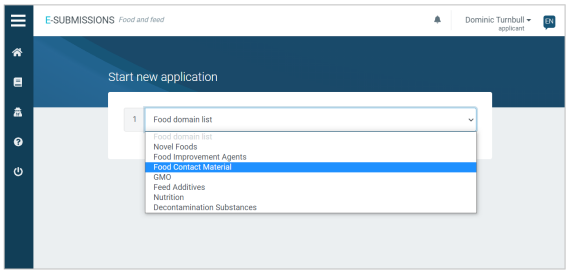
4.1.1 Getting started

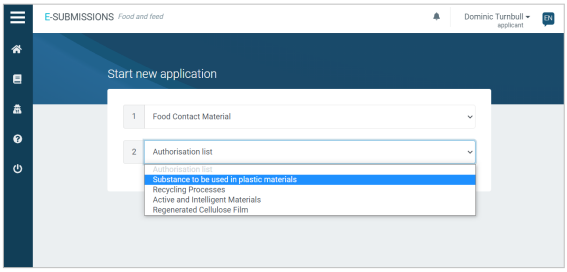
Create a dossier: Substance to be used in plastic materials

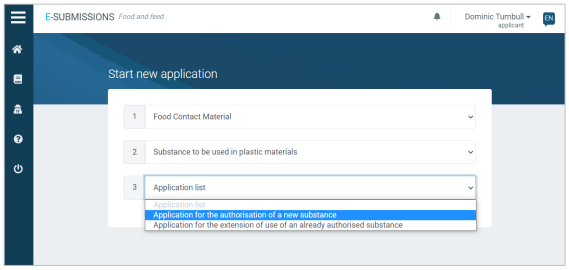
The following procedures and interactions with the ESFC platform are applicable for all domains.

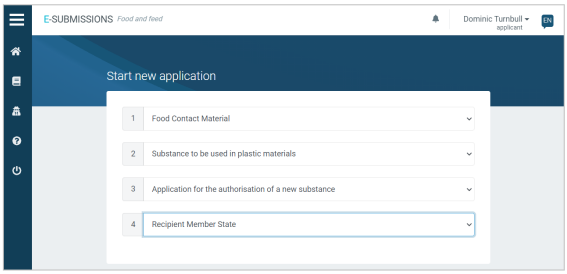
1. According to EFSA guidance and EC regulation, the distinct domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose your domain, in this example we select **Substance to be used in plastic materials**, the **Application type**,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

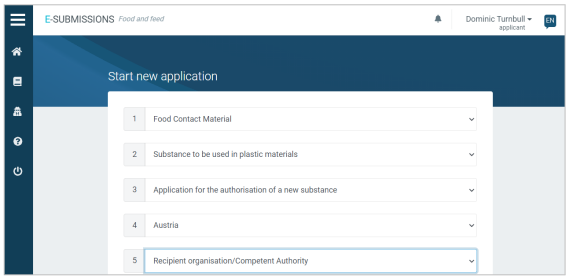




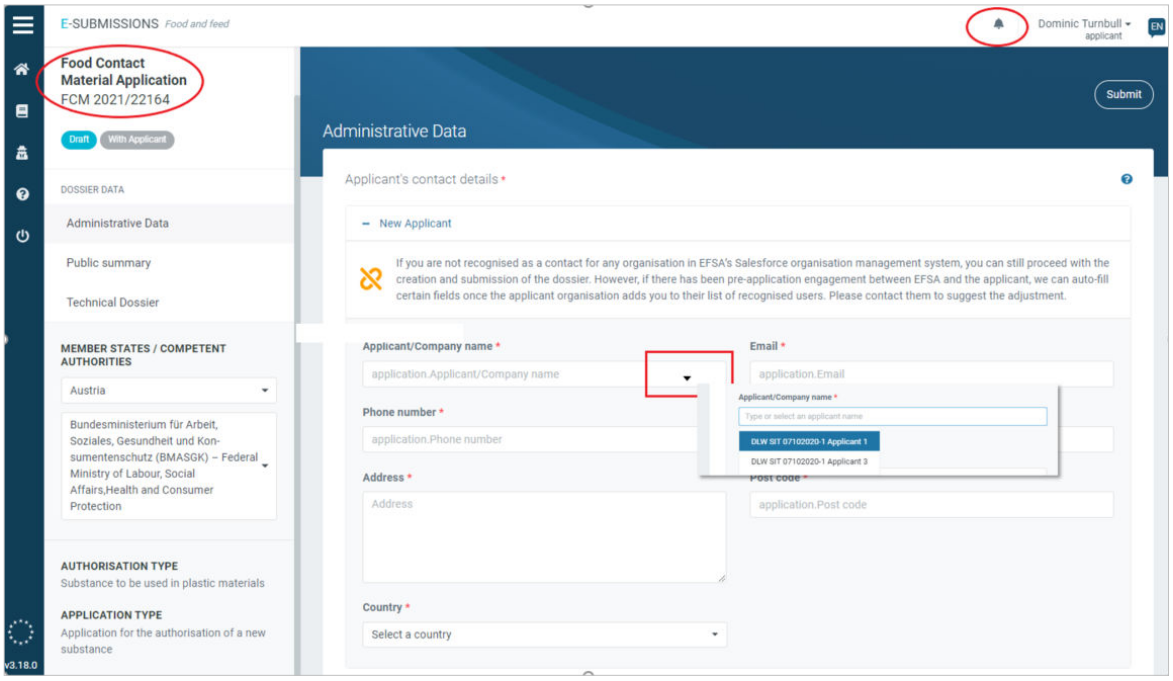




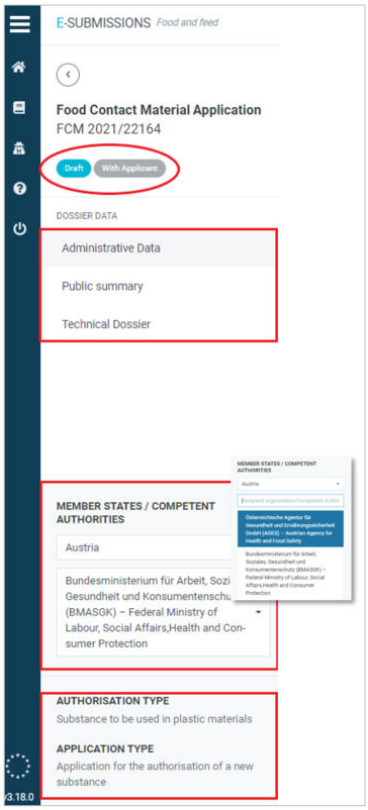




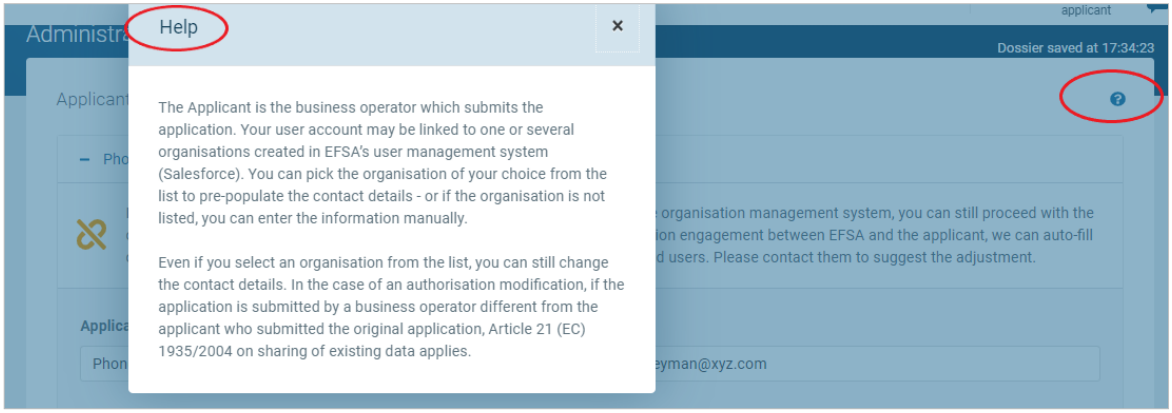
2. Complete the administrative data. Note the mandatory fields (*). If your login email is associated with one or more applicant companies, a list will drop down. From this you can select the appropriate Applicant. The system assigns a dossier number that remains throughout the process. The top-right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



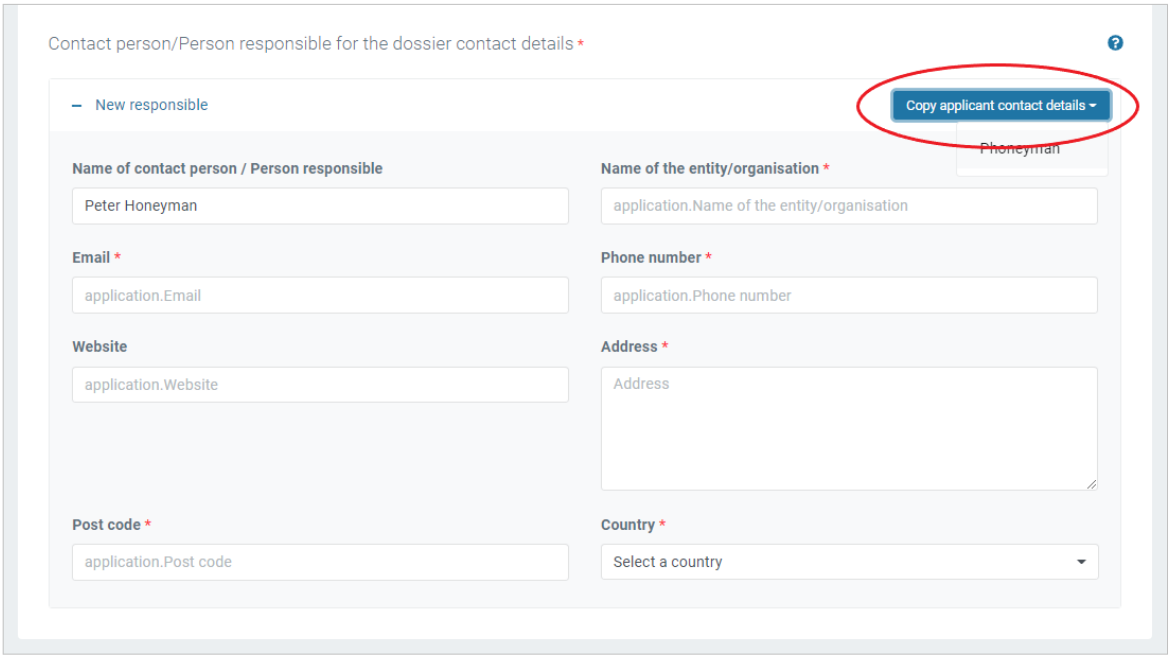
3. The top of the left pane shows the dossier status and phase. The three dossier sections (Administrative Data, Public summary, Technical Dossier) remain throughout. Your selected MS-CA displays, but you can select an alternative MS-CA, if one exists, via the dropdown menu that appears. The bottom section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



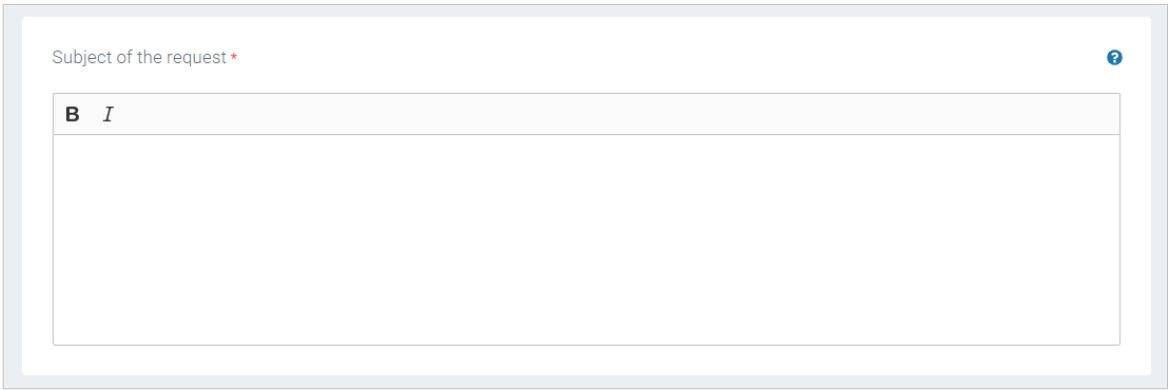
4. Click the '**?**' to see contextual help for the section, if available.



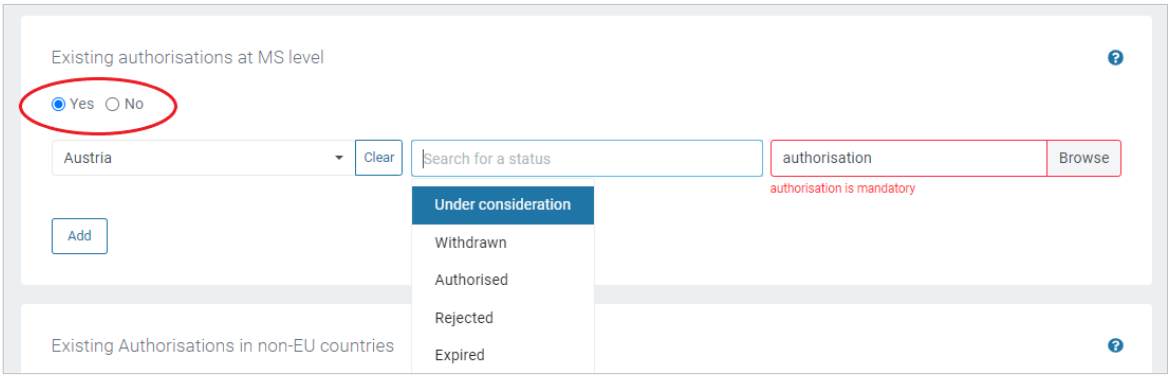
5. Click on '**Copy applicant contact details**' to duplicate the Applicants' data inserted in *Step 2*, in case the person responsible is working in the same company as the Applicant. Fields can be manually overwritten.



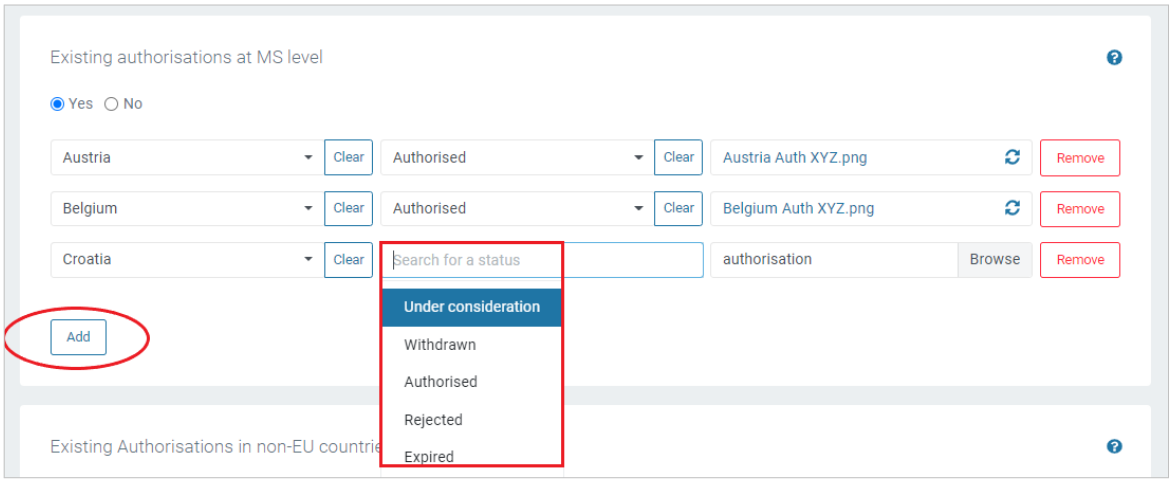
6. Enter the '**Subject of the request**'. You may consult the contextual help '**?**' for additional information.



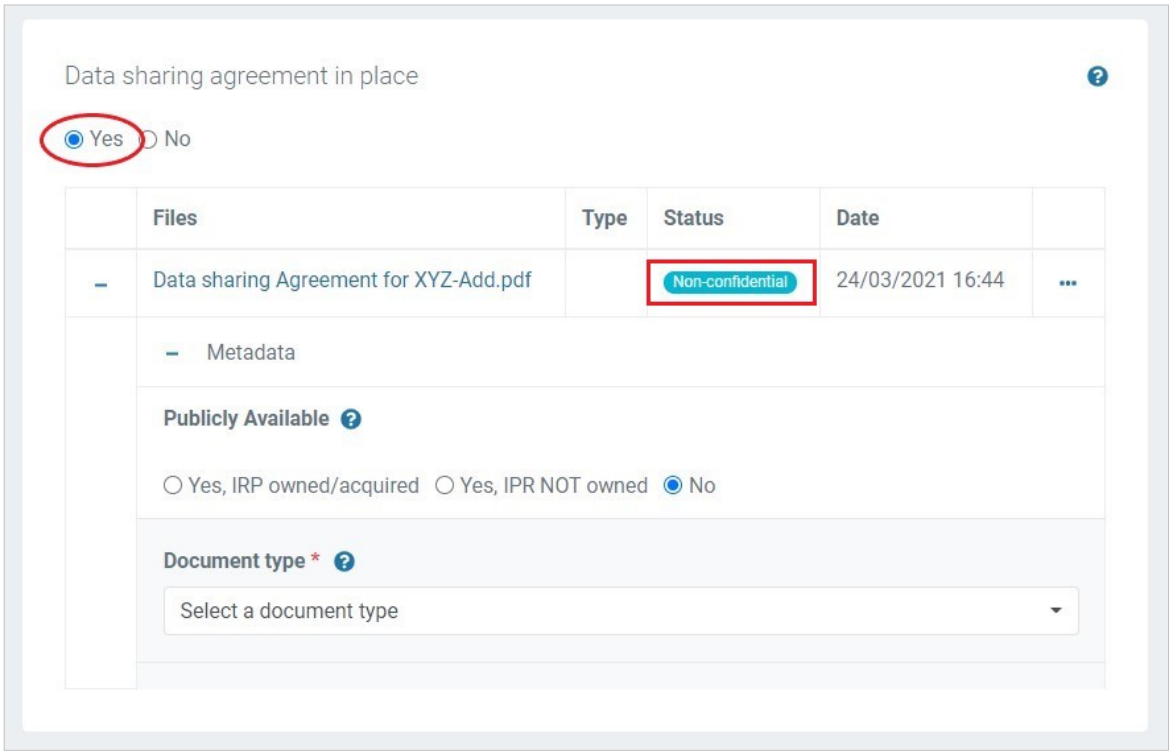
7. If there is authorisation history to the subject of this dossier, click '**Yes**', then indicate the related Member State. Select the status, then browse to and upload relevant documents with supporting information.



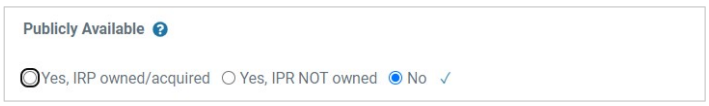
8. Click '**Add**' to detail other Member States where the subject of the dossier has history, and upload documents as before.



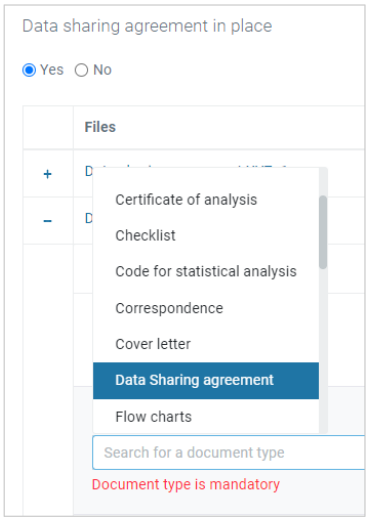
9. If a data-sharing agreement is available relating to the entire dossier, click the '**Yes**' radial. Click '**Add document**' for multiple agreements.



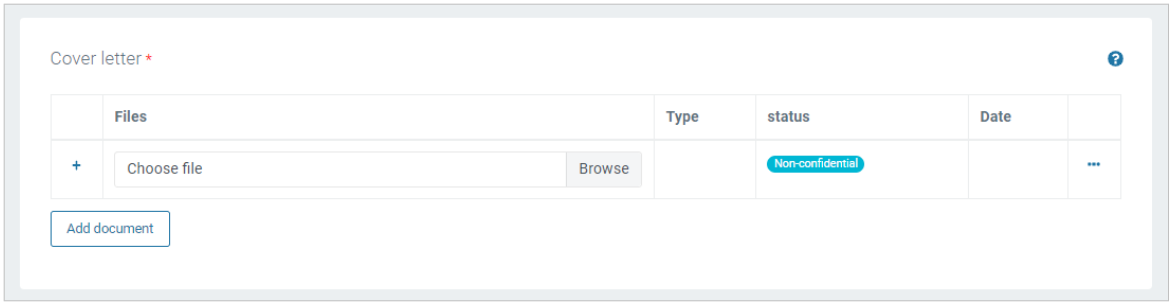
10. Indicate for each document whether it is '**Publicly available**', or whether there are related IPR considerations. The default setting is '**no**'. For more information on how IPR impacts disclosure, read the chapter Intellectual Property Rights [119].



11. Now identify the '**Document type**' via the metadata dropdown (see Appendix A [157]). In this instance, select '**Data Sharing agreement**'.

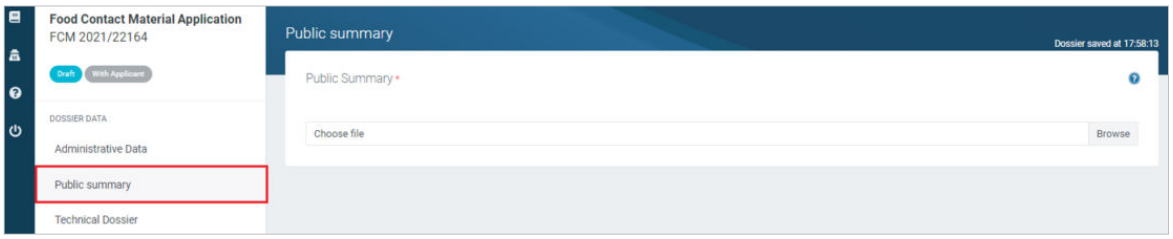


12. Upload the cover letter.

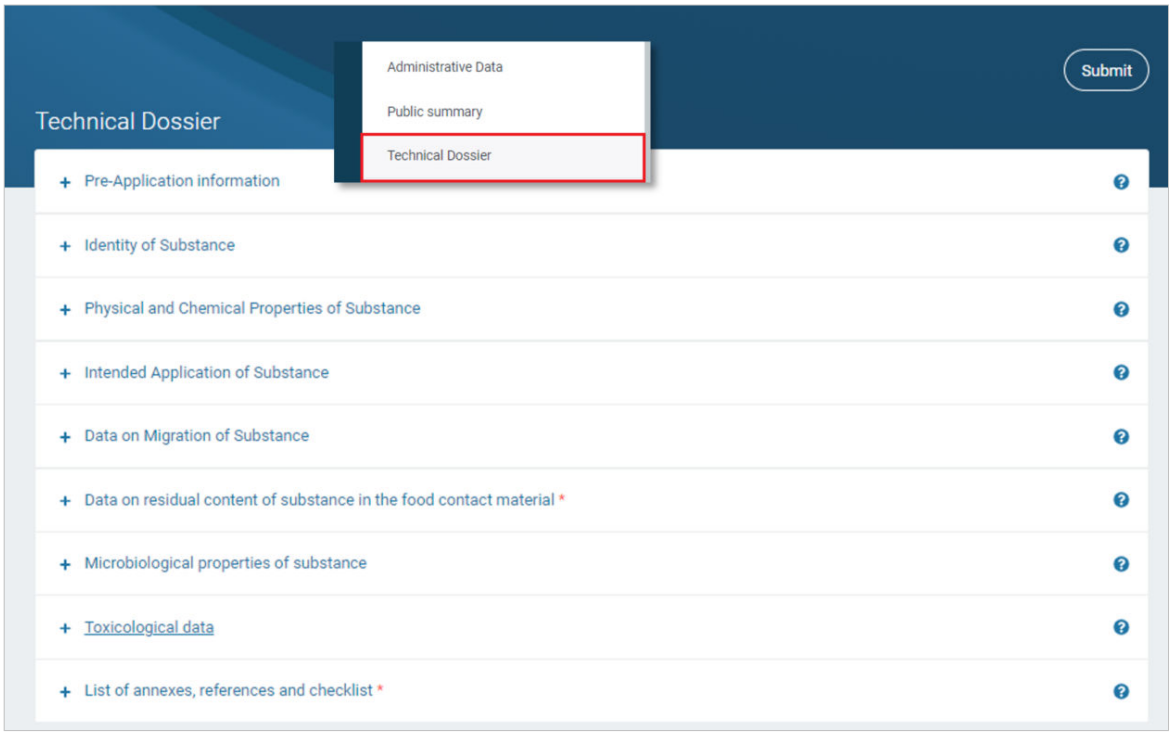


13. State whether the substance of this dossier has previously been made '**non valid**' by EFSA due to irregularities in the provided Notification of Studies information. If 'No', then continue. If you state 'Yes' however, you then need to identify the earlier dossier submission(s) which EFSA blocked.

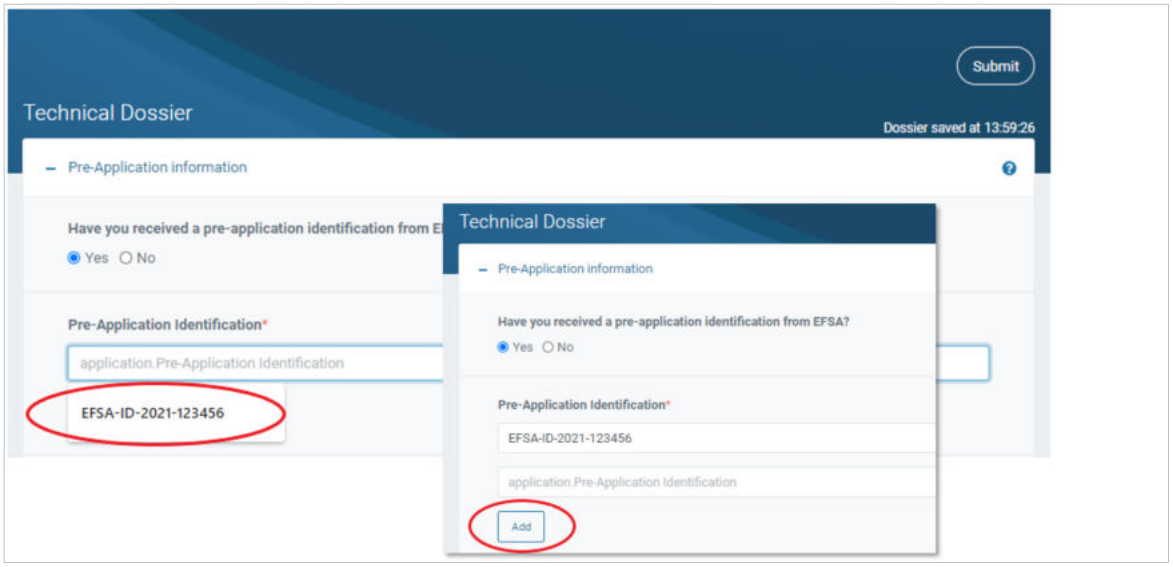
14. Click the '**Public summary**' tab, upload a public summary.



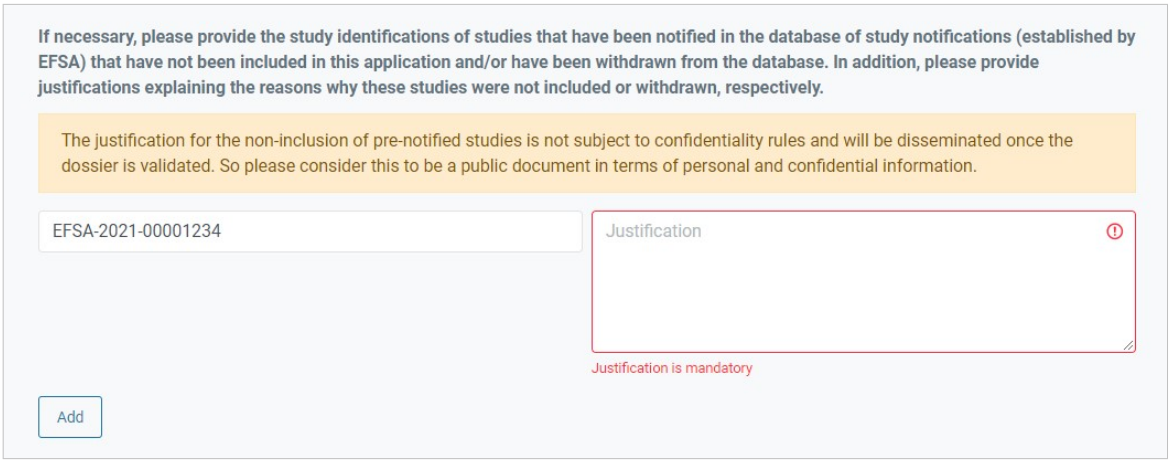
15. Click to the '**Technical dossier**'. The table of contents reflects the sections required by legislation and/or outlined in EFSA guidance.



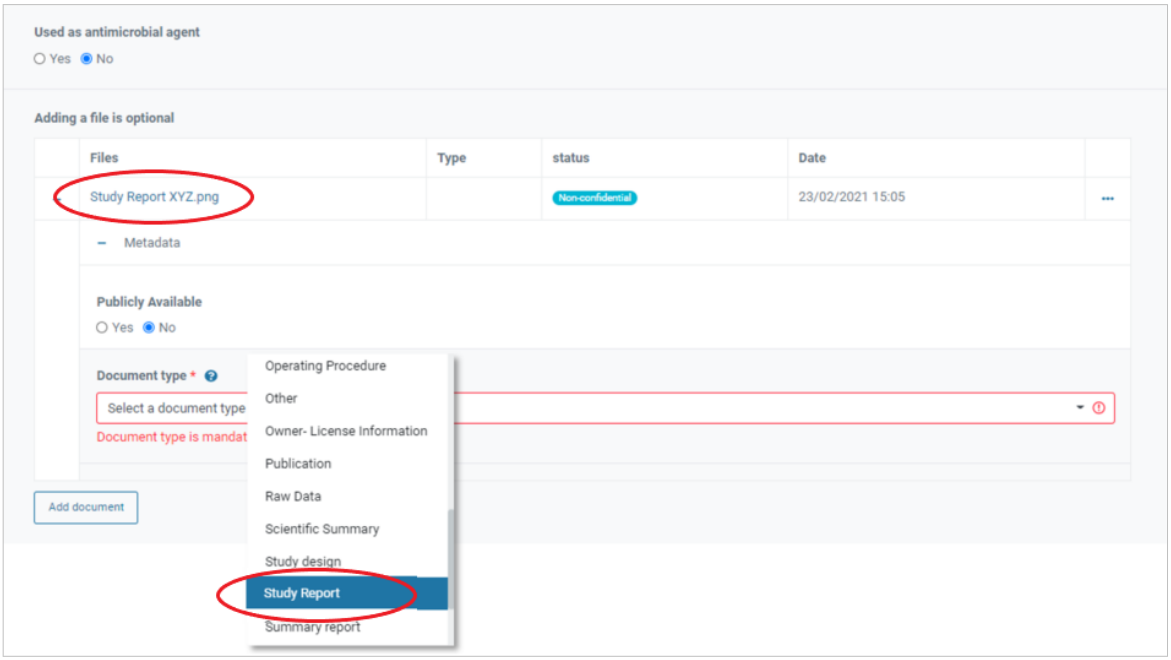
16. If the Applicant engaged with EFSA during the pre-submission phase, they would have been assigned a pre-Application Identification number. Please input it here. Note the format. Click '**Add**' to include multiple IDs.



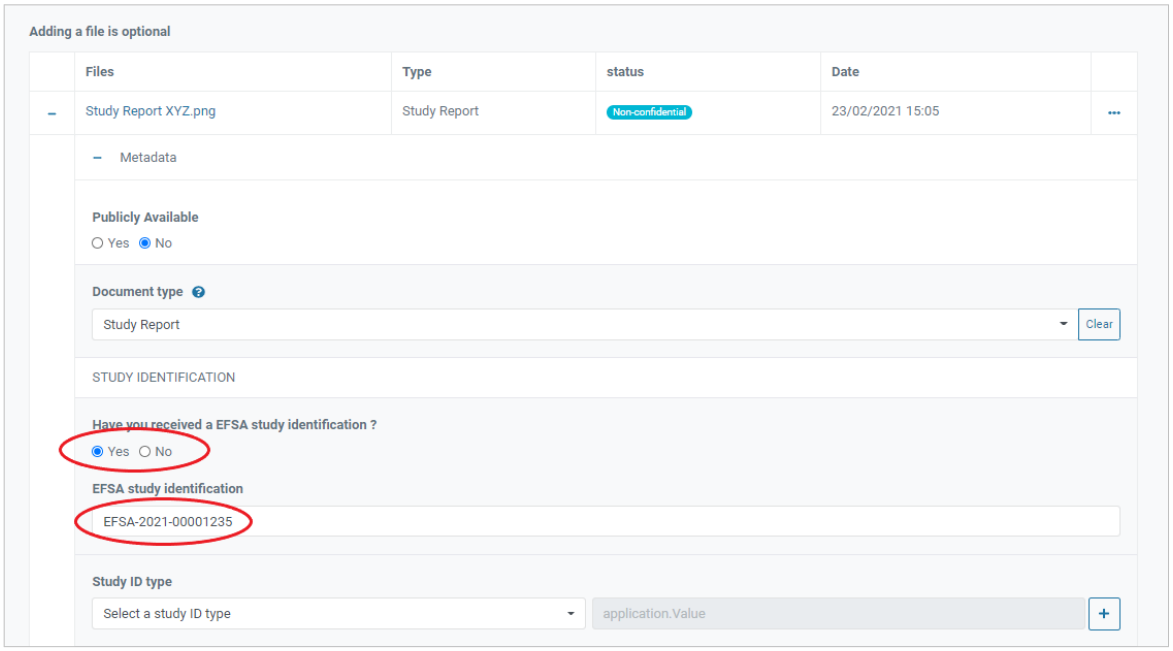
17. If the Applicant notified a study which was withdrawn or otherwise is not present within this dossier, input its EFSA study ID here, including a justification for why it has been omitted. Click '**Add**' if there are multiple study omissions.



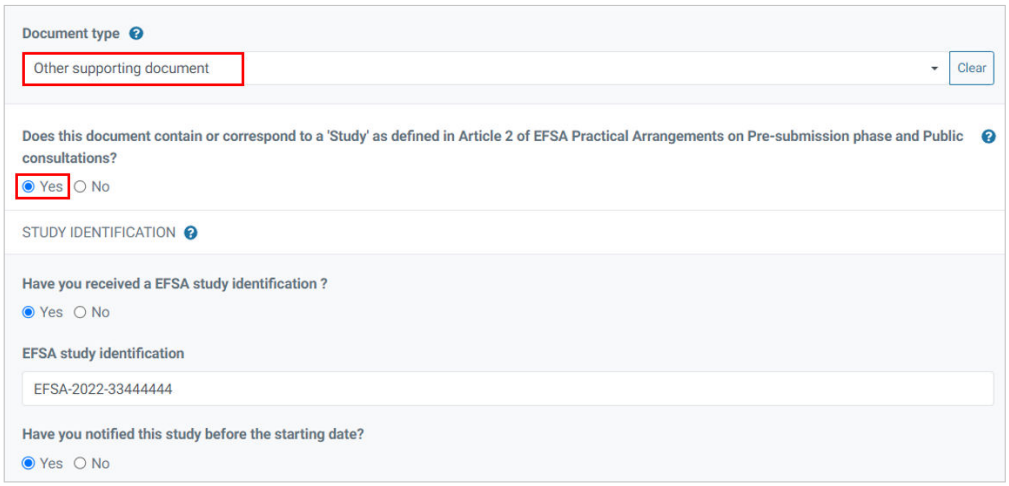
18. When you upload a file in any section, you must select the metadata '**Document type**' from the dropdown menu. If you upload a study report, select '**Study Report**', which will launch some additional fields (e.g. EFSA study ID, Study type, Title, authors etc).



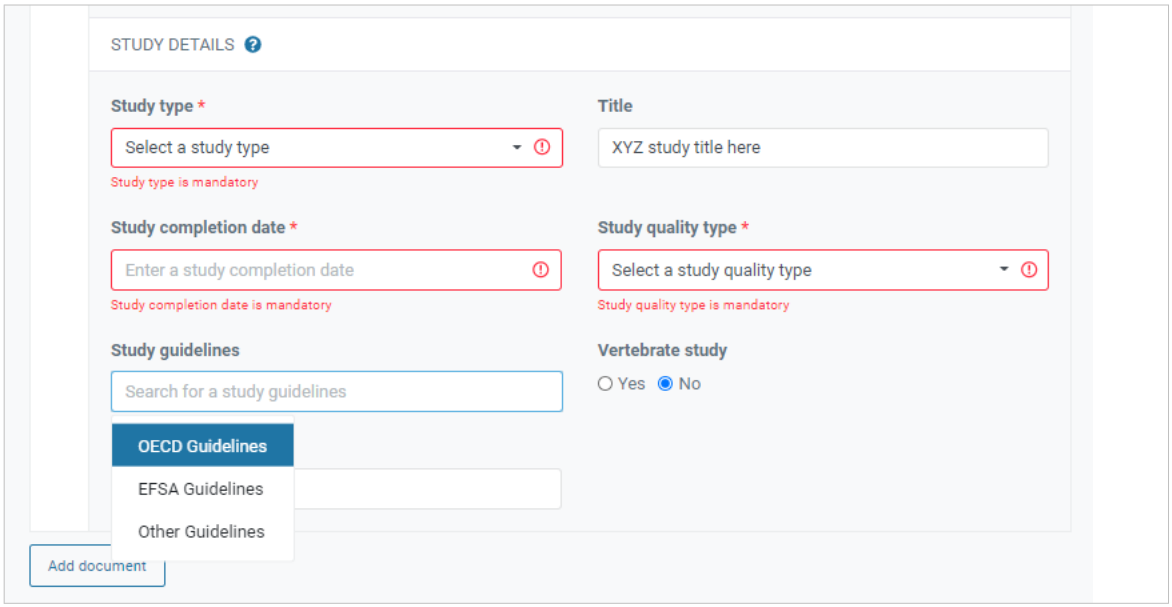
19. Input the **Study ID** as assigned by EFSA when the study was notified. If you select **No** or **you haven't notified the study before the starting date**, you need to provide a justification.
    Now complete the study ID type and identifier.



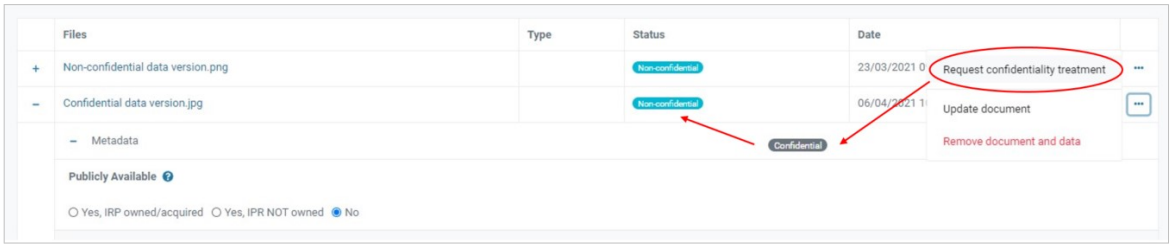
20. Documents with selected metadata **'Certificate of Analysis'**, **'Raw Data'** or **'Other supporting document'** will also trigger the option to provide an EFSA study ID.
    If the document contains or corresponds to a study, click **Yes**. Once the EFSA Study ID is filled in, a new field related to notifying the study before the starting date is displayed. If there is no EFSA study identification for that study, click **No** and provide a justification.



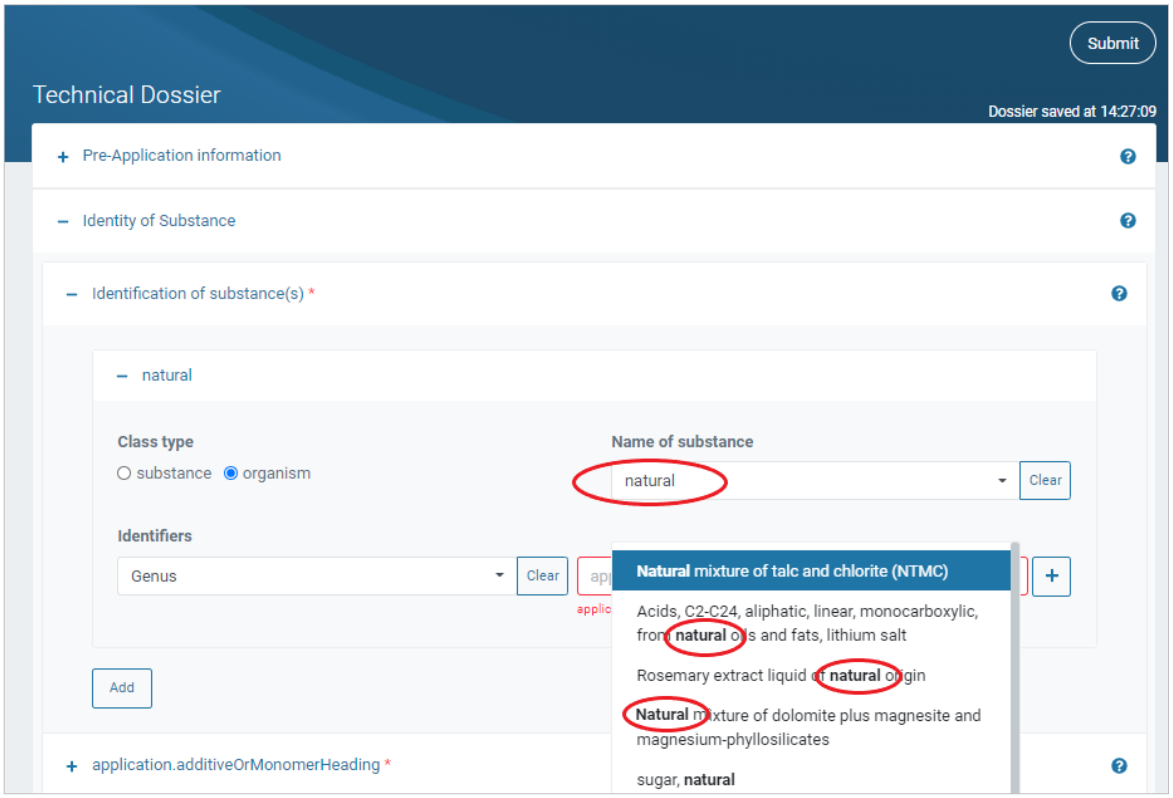
21. Complete the study fields, with related dates and values. These entries will be disseminated.



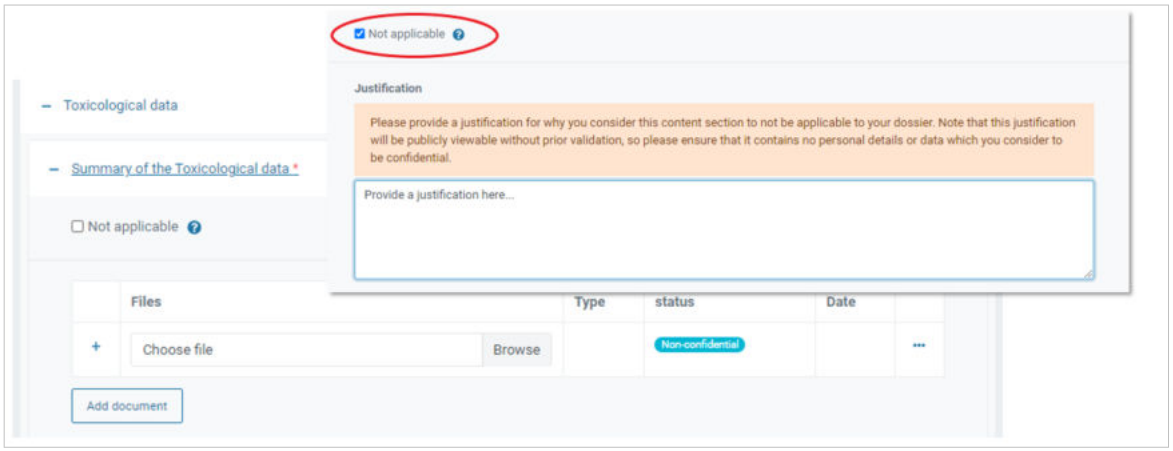
22. You can upload non-confidential files. By default, the green badge indicates 'Non confidential'. You can also upload files in which you will make one, or multiple, requests for confidentiality. Click the three dots and select '**Request confidentiality treatment**' once each is uploaded. The badge will now indicate 'Confidential'. See How the request confidentiality [130] for more details.



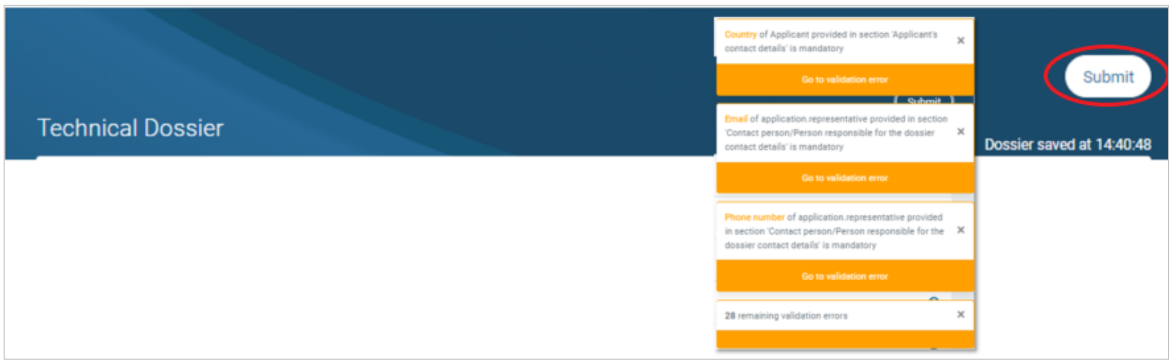
23. When you select from a dropdown menu '▾', type a key word and options will be presented if that word exists in the database. Here we see the free-typing option available for substance selection. But note that in some cases there is a 'closed list' of selections.



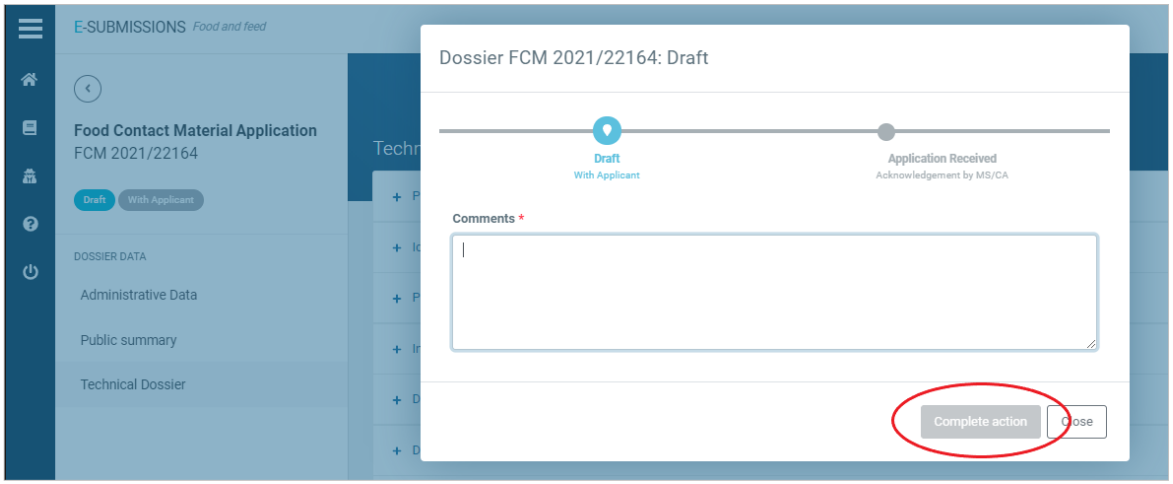
24. Some mandatory fields may not apply to your dossier. Click '**Not applicable**' and provide a justification.



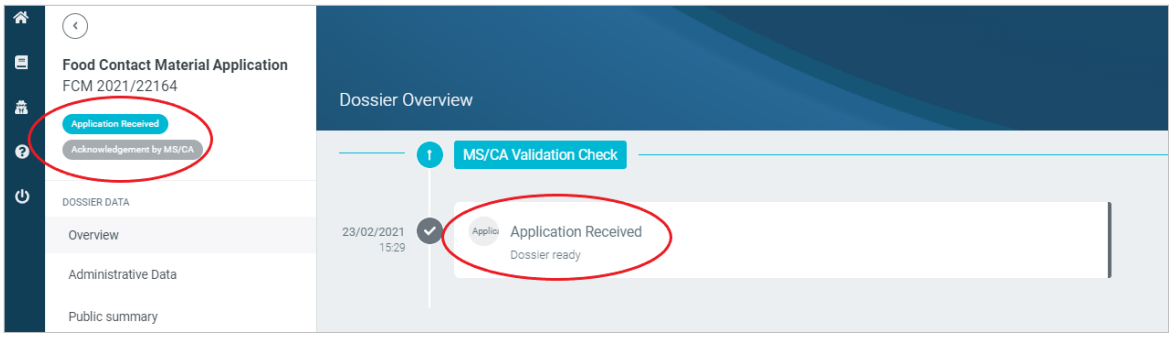
25. When all dossier sections have been completed, click '**Submit**'. If mandatory fields remain incomplete, error messages will appear. These needs to be addressed. Click on '**Go to validation error**' to arrive at each blocking section.



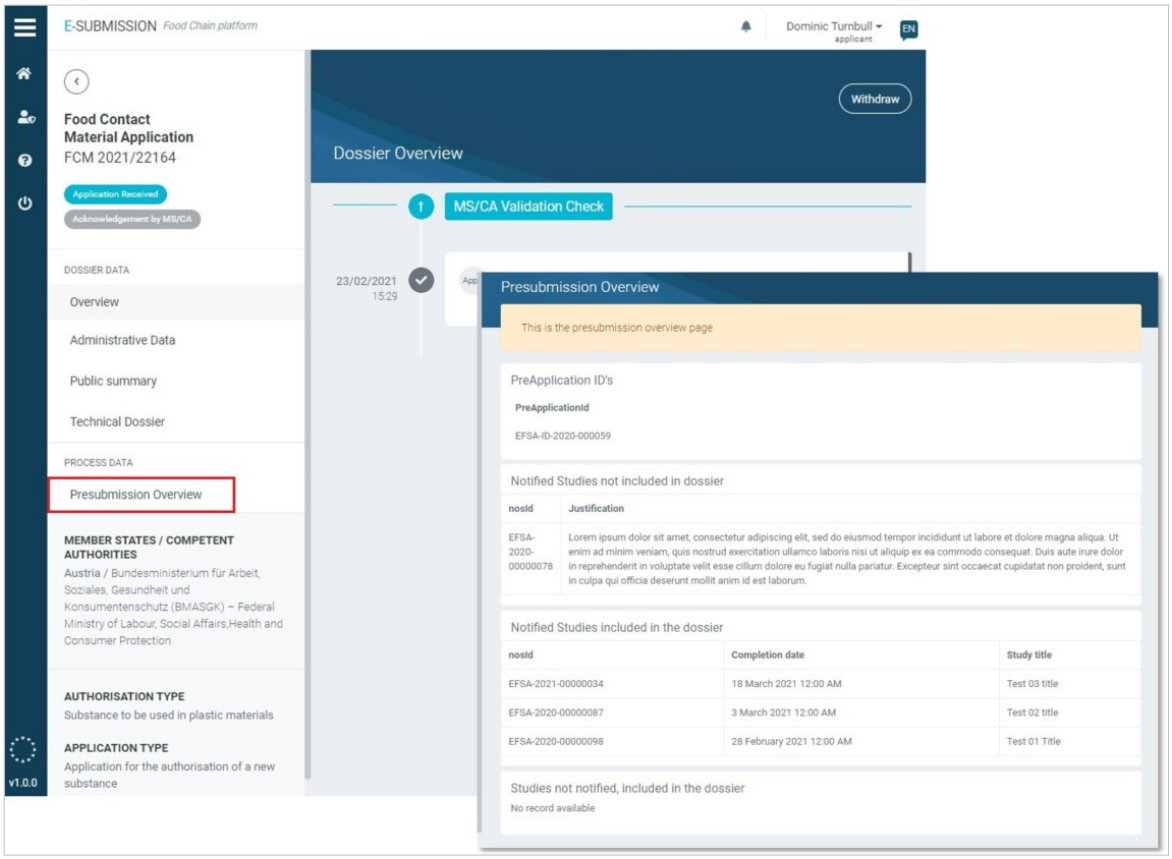
26. Click '**Submit**', then add a final message in the box which displays. Click '**Complete action**' to send. The dossier is sent and cannot now be edited without invitation.



27. 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.



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



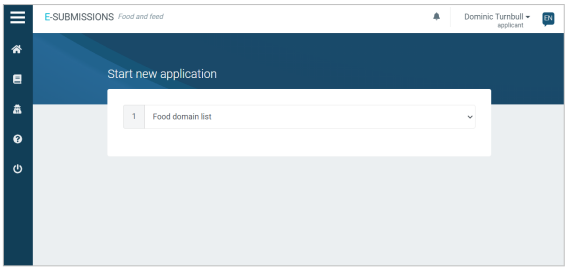
NOTE

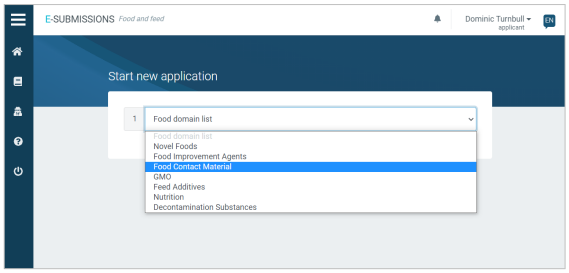
EFSA landing page for all FCM regulations and guidance documents.

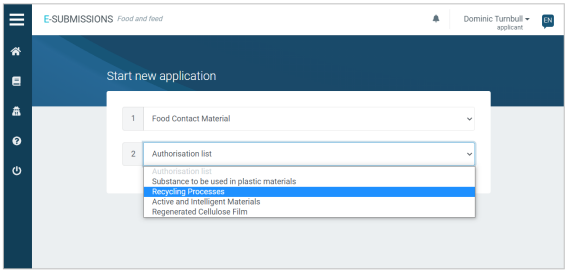
Note for Guidance: For the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials.

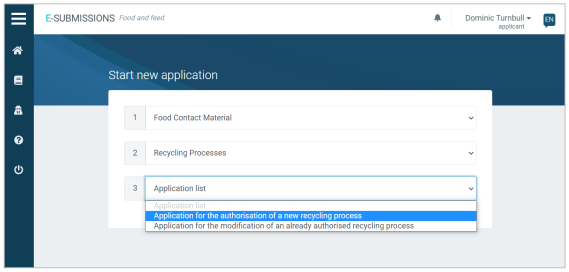
Create a dossier: Recycling Processes

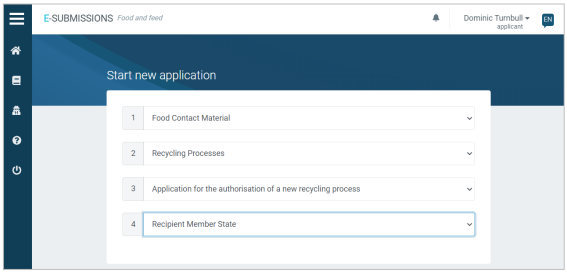
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose your domain type **Recycling Processes**, the **Application type**, the **Recipient Member State** and the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

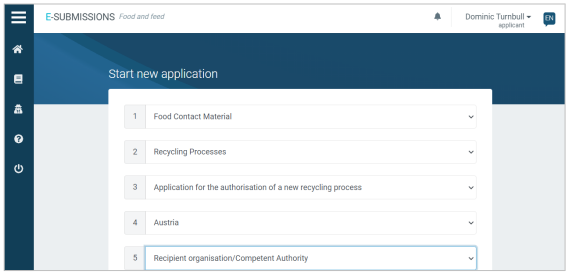




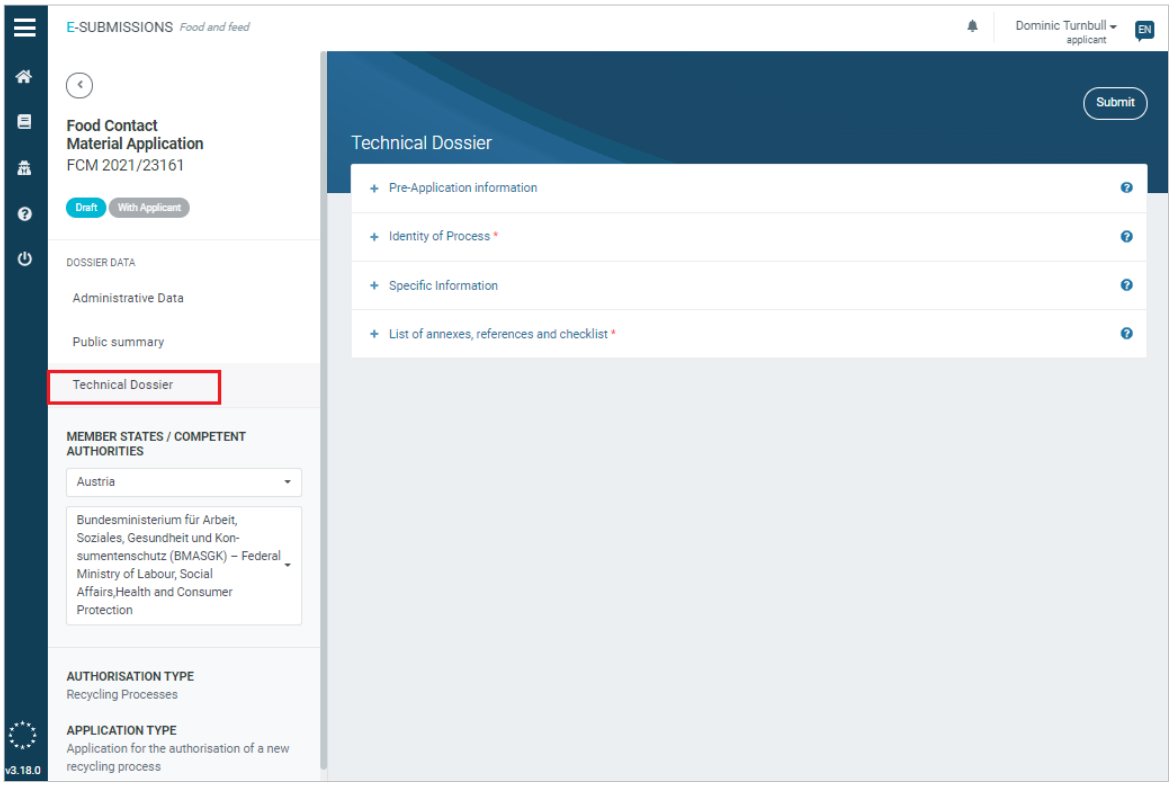








2. The Technical Dossier section is structured according to legislation and/or guidance and is unique to each domain.



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 [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

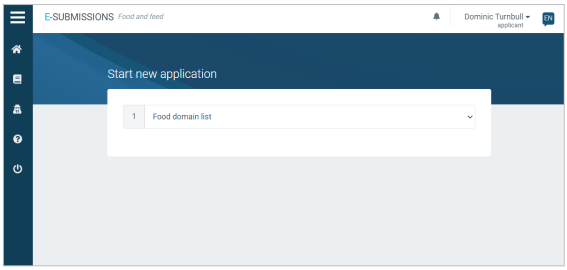
NOTE

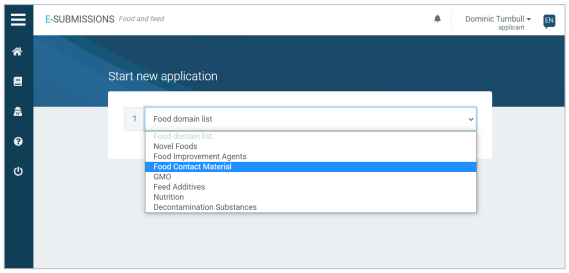
EFSA landing page for all FCM Regulations and Guidance documents.

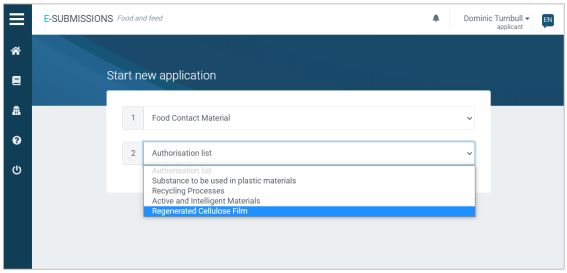
You can only apply for the authorisation of a complete recycling process.

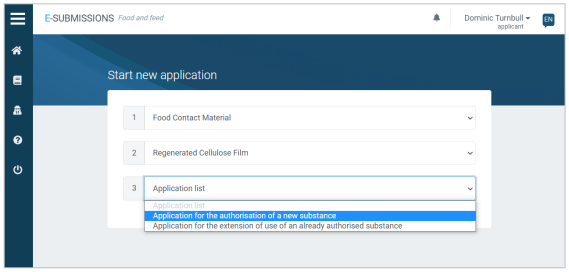
Create a dossier: Regenerated Cellulose Film

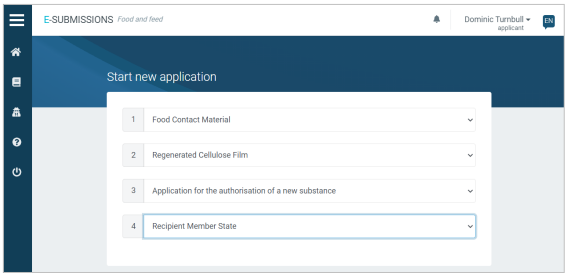
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose **Regenerated Cellulose Film**, the **Application type**, the **Recipient Member State** and the appropriate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

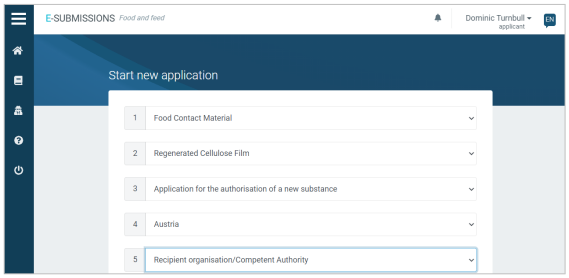




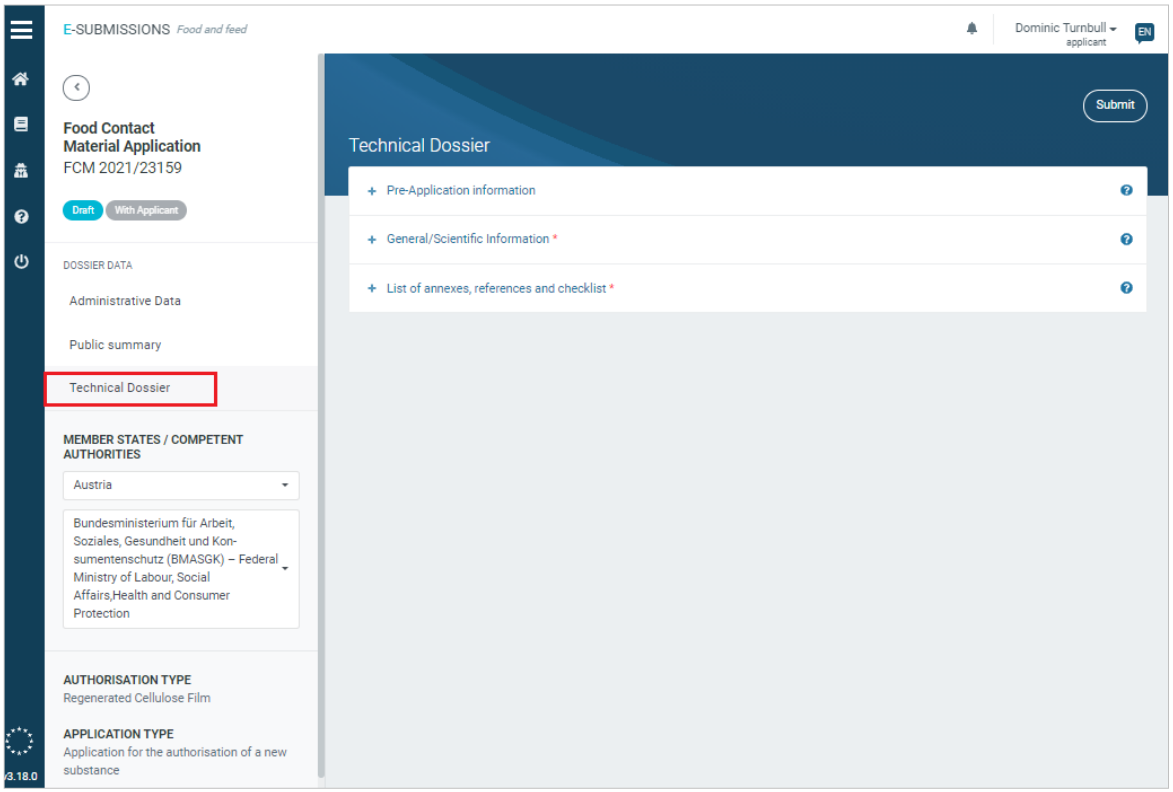








2. The Technical Dossier section is structured according to legislation and/or guidance and is unique to each domain.



NOTE

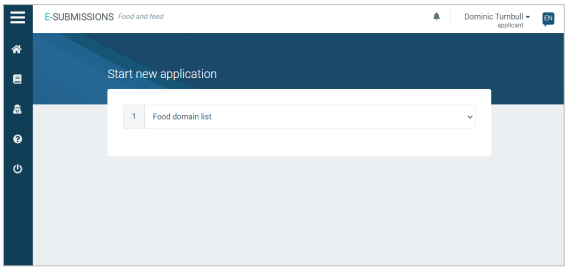
The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in Food Contact Materials [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study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

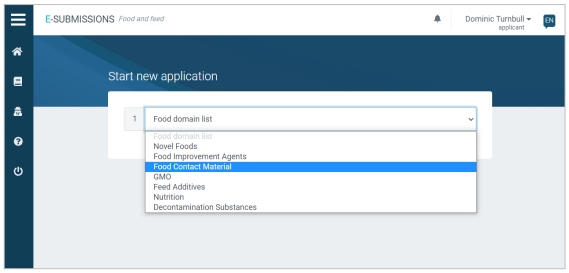
NOTE

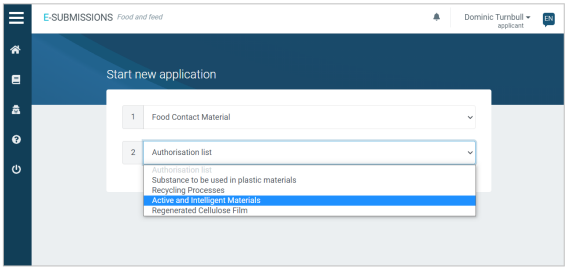
EFSA landing page for all FCM Regulations and Guidance documents.

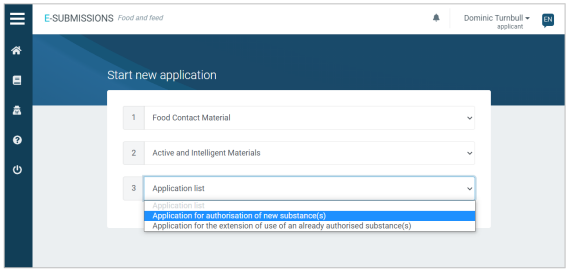
Create a dossier: Active & Intelligent material

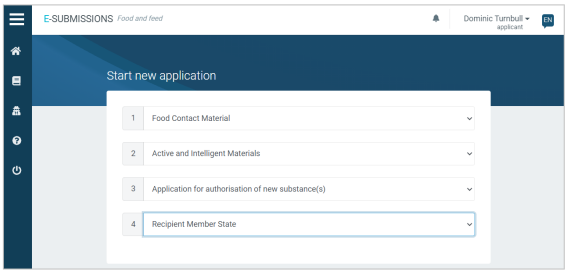
1. Your domain template will be generated via the following steps. Select **Food Contact Materials** from the Food domain list. Then choose **Active & Intelligent material**, the **Application type**, the **Recipient Member State** and the appropriate **Competent Authority**

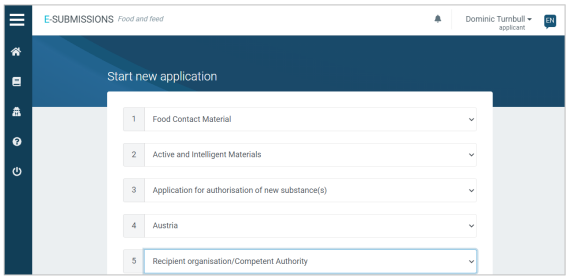




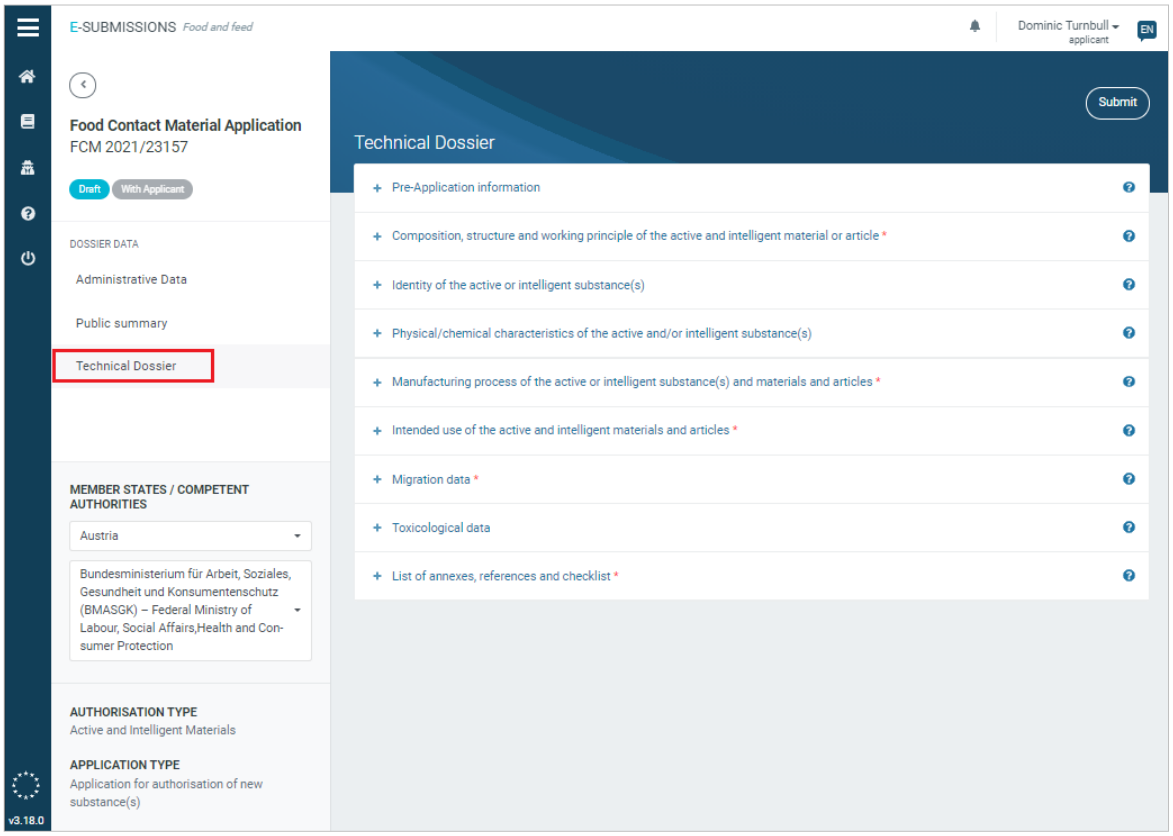








2. The Technical Dossier section is structured according to legislation and/or guidance and is unique to each domain.



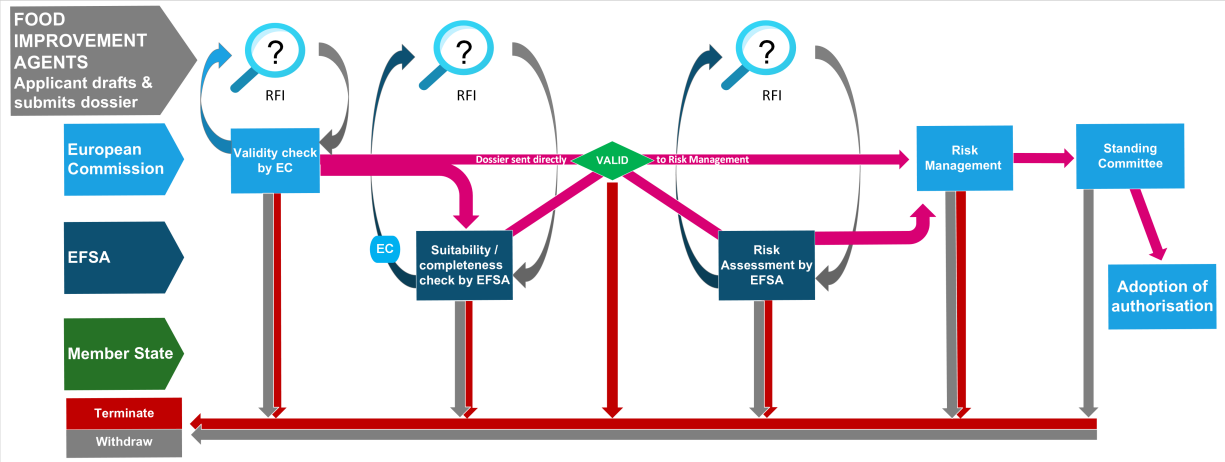
NOTE

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 [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

NOTE

EFSA landing page for all FCM Regulations and Guidance documents.

4.2 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.

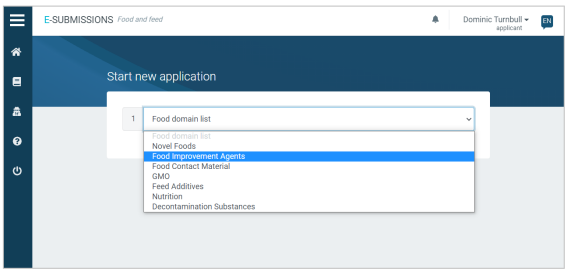
Submission types and legislation

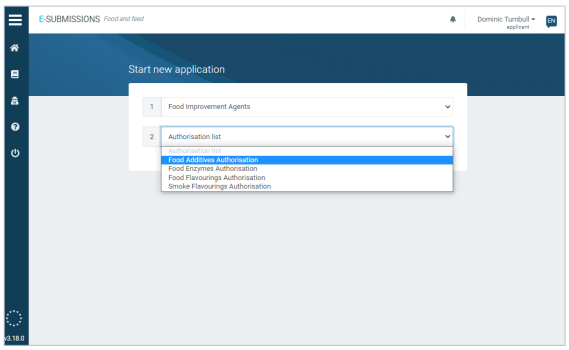
Authorisation type	Application type	In accordance with
Food Additives	Application for the authorisation of a new food additive	Regulation EC 1331/2008
	Application for the modification of an already authorised food additive	Regulation (EU) 234/2011
		Regulation (EC) 1333/2008
Food Enzymes	Application for the authorisation of a new food enzyme	Regulation EC 1331/2008
	Application for the modification of an already authorised food enzyme	Regulation (EU) 234/2011
		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	

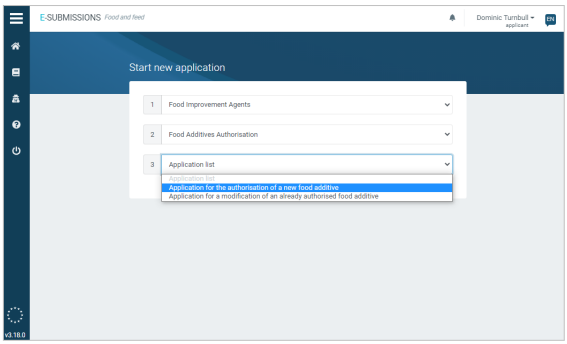
4.2.1 Getting started

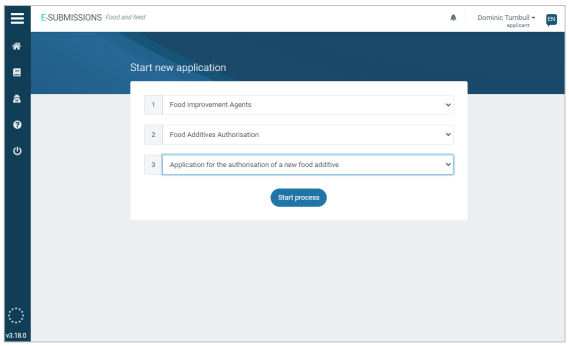
Create a dossier: Food Additives

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**'.

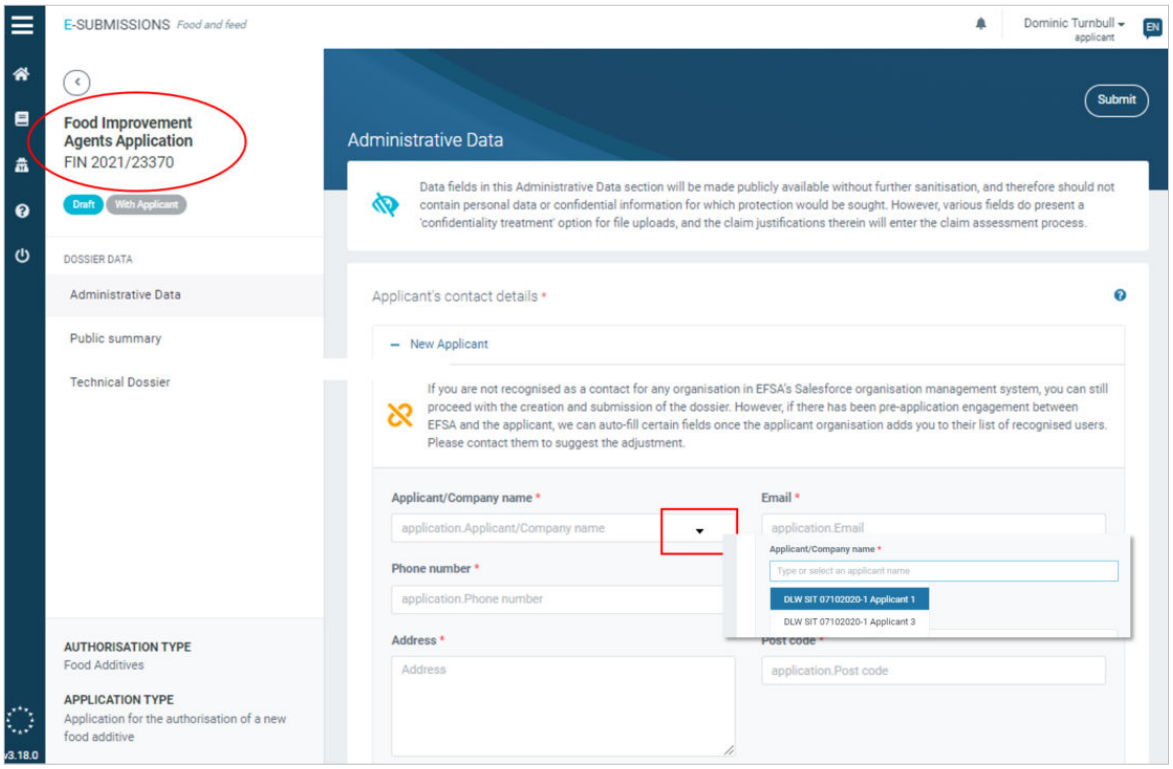




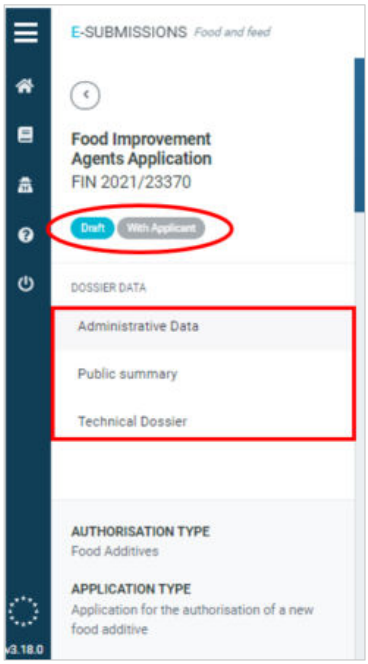




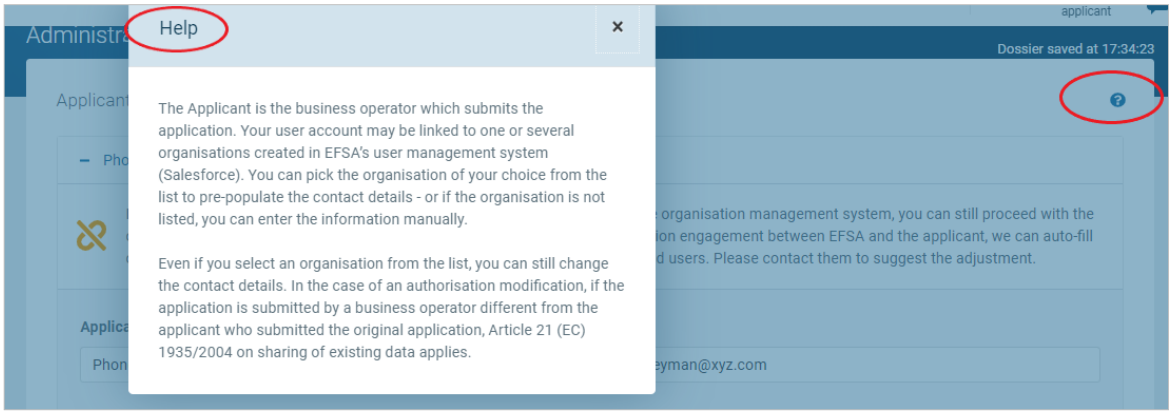
2. Complete the administrative data. Note the mandatory fields (*). The top-left dossier number will remain throughout. The top-right notification bell indicates activity. Note that the user recognition function is currently disabled. Applicants should proceed and input the information manually.



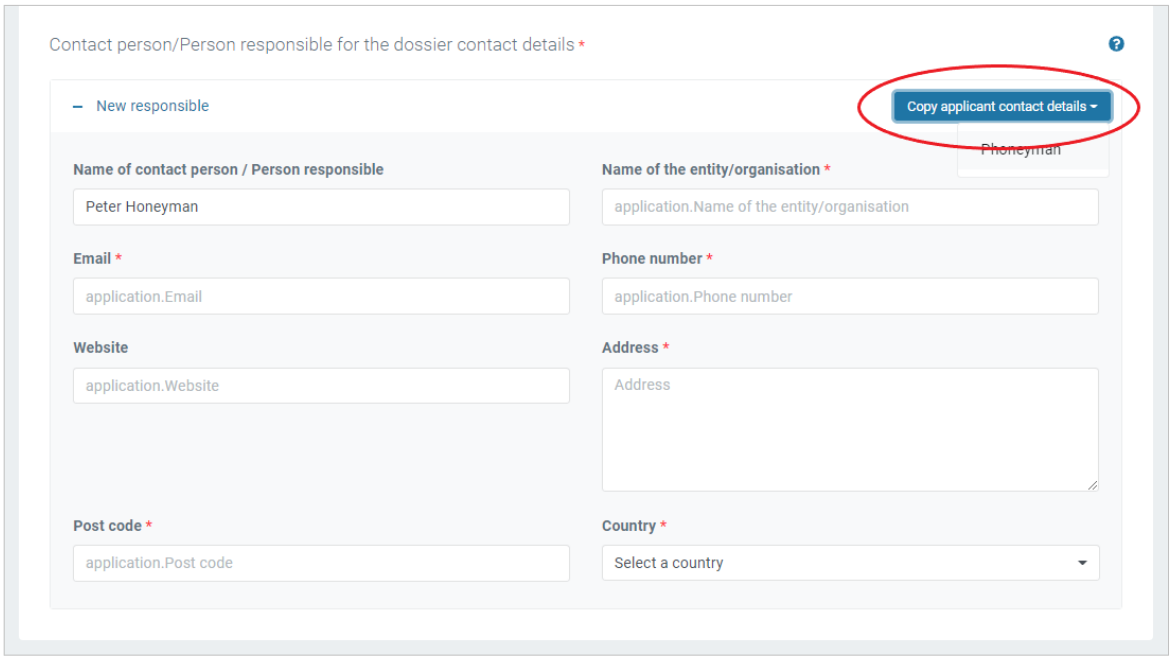
3. The column top shows the dossier status and phase. The three dossier sections remain throughout. The bottom section displays the authorisation and application type.



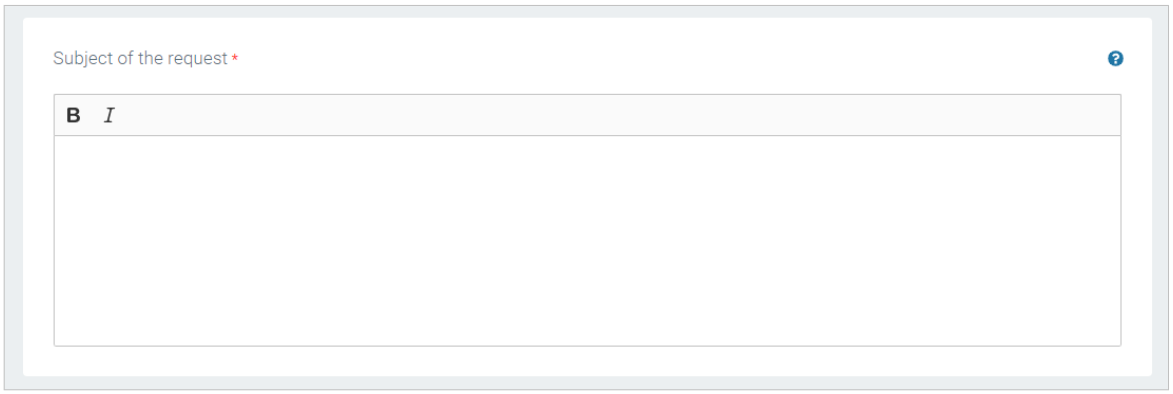
4. Click the '**?**' to see contextual help for the field.



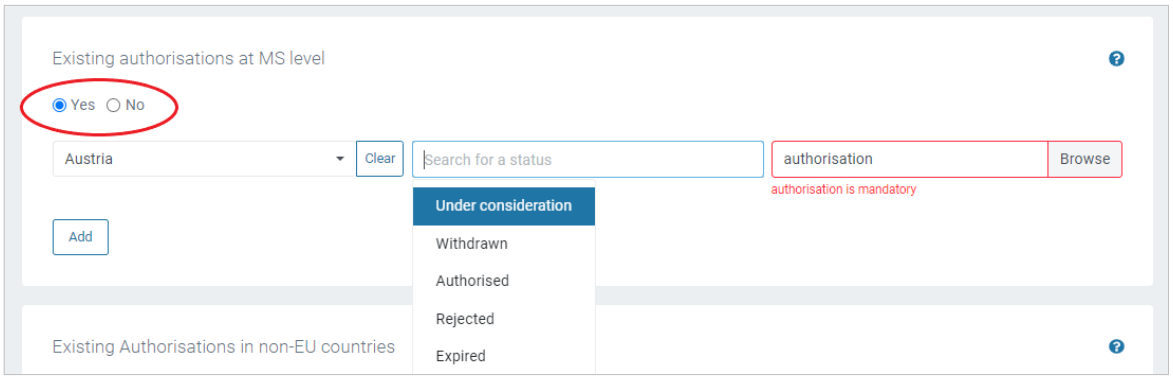
5. Click on '**Copy applicant contact details**' to duplicate the Applicants' data inserted in *Step 2* in case the person responsible is working in the same company as the Applicant. Fields can be manually overwritten.



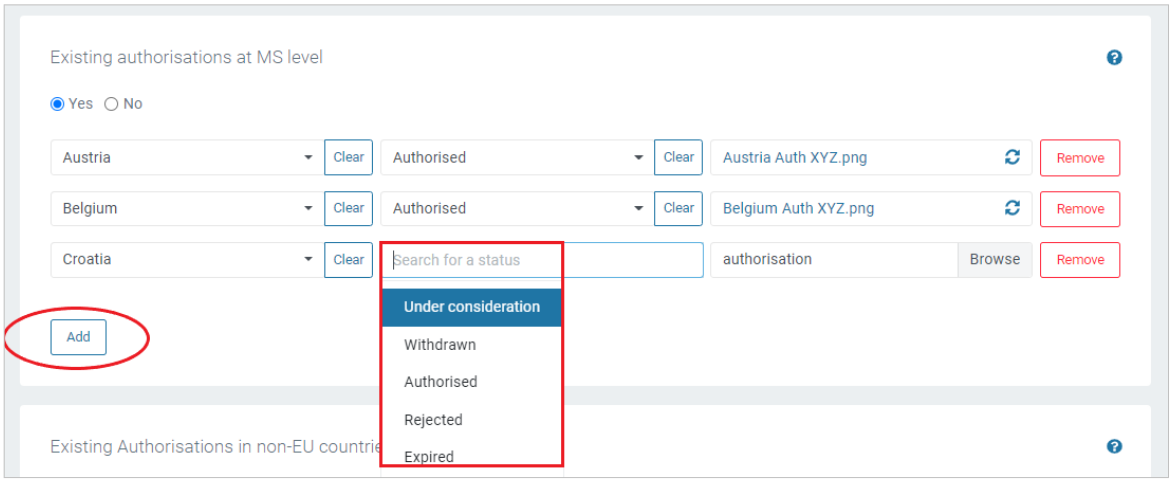
6. Enter the '**Subject of the request**'. You may consult the contextual help note '**?**' for additional information.



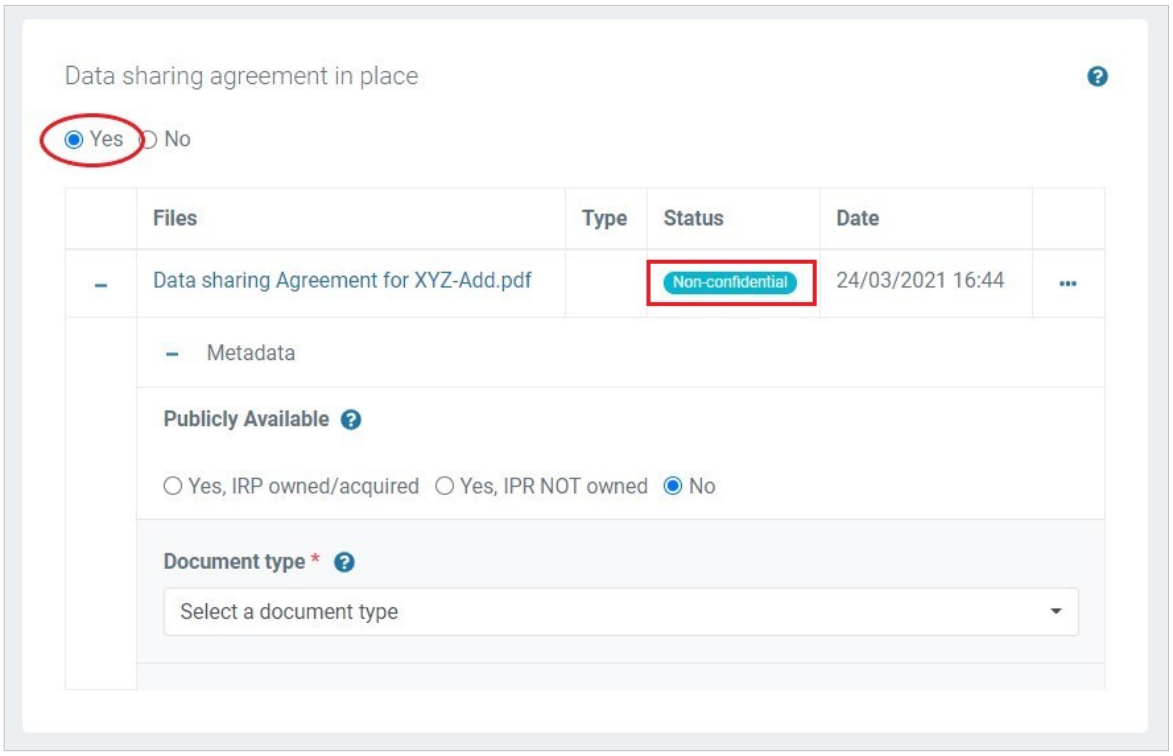
7. If there is authorisation history to the subject of this dossier, click '**Yes**', then indicate the related Member State. Select the status, then browse to and upload relevant documents with supporting information.



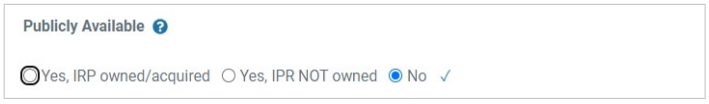
8. Click '**Add**' to detail other Member States where the subject of the dossier has history, and upload documents as before.



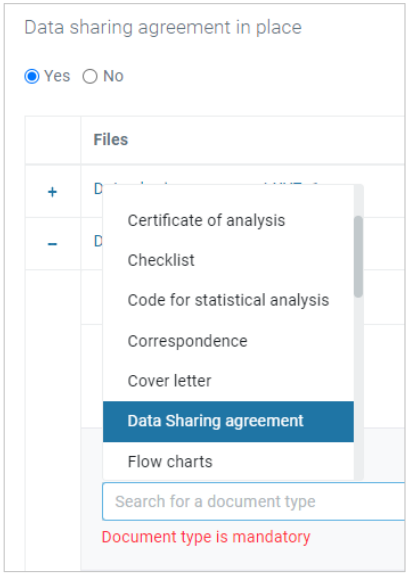
9. If a data-sharing agreement is available, relating to the entire dossier, click the '**Yes**' radial. Click '**Add document**' for multiple agreements. Note the default 'Non-confidential' badge.



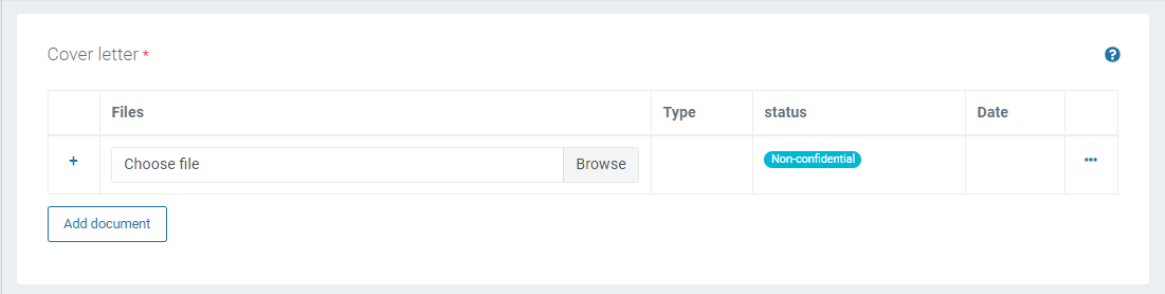
10. Indicate for each document whether it is '**Publicly available**', or whether there are related IPR considerations. The default setting is '**no**'. For more information on how IPR impacts disclosure, read the chapter on Intellectual Property Rights [119].



11. Now identify the '**Document type**' via the metadata dropdown menu (see Appendix A [157]). In this instance, we select '**Data Sharing agreement**'.

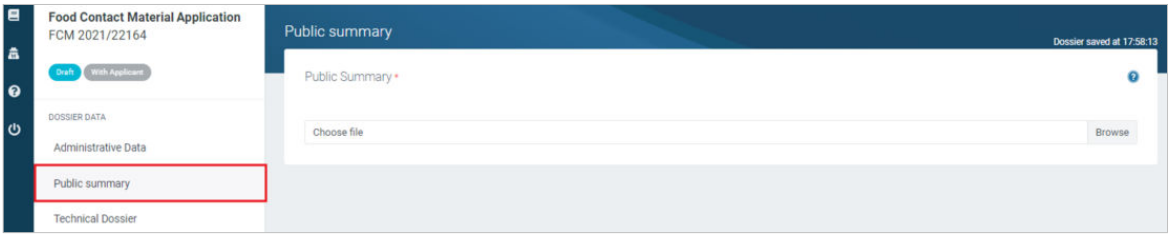


12. Upload the cover letter.

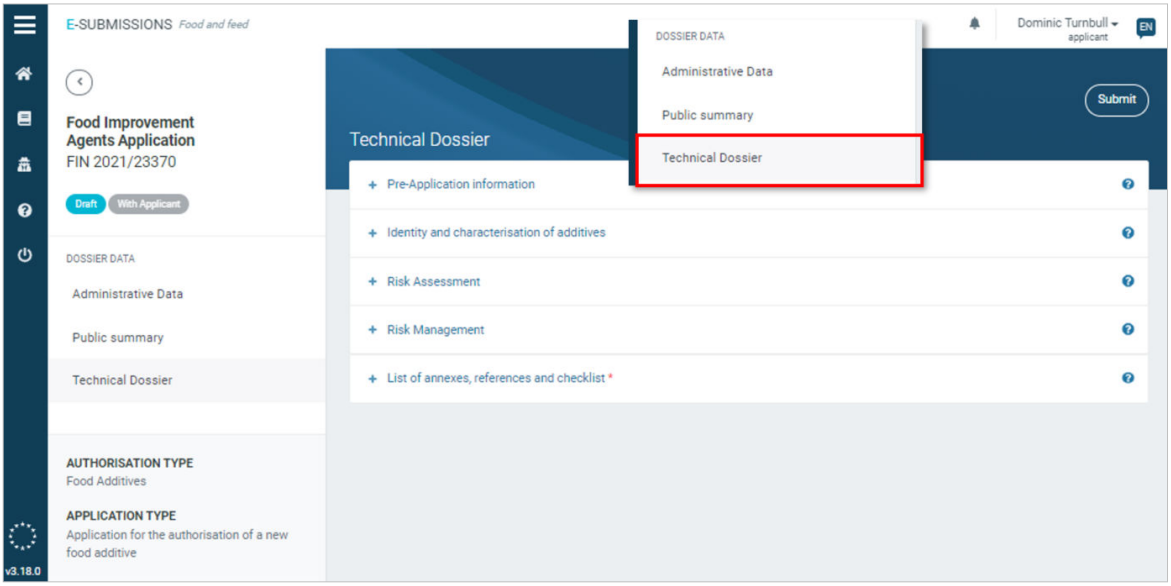


13. State whether the substance of this dossier has previously been made '**non valid**' by EFSA due to irregularities in the provided Notification of Studies information. If 'No', then continue. If you state 'Yes' however, you then need to identify the earlier dossier submission(s) which EFSA blocked.

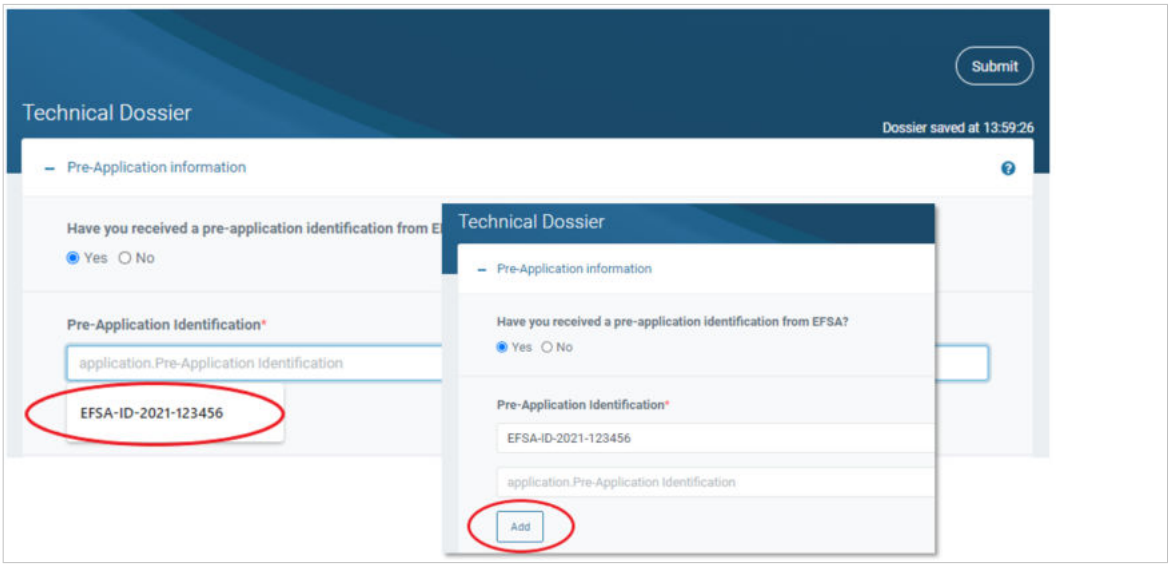
14. Click the '**Public summary**' tab, upload a public summary.



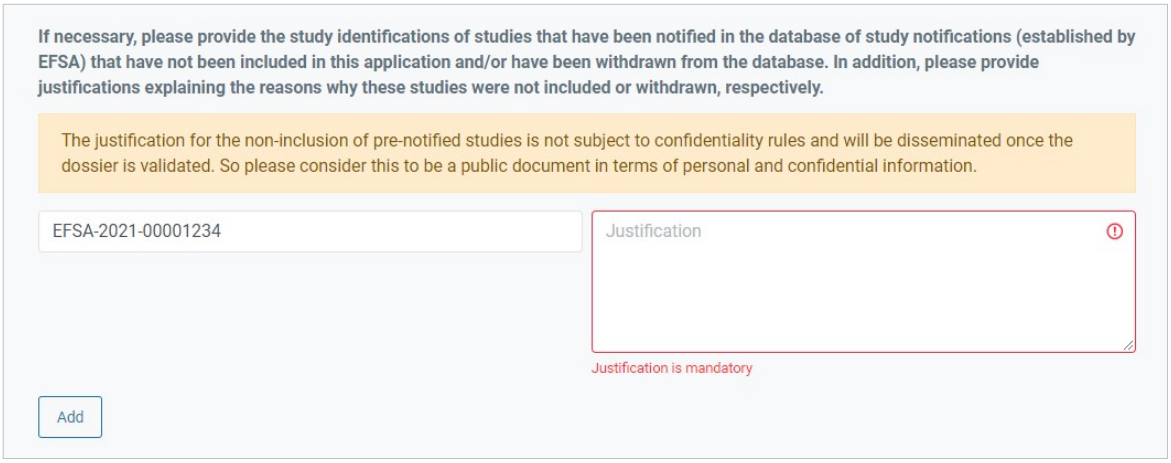
15. Click to the Technical dossier. The full table of contents reflects the sections required by legislation and outlined in EFSA guidance.



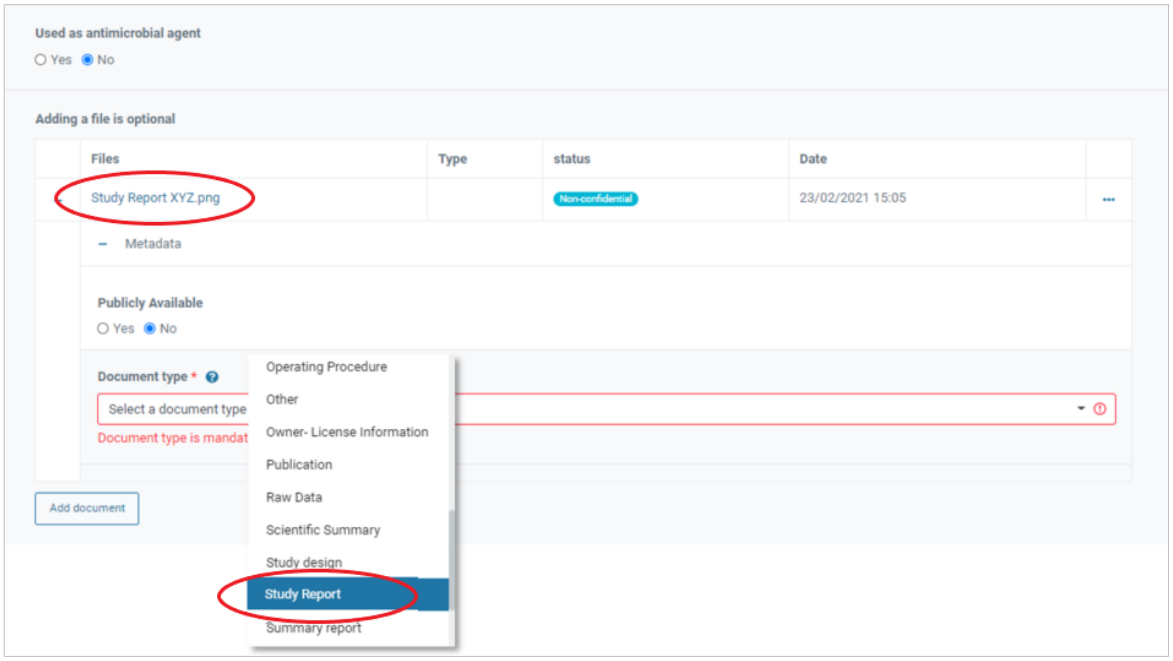
16. If you engaged with EFSA during the pre-submission phase, you would have been assigned a Pre-Application Identification number. Please input it here. Note the format. Click '**Add**' to include multiple IDs.



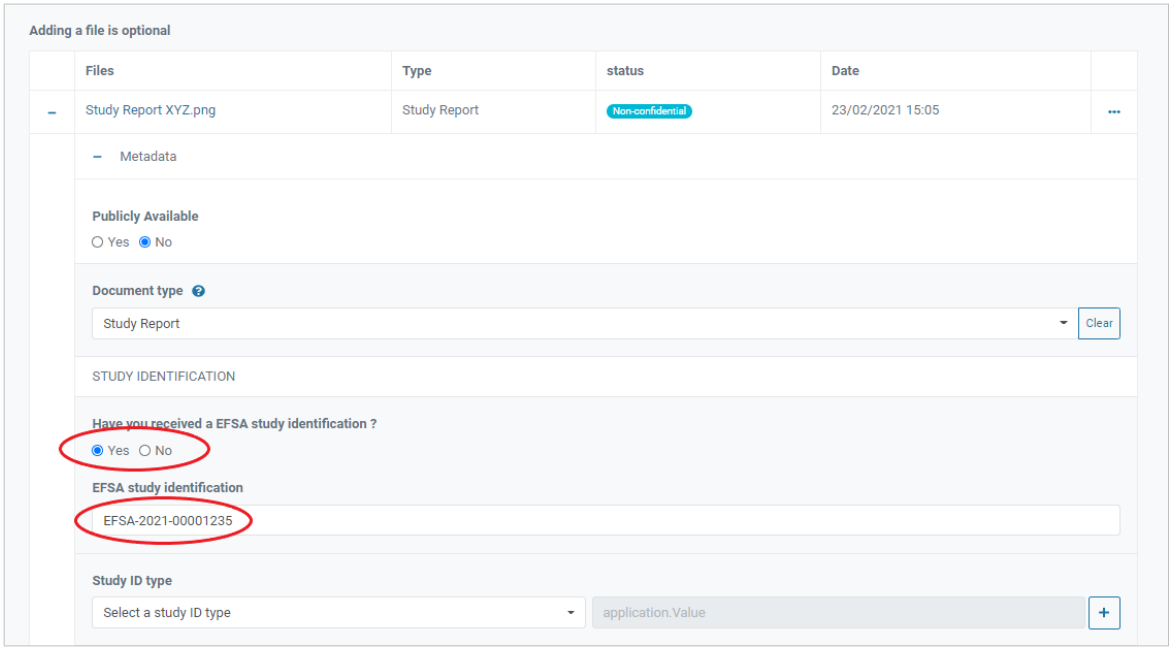
17. If you pre-notified any study which was withdrawn or is otherwise not present within this dossier, input its Pre-Notification ID here, including a justification for why it has been omitted. Click '**Add**' if there are multiple study omissions.



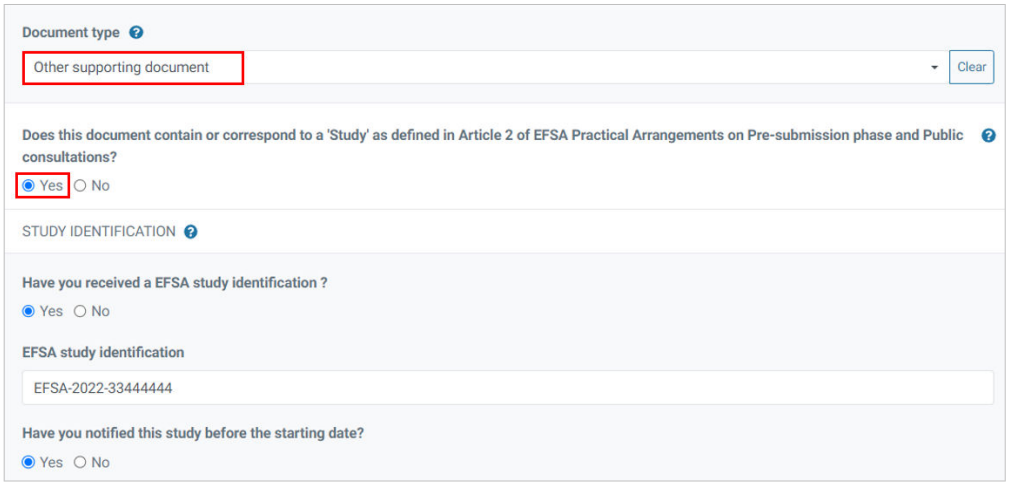
18. When you upload a file in any section, you must select the metadata '**Document type**' from the dropdown menu. If you upload a study report, select '**Study Report**'. This will launch some additional fields (e.g. EFSA study ID, Study type, Title, authors etc.)



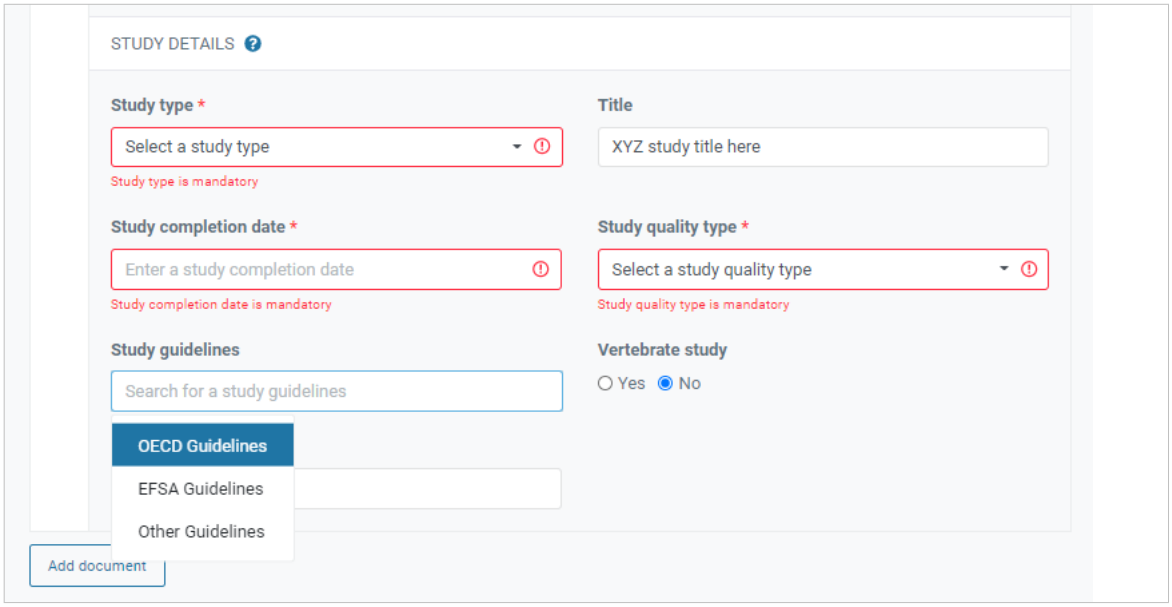
19. Input the Study ID assigned by EFSA when the study was notified. Now complete the study ID type and identifier.
Click **No** if you have no Study ID and provide a justification.



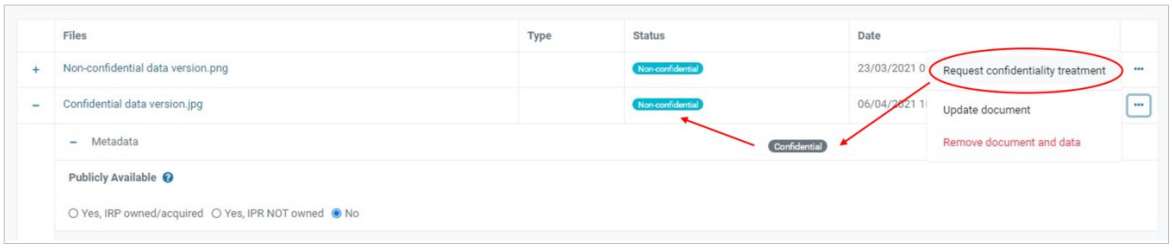
20. Documents with selected metadata '**Certificate of Analysis**', '**Raw Data**' or '**Other supporting document**' will also trigger the option to provide an EFSA study ID.
If the document contains or corresponds to a study, click **Yes**. Once the EFSA Study ID is filled in, a new field related to notifying the study before the starting date is displayed. If there is no EFSA study identification for that study, click **No** and provide a justification.



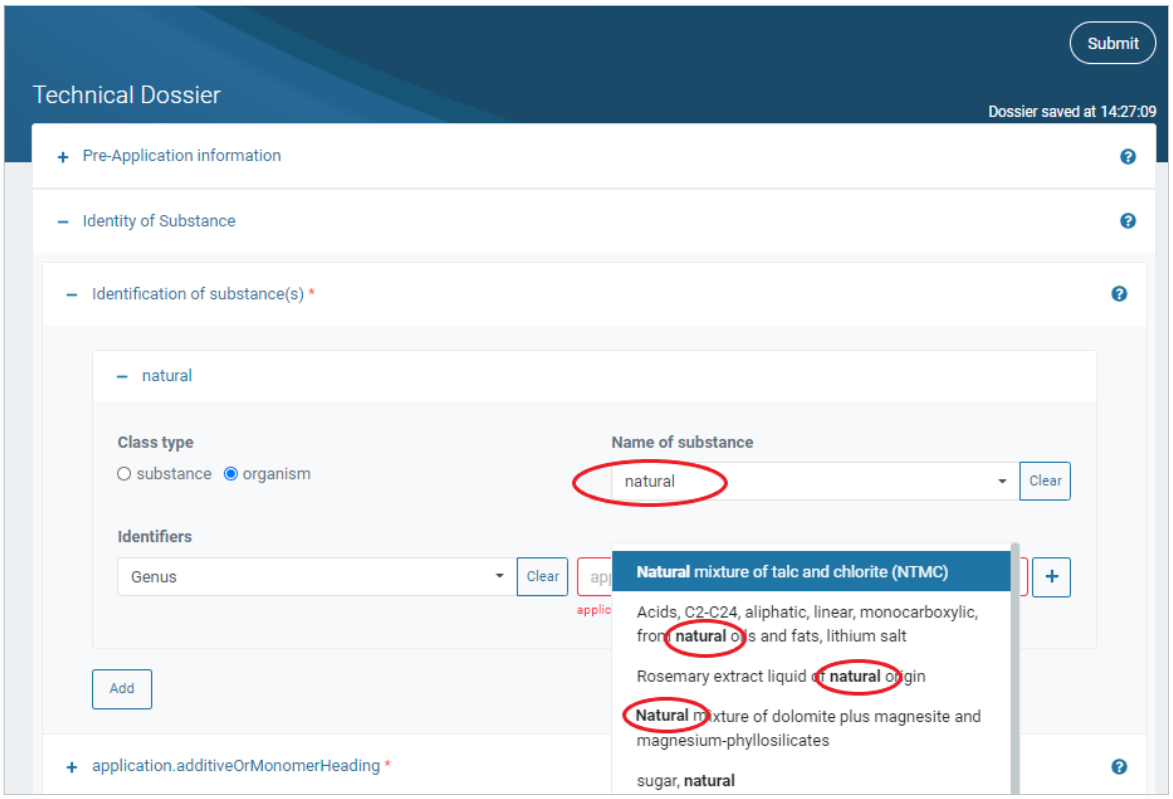
21. Complete the study fields, with related dates and values. Note that these entries will be published.



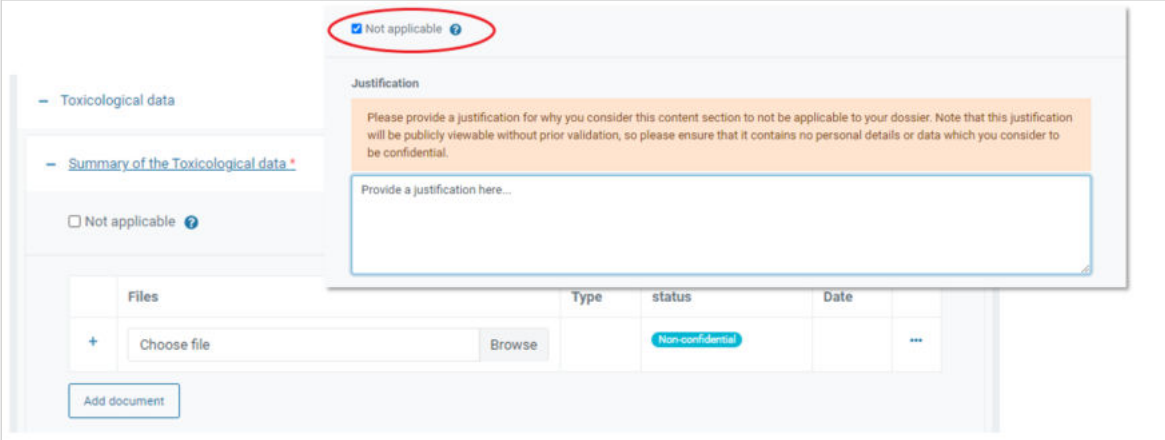
22. You can upload non-confidential files. By default, the green badge indicates 'Non confidential'. You can also upload files in which you will make one, or multiple, requests for confidentiality. Click the three dots and select '**Request confidentiality treatment**' once each is uploaded. The badge will now indicate 'Confidential'. See How the request confidentiality [130] for more details.



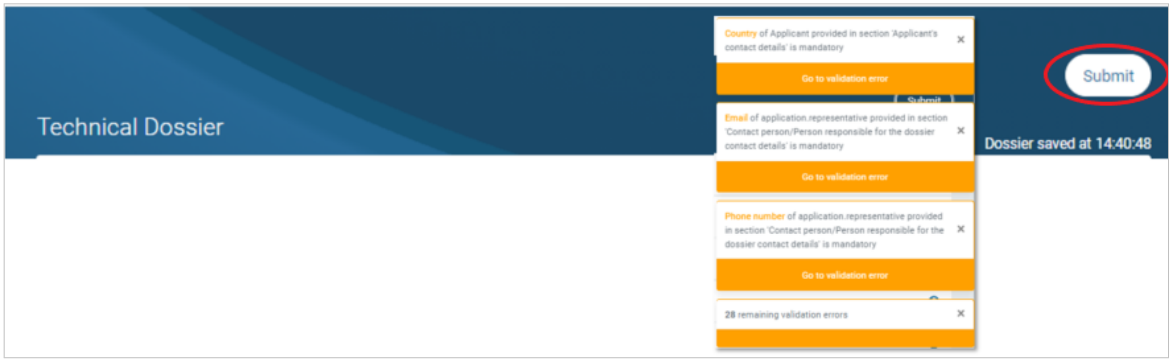
23. When you select from the dropdown menu '▾', type a key word and options will be presented if that word exists in the database. Here we see the free-typing option available for substance selection. But note that in some cases there is a 'closed list' of selections.



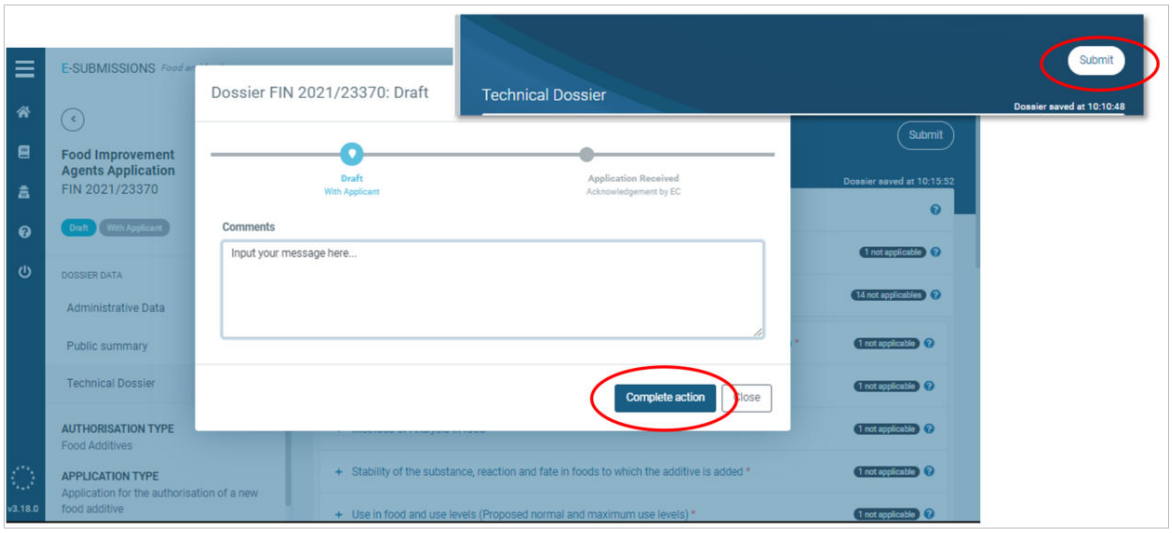
24. Some mandatory fields may not apply to your dossier. Click '**Not applicable**' and provide a justification.



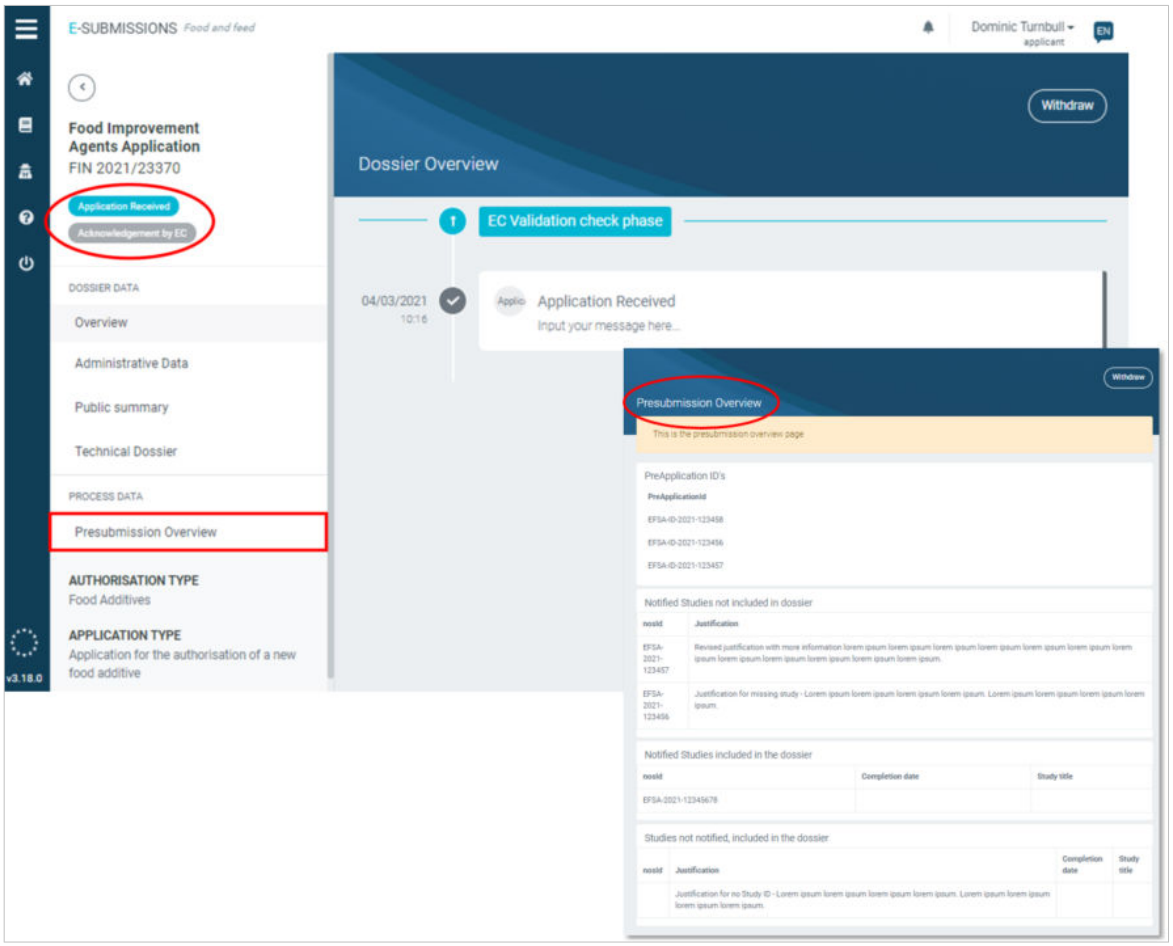
25. When all dossier sections have been completed, click '**Submit**'. If mandatory fields remain incomplete, error messages will appear. These need to be addressed. Click on '**Go to validation error**' to arrive at the blocking section.



26. 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.



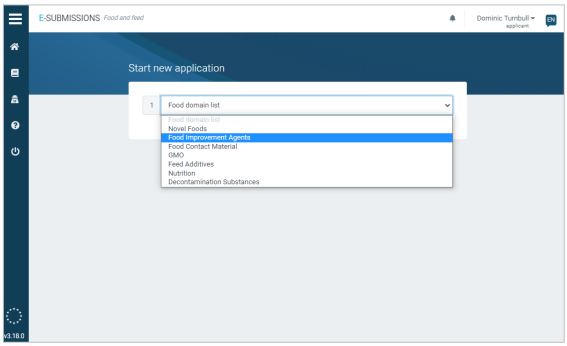
27. The dashboard status changes to '**Application received**'. Acknowledgement will follow, then the validation process begins. A 'Pre-submission overview' tab appears, which collates on one screen the data, as input, relating to the pre-submission phase. You now need to wait. For any action taken in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

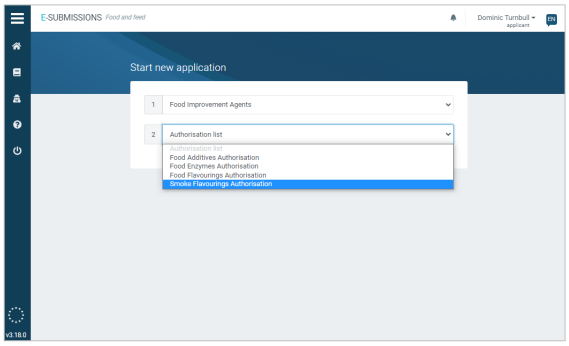


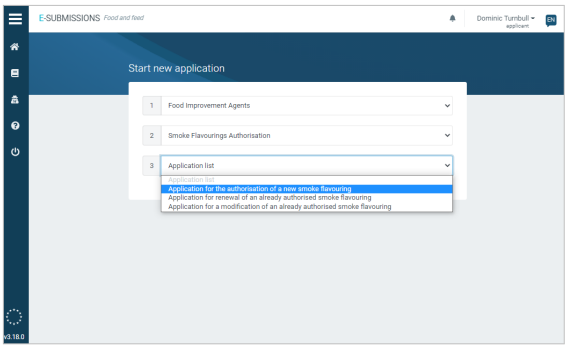
NOTE
EFSA landing page for all FIA: Overview and procedures.

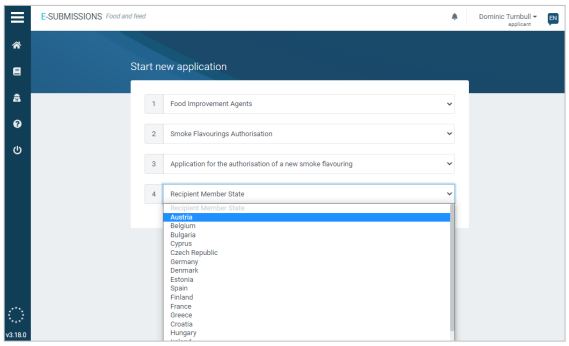
Create a dossier: Smoke Flavourings

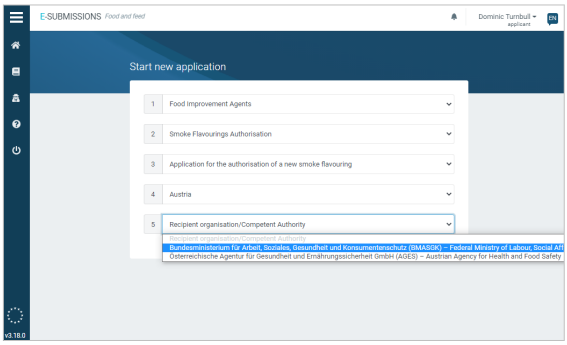
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then choose your domain type **Smoke Flavourings**, the **Application type**, the **Recipient Member State** (not for renewals) and the appropriate **Competent Authority**, and then click '**Start process**'.

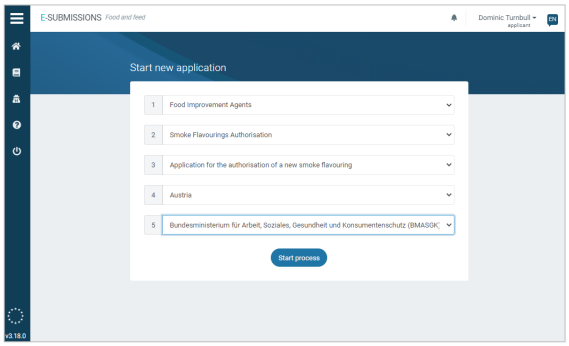




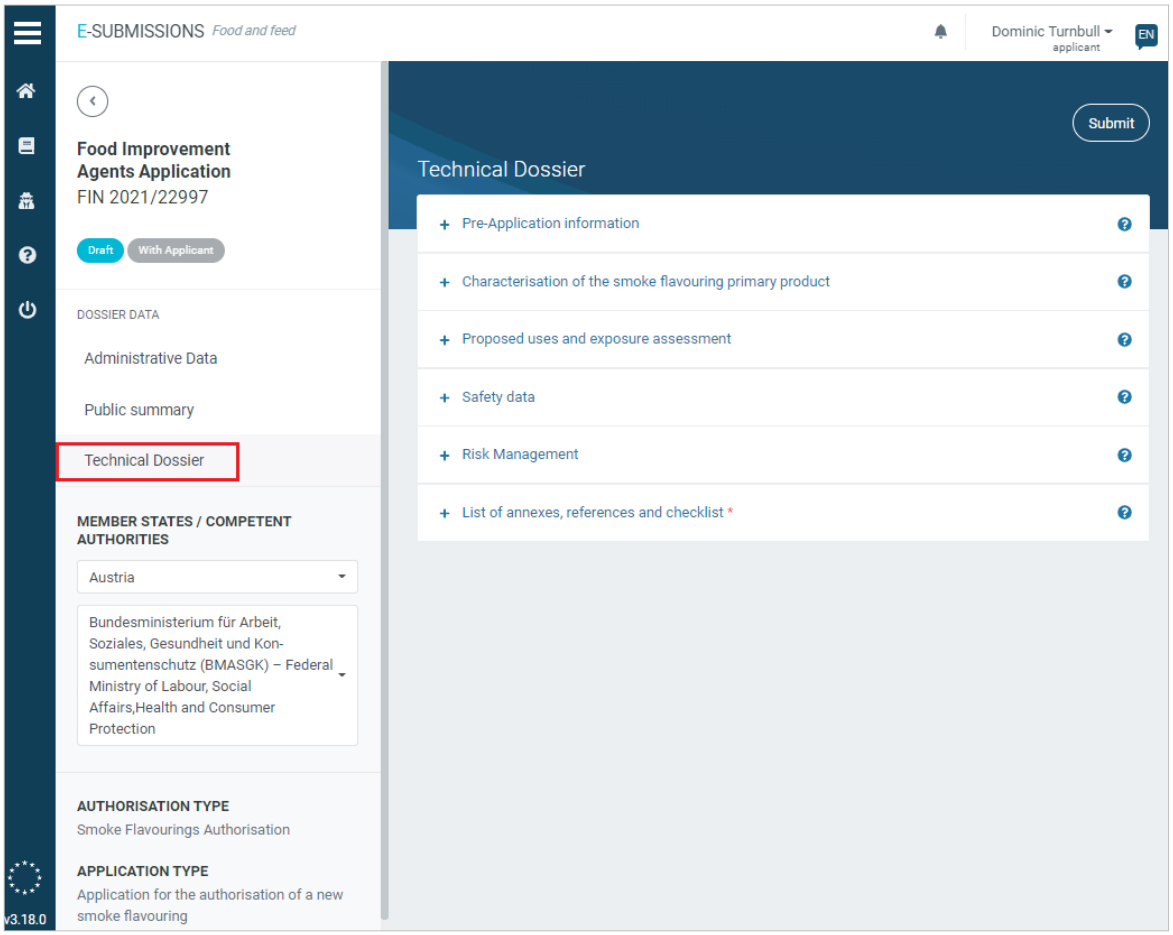








2. The Technical Dossier section is structured according to legislation and unique to each domain.



NOTE

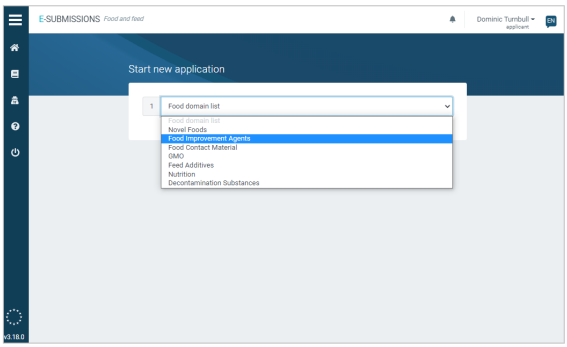
The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in Food Contact Materials [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study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

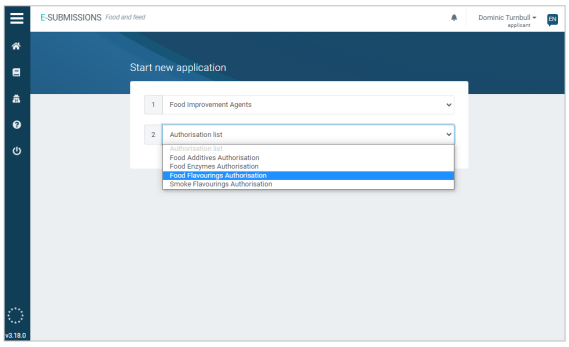
NOTE

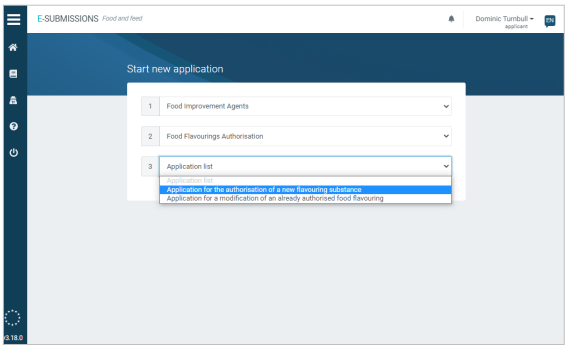
EFSA landing page for all FIA Regulations and Guidance documents.

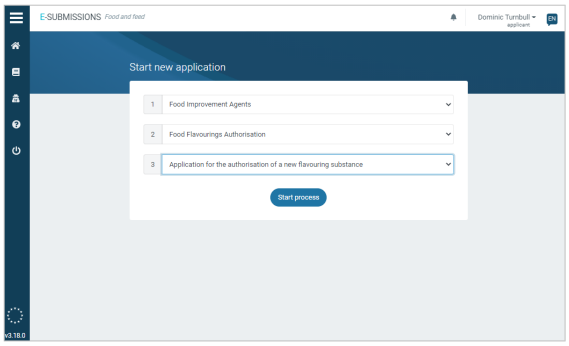
Create a dossier: Food Flavourings

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**'.

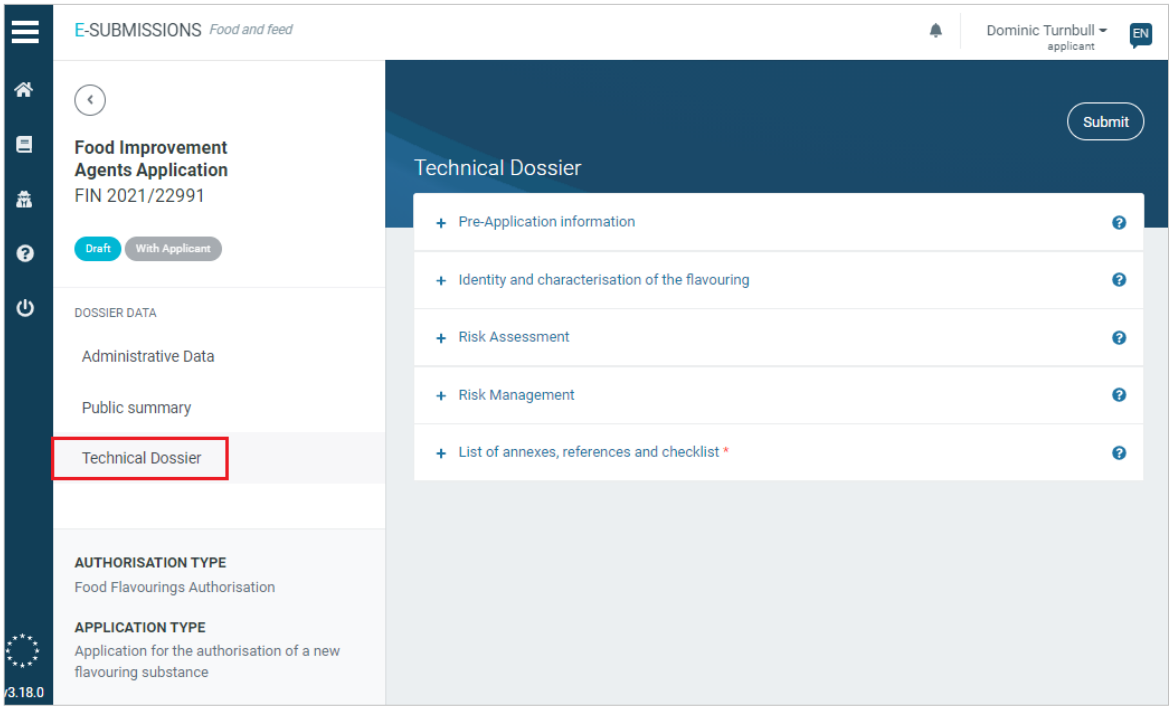








2. The Technical Dossier section is structured according to legislation and unique to each domain.

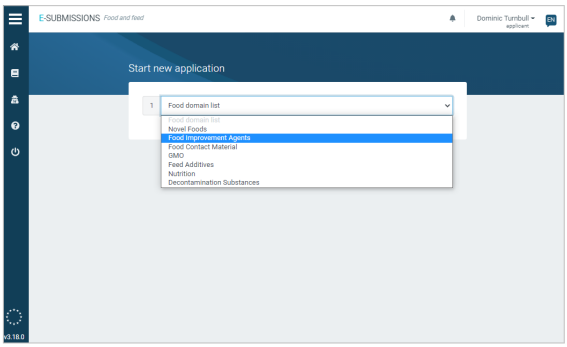


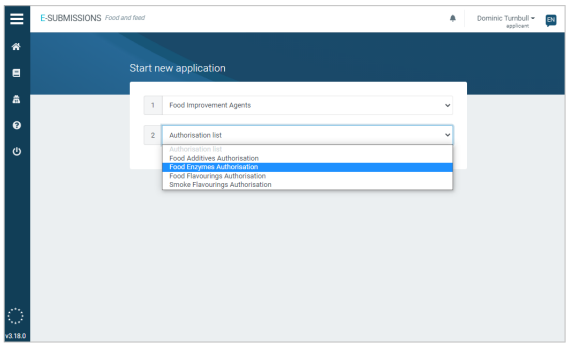
NOTE
The submission process is the same for all dossiers which are assessed by EC and EFSA. This Food Additives [34] submission example illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable',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

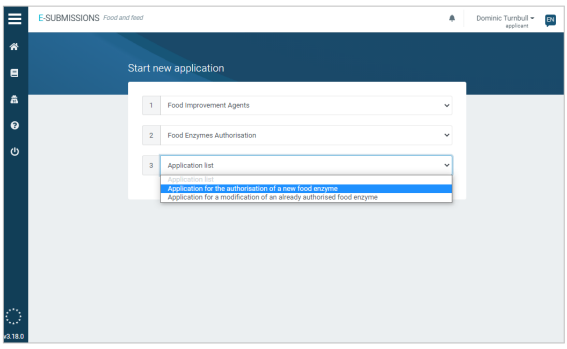
NOTE
EFSA landing page for all FIA Regulations and Guidance documents.

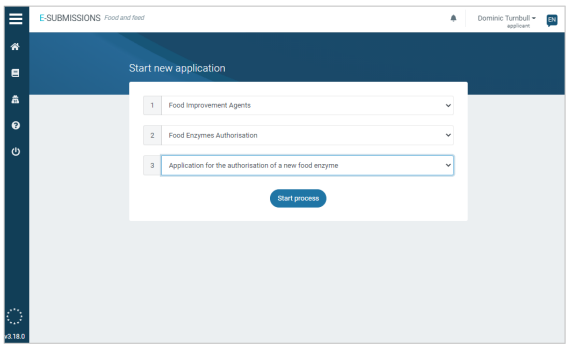
Create a dossier: Food Enzymes

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**'.

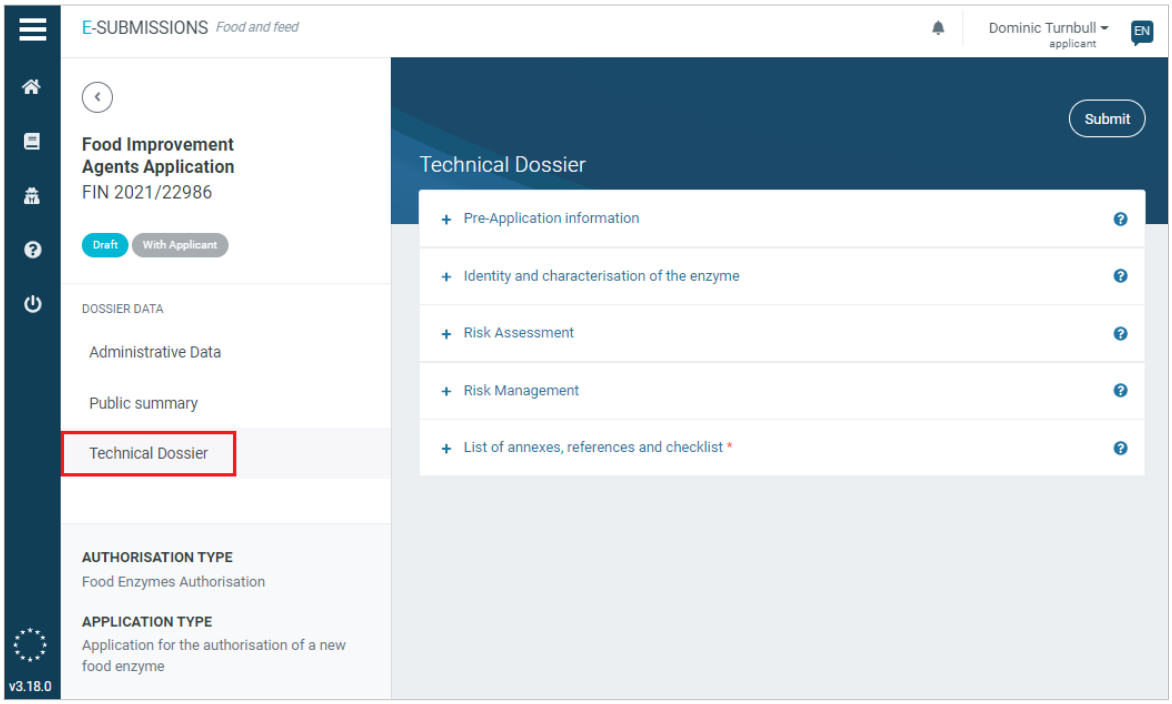








2. The Technical Dossier section is structured according to legislation and unique to each domain.



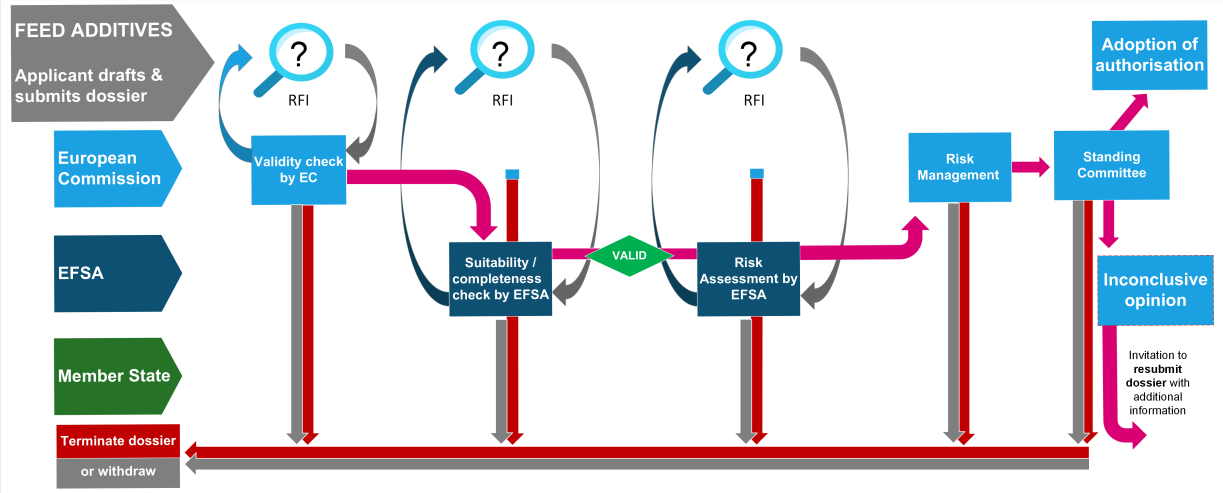
NOTE

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

NOTE

EFSA landing page for all FIA Regulations and Guidance documents.

4.3 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.

In the event of an EFSA **inconclusive opinion**, applicants are invited by EC to provide a new dossier containing only the complementary information needed to reach a conclusion.

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 authorisation of a modification and/or renewal of an already authorised feed additive	Article 13.3 & 14 (EC) 1831/2003
	Application for urgent authorisation of a feed additive	Article 15 (EC) 1831/2003
	Submission of complementary information following EFSA's inconclusive opinion	Article 29 of Regulation 178/2002

NOTE

EFSA guidance: Administrative guidance for the preparation of applications on additives for use in animal nutrition.

EFSA landing page for all Feed Additives Regulations and Guidance documents.

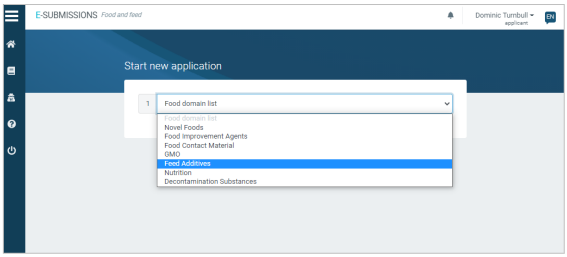
NOTE

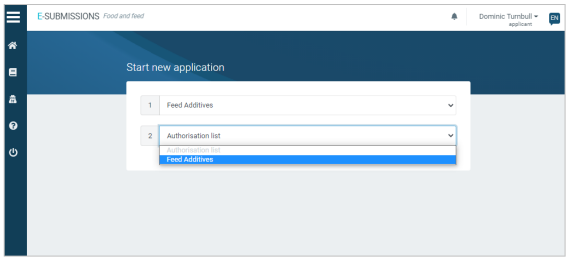
The European Union Reference Laboratory for Feed Additives has prepared practical guidance for applicants regarding their analytical approach and sample-testing fee. See Commission Regulation (EC) 429/2008.

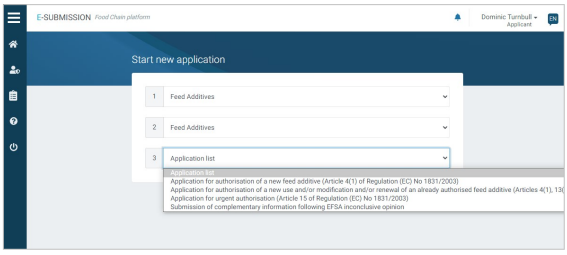
4.3.1 Getting started

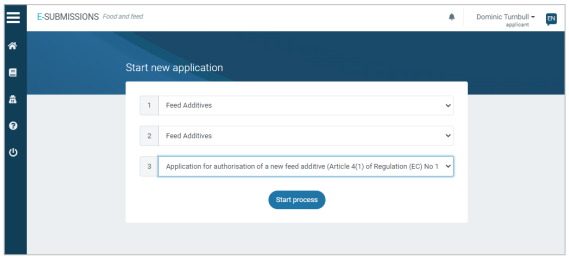
Create a dossier: Feed Additives

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**'.

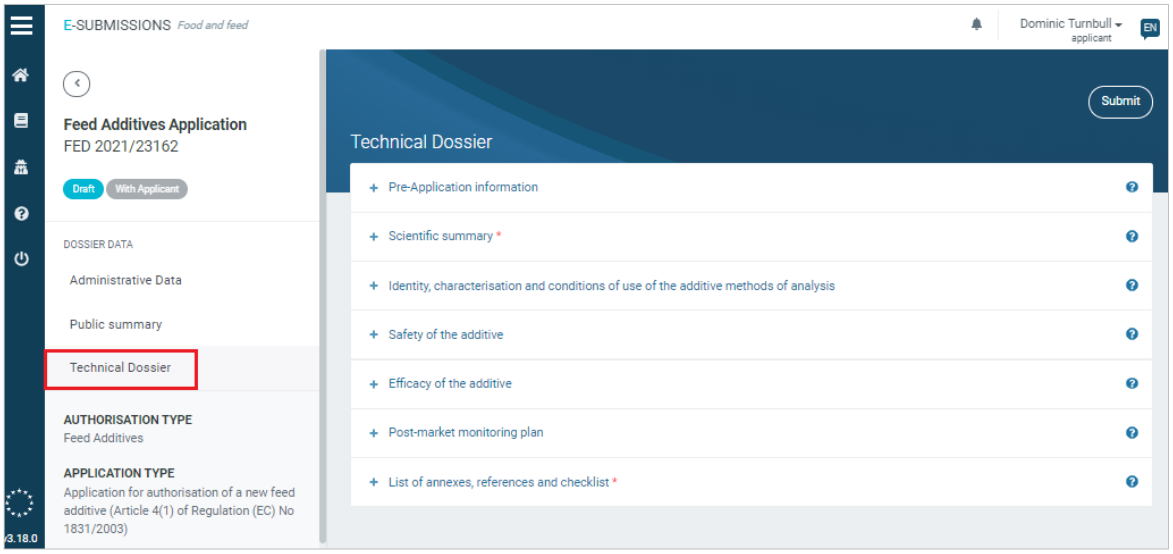








2. The Technical Dossier section is structured according to legislation and unique to each domain.



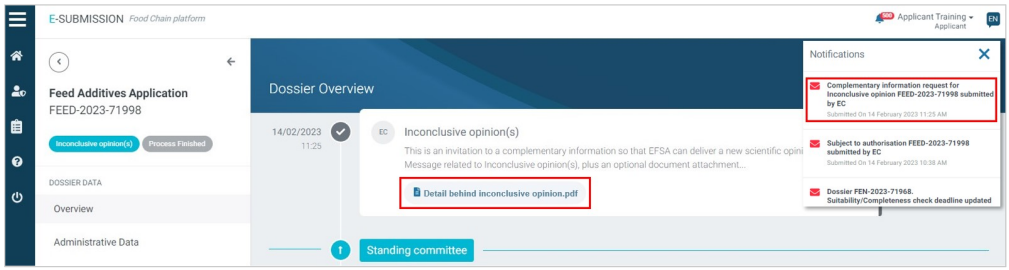
NOTE

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

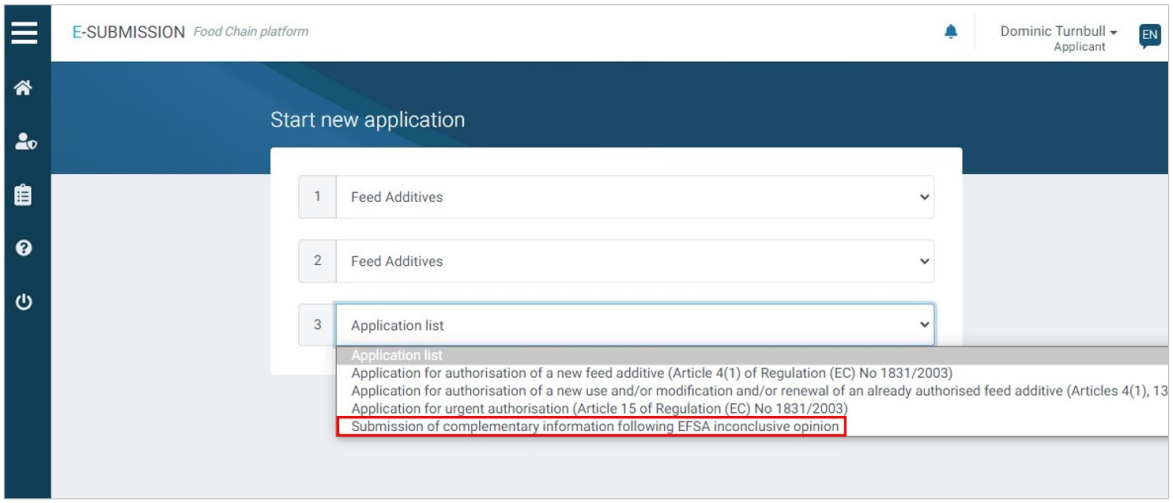
NOTE
EFSA landing page for Feed Additives Regulations and Guidance documents.

EFSA Inconclusive Opinion

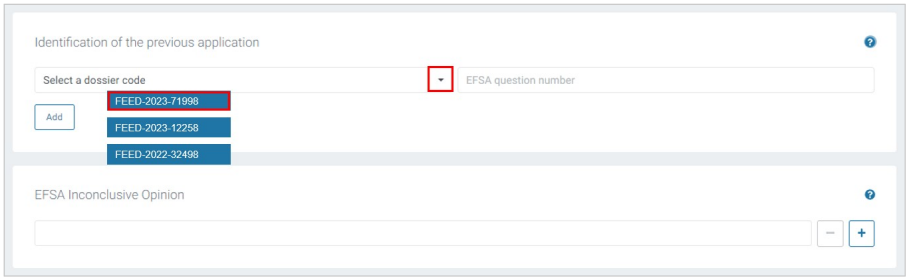
Rather than ending the process entirely, the risk assessment of a Feed Additives dossier can result in an inconclusive opinion concerning certain aspects of the risk assessment. If that is the case, the dossier is labelled as **Inconclusive opinion(s)** and additional justifications may be available for the applicant in an EC-attached file. The applicant(s) are invited to submit a new dossier that complements the previous one, so that EFSA can finalise the scientific output(s) on this Feed Additive.



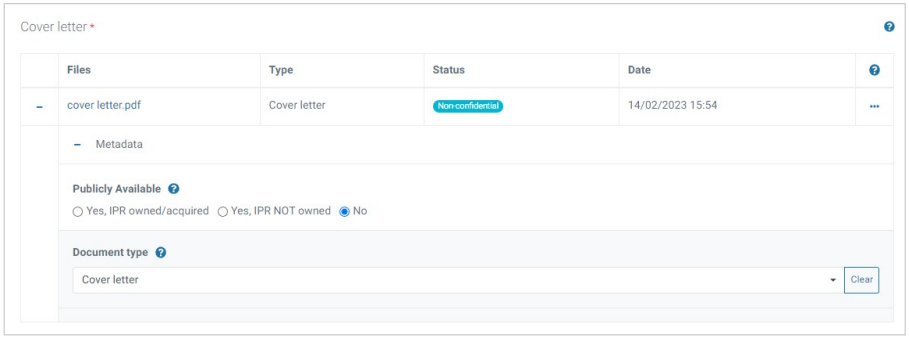
1. Create a new Feed Additives dossier as indicated before, but ensure to select **Submission of complementary information following EFSA inconclusive opinion** from the dropdown menu.
   Click **Start process**.



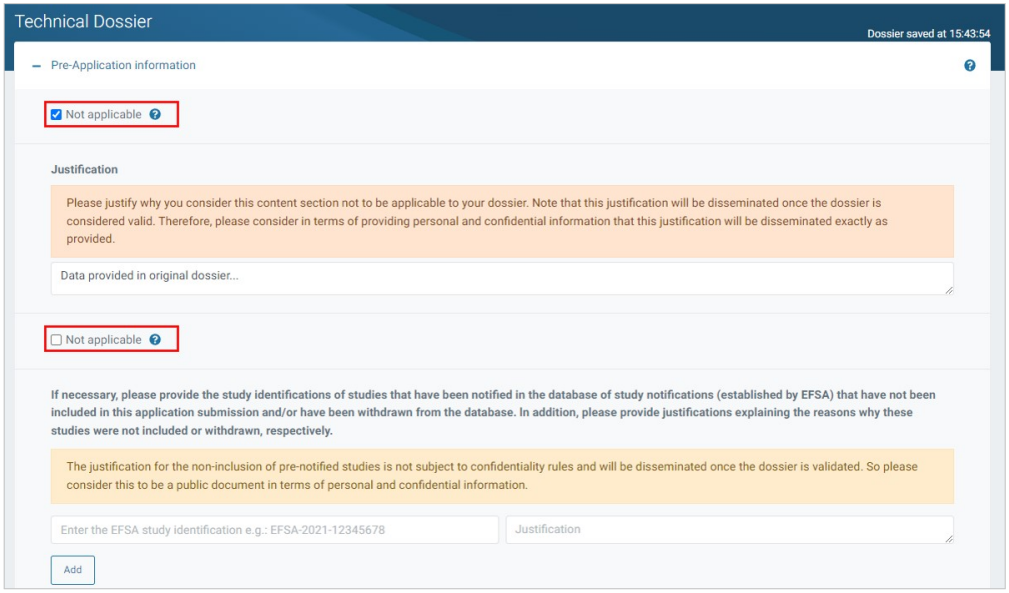
2. Complete the **Administrative Data** section. Note the last two fields are related to the previous submission.
   – Identify the original application. Select the correct dossier displayed using the pull-down to ensure the linkage of both dossiers.
   – Provide the EFSA Journal link(s) of the EFSA Inconclusive Opinion(s). Several EFSA Opinions may be added if deemed necessary.



3. Provide a **Cover Letter** and its supporting metadata, and the letter that you have received from EC inviting you to submit complementary information. Please merge both documents in a single PDF file.

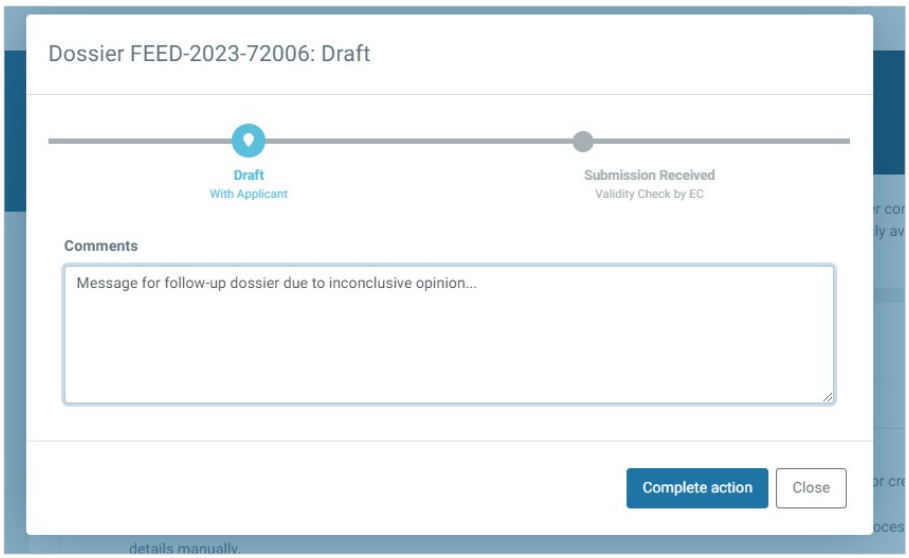


4. By default, all fields in the **Technical Dossier** section are marked as 'Not applicable'. The dossier linkage means that the original data submitted for that section are still accessible to EFSA.
   – Justify keeping the ‘Not applicable’ mark in the unmodified fields of the new dossier.
   – Unmark the 'Not applicable' box and provide new information in the field(s) which triggered the Inconclusive Opinion(s). The same confidentiality principles apply.

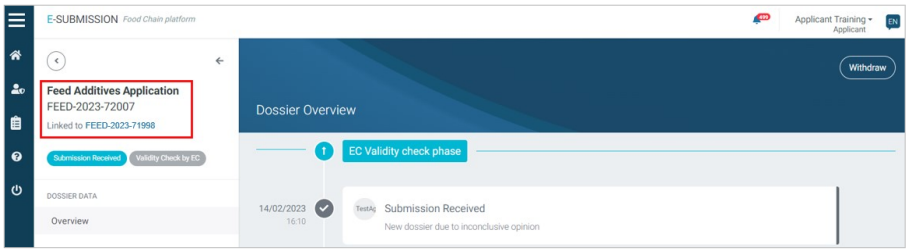


5. Click **Submit**.

6. Enter a message and click **Complete action**.



7. The dashboard displays the linkage between the original and the new application, and it confirms that EC has received the submission.



4.4 Decontamination Substances

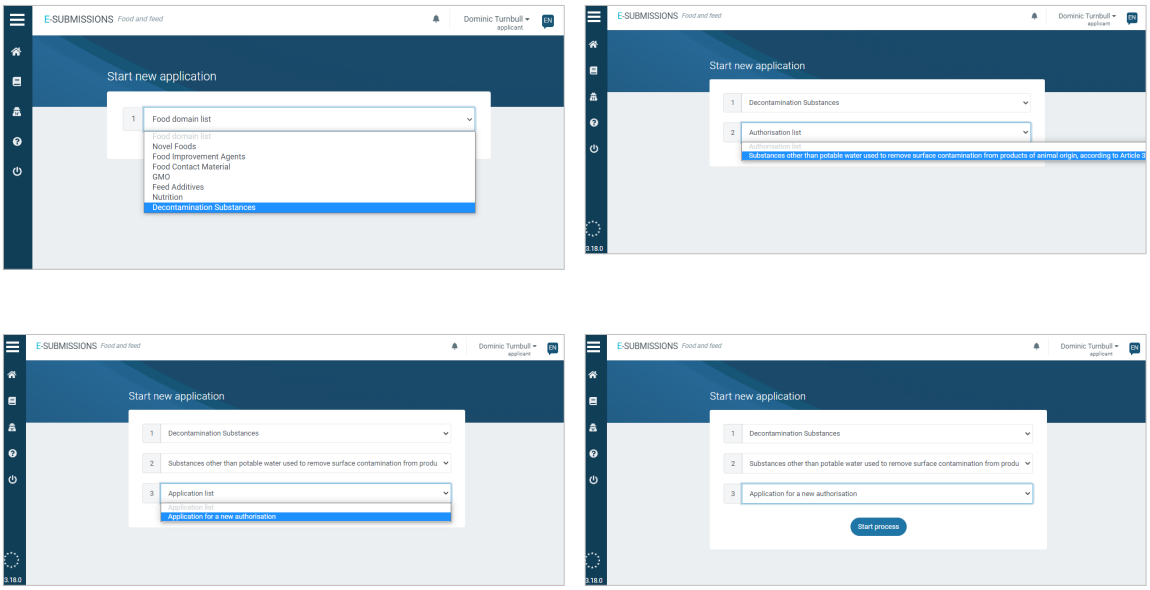
In the field of decontamination substances, EFSA evaluates applications for decontamination substances other than potable water.

NOTE
See EFSA's overview: Biological hazard applications: overview and procedure

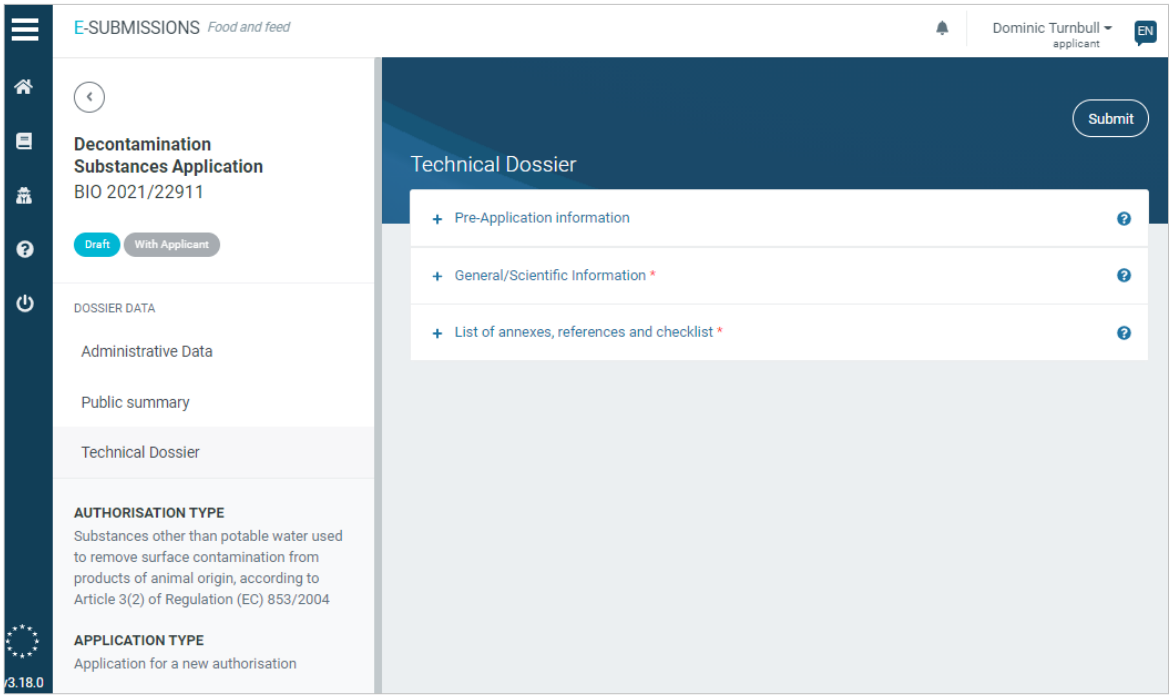
4.4.1 Getting started

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 [34] submission example illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

NOTE
EFSA landing page for Biological Hazards Regulations and Guidance documents.

4.5 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.

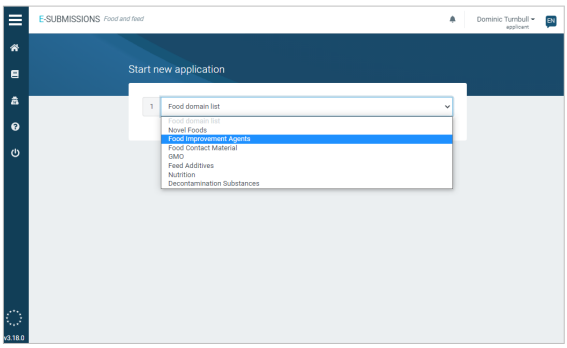
Submission types and legislation

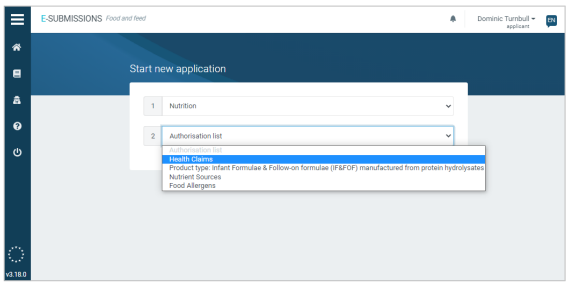
Authorisation type	Application type	In accordance with
Heath Claims	Application for the authorisation of a new health claim	Regulation EC 1924/2006
	Application for the modification of an existing health claim authorisation	
Infant Formulae & Follow-on formulae (IF&FOF) manufactured from protein hydrolysates	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

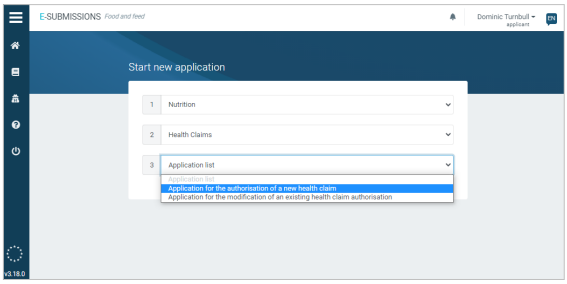
4.5.1 Getting started

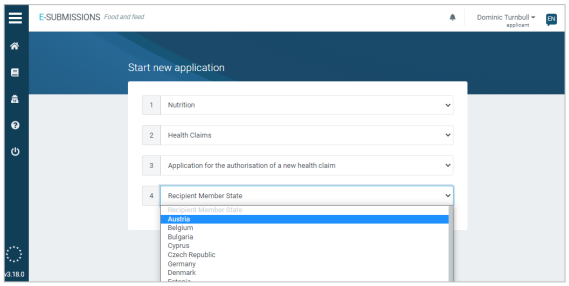
Create a dossier: Health Claims

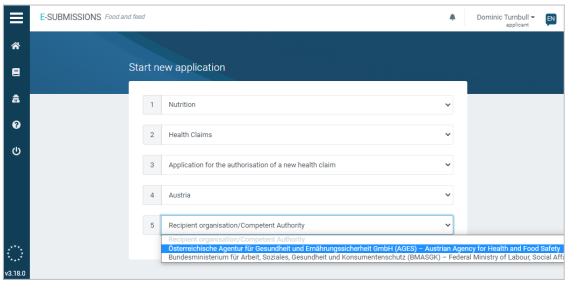
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Food Improvement Agents** from the Food domain list. Then choose your domain type **Health Claims**, the **Application type**, the **Recipient Member State** and the appropriate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

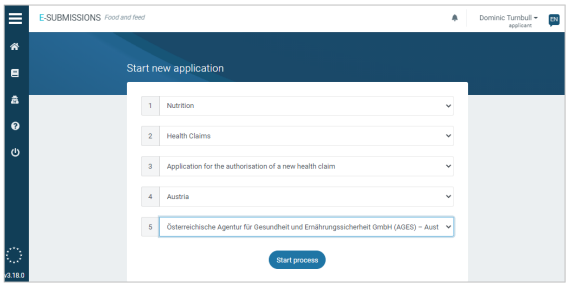




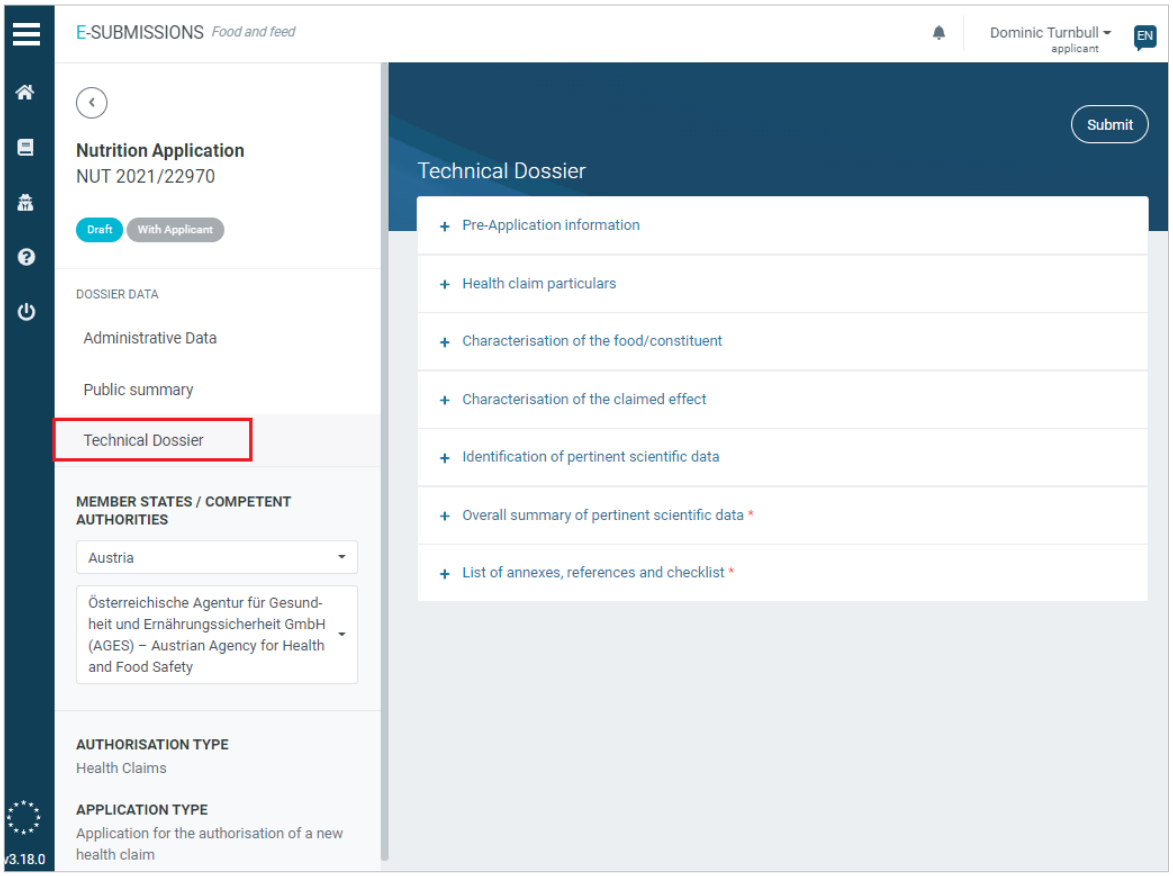








2. The Technical Dossier section is structured according to legislation and unique to each domain.



NOTE

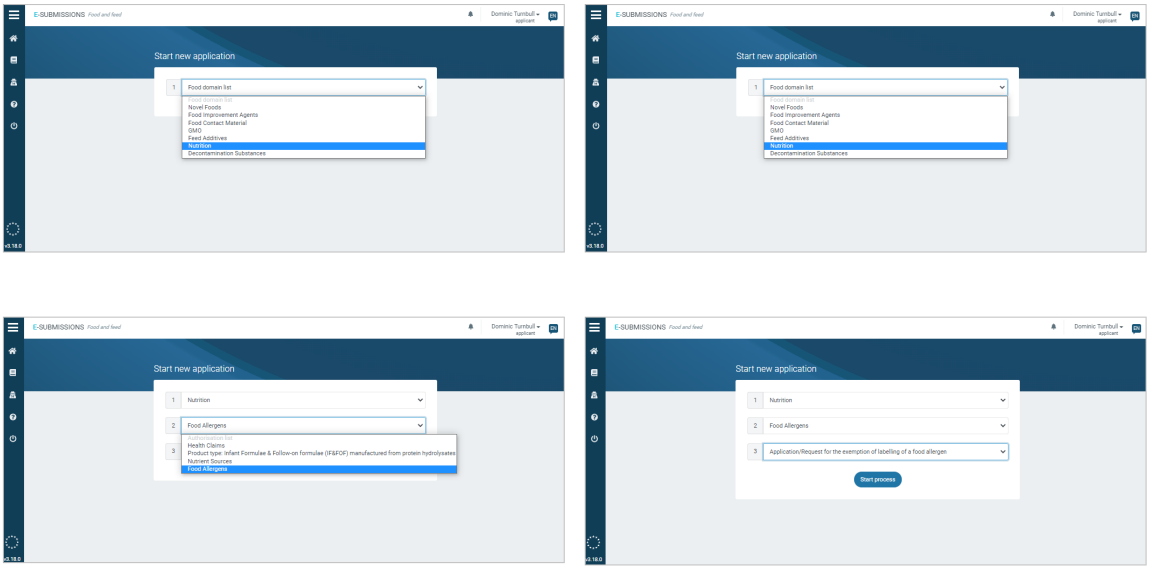
The submission process is the same for all dossiers which are partly assessed by a MS-CA. This 'Substance to be used in plastic material' submission example, in Food Contact Materials [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study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

NOTE

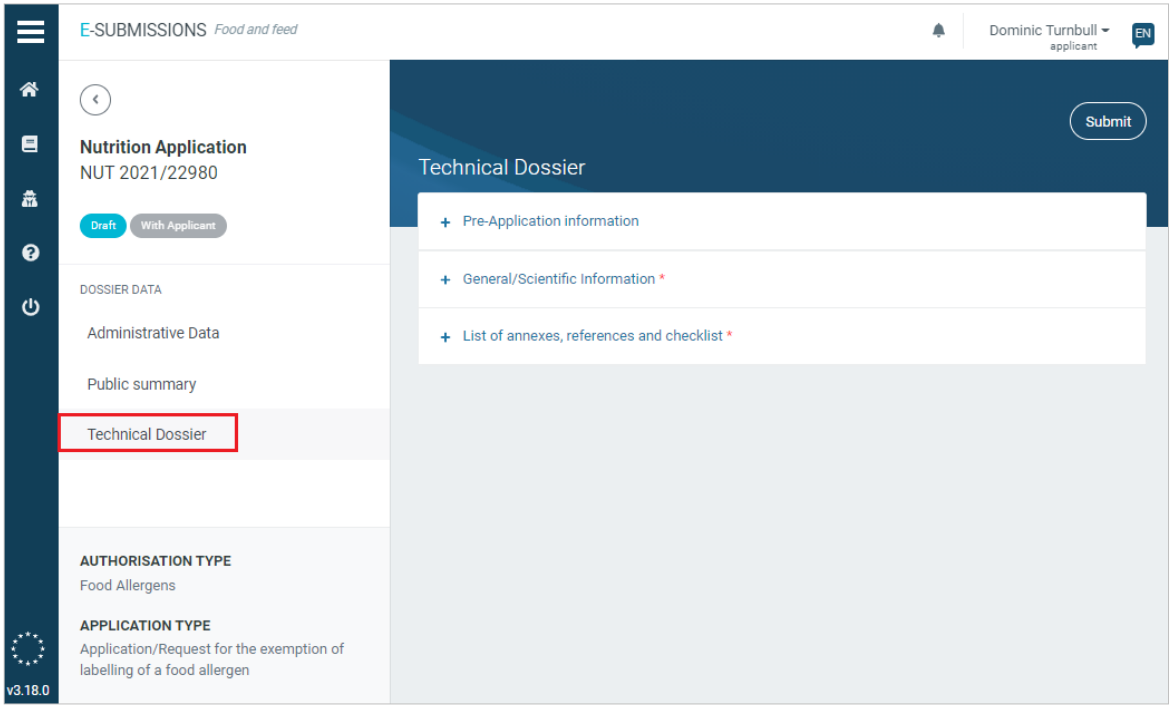
EFSA landing page for all Nutrition Regulations and Guidance documents.

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.

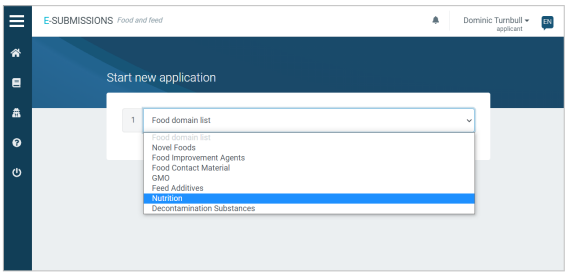


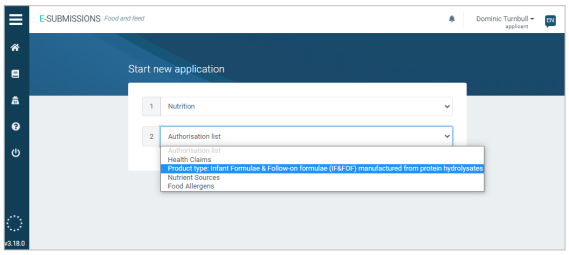
NOTE
The submission process is the same for all dossiers which are assessed by EC and EFSA. This Food Additives [34] submission example illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable',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

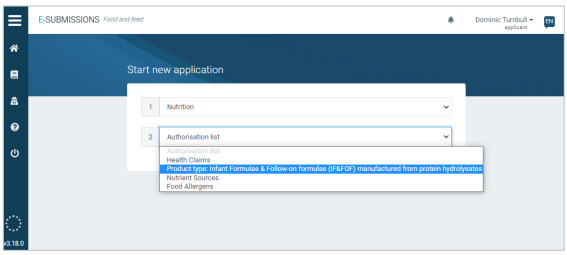
NOTE
EFSA landing page for all Nutrition Regulations and Guidance documents.

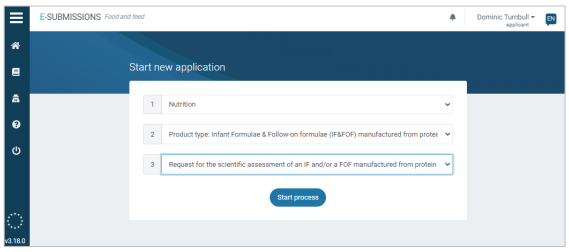
Create a dossier: Infant Formulae & Follow-on Formulae

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**'.

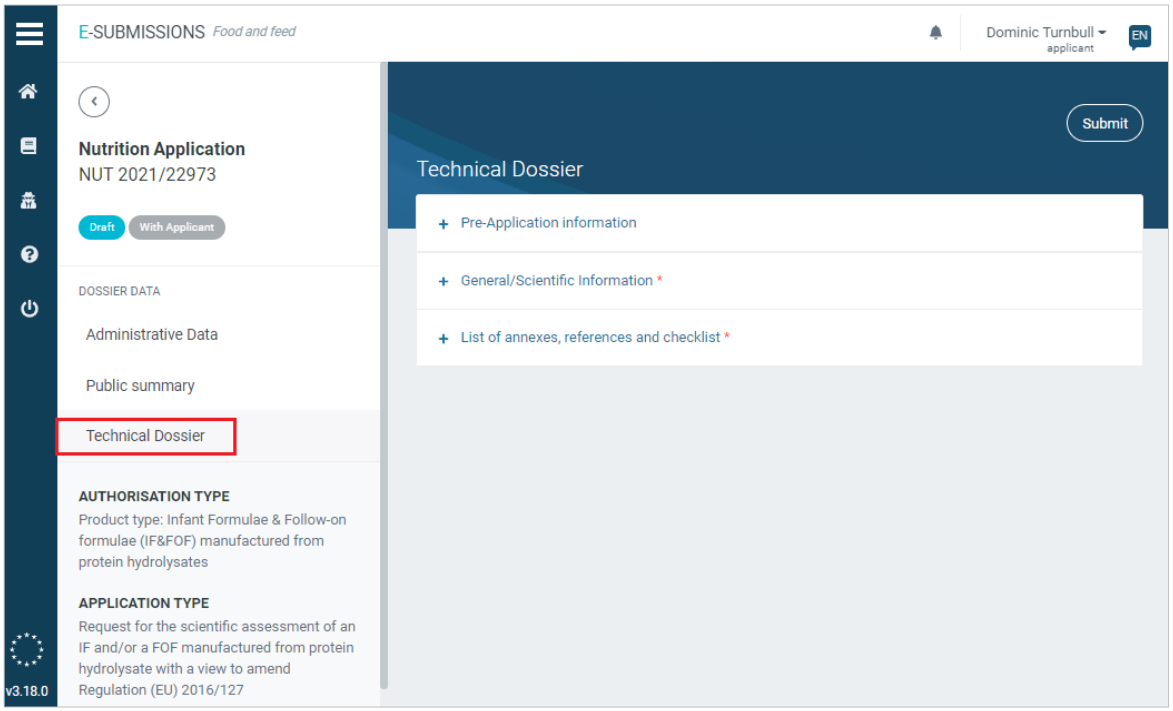








2. The Technical Dossier section is structured according to legislation and unique to each domain.



NOTE

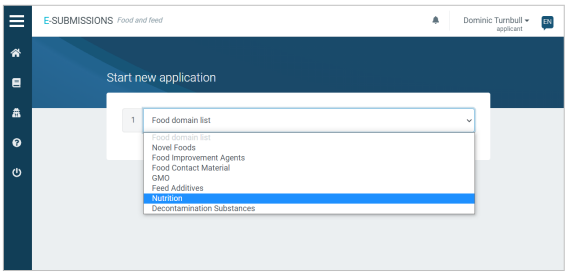
The submission process is the same for all dossiers which are assessed by EC and EFSA. This Food Additives [34] submission example illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable',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

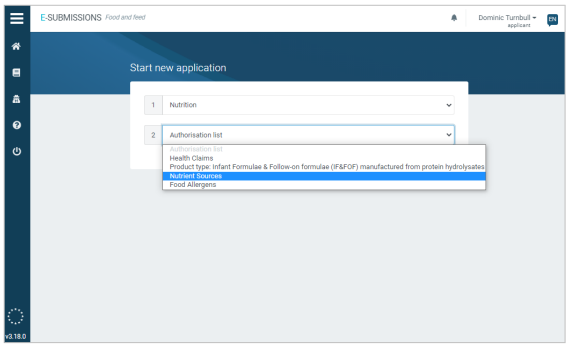
NOTE

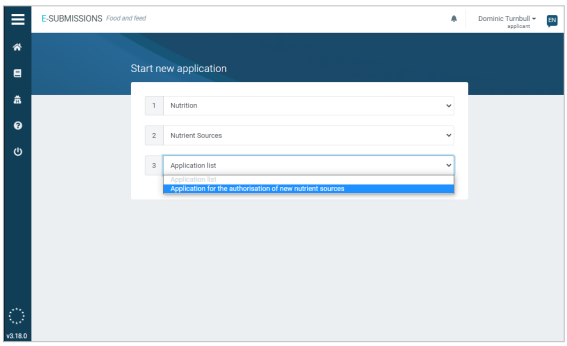
EFSA landing page for all Nutrition Regulations and Guidance documents.

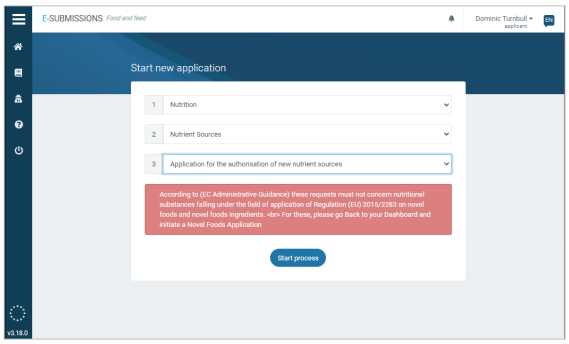
Create a dossier: Nutrient Sources

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**'.

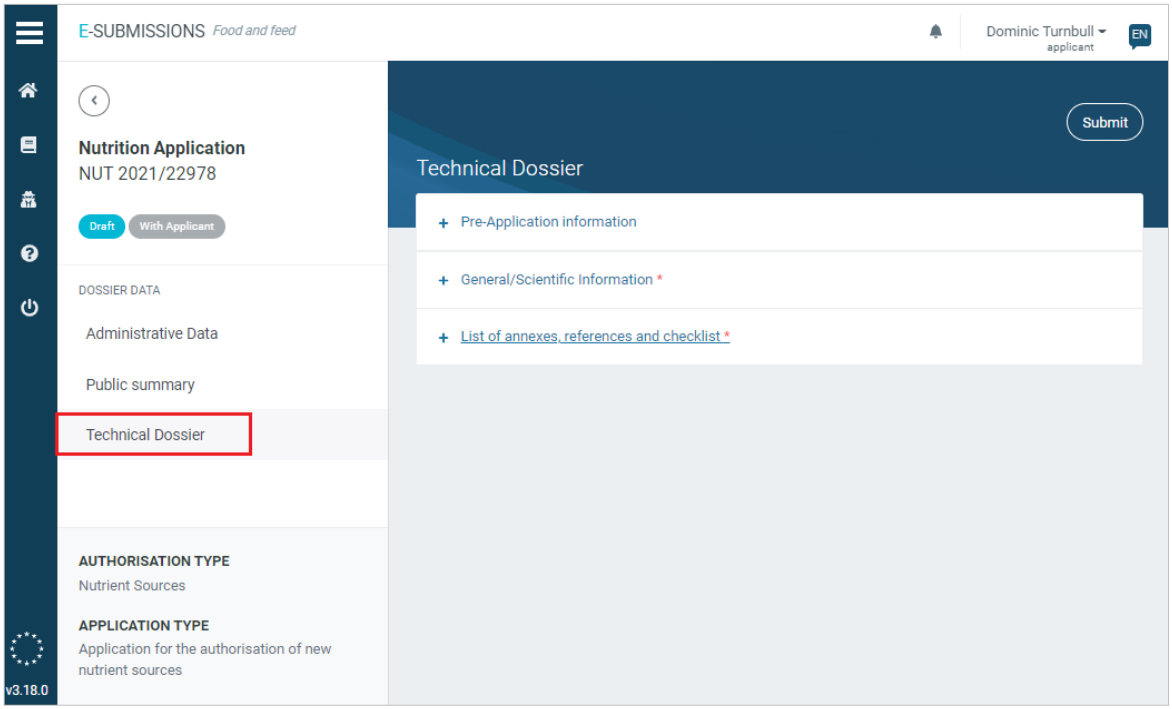








2. The Technical Dossier section is structured according to legislation and unique to each domain.



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

NOTE
EFSA landing page for all Nutrition Regulations and Guidance documents.

4.6 Novel & Traditional 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[1]. Novel food can be newly developed, innovative food, food produced using new technologies and production processes. The Traditional Foods domain is a subset of Novel Foods[2], relating to food traditionally consumed in countries outside the EU.

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	Article 16, Regulation (EU) 2015/2283
	Application for the modification of an already authorised traditional food	

NOTE

The '**Traditional Foods application**' option in the ESFC dropdown menu is not visible because the *application* submission is only possible if the Traditional Foods *notification* is rejected for safety reasons. In that instance, the Applicant may resubmit according to the conditions as outlined in Article 16 of Regulation (EU) 2015/2283.

NOTE

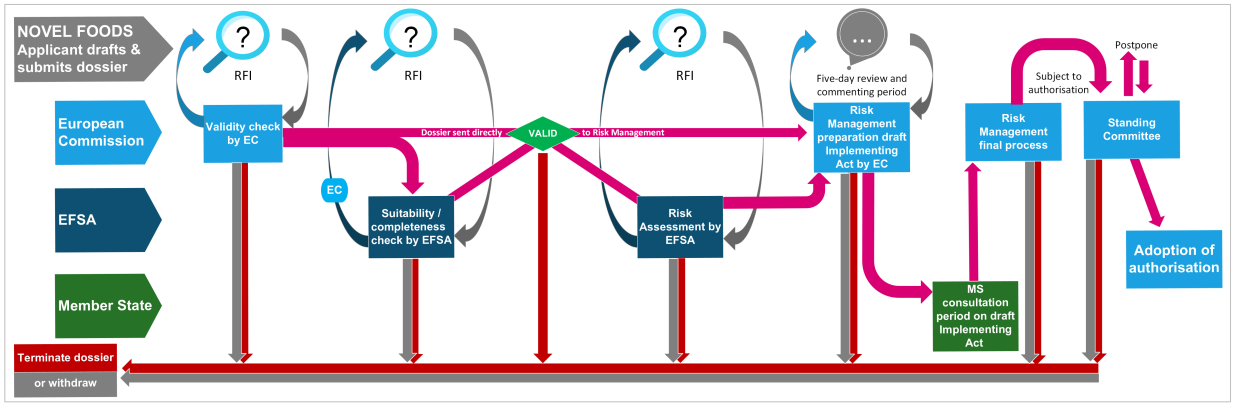
EFSA guidance: Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation EU 2015/2283 (Revision 1) (update 2021).

EFSA landing page for all Novel Foods Regulations and Guidance documents

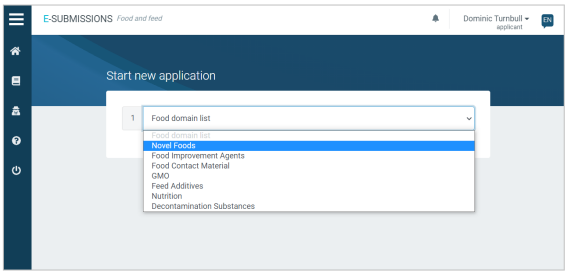
[1]Article 3, paragraph 2 of Regulation (EU) 2015/2283
[2]Article 3, paragraph 2(c) of Regulation (EU) 2015/2283

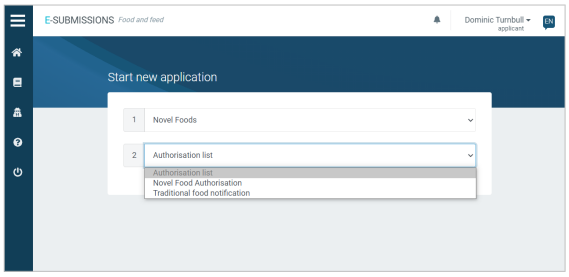
4.6.1 Getting started

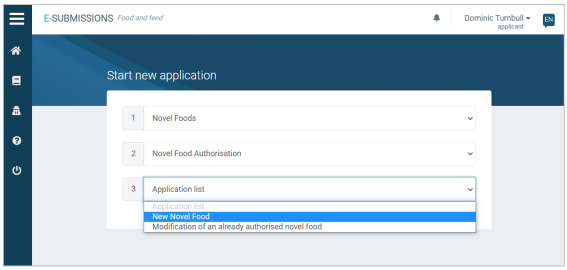
Create a dossier: Novel Foods

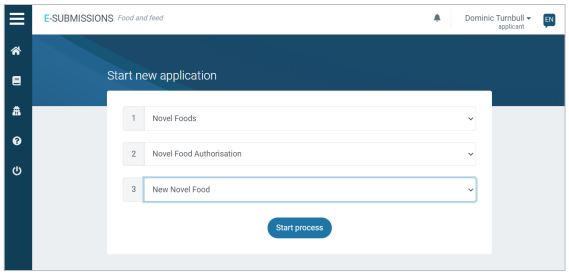


1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Novel Foods** from the Food domain list. Then choose your Authorisation type **Novel Foods** and the **Application type**, then press '**Start process**'.

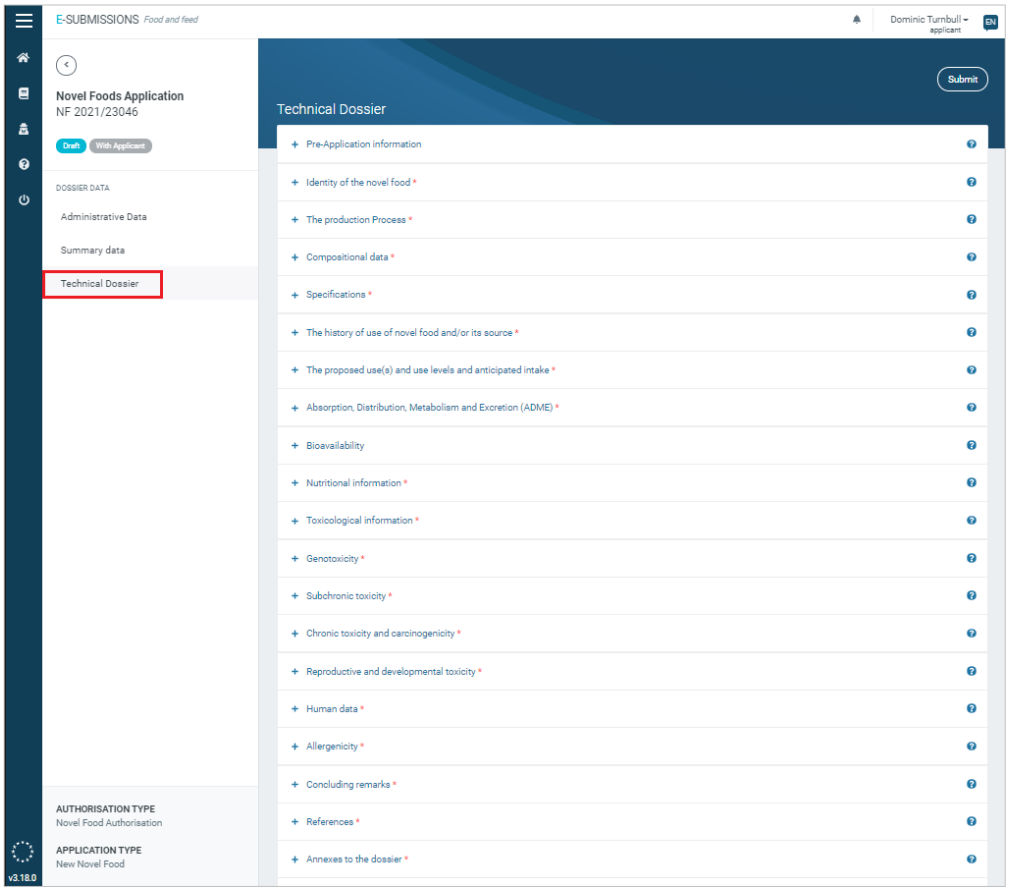








2. The Technical Dossier section is structured according to legislation and unique to each domain.



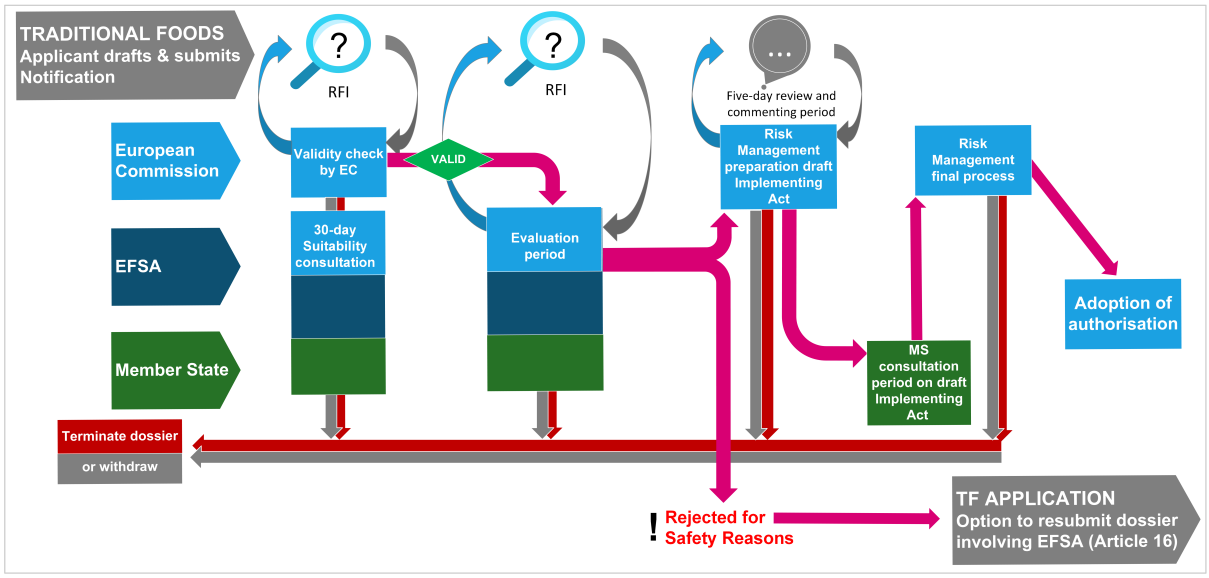
NOTE

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

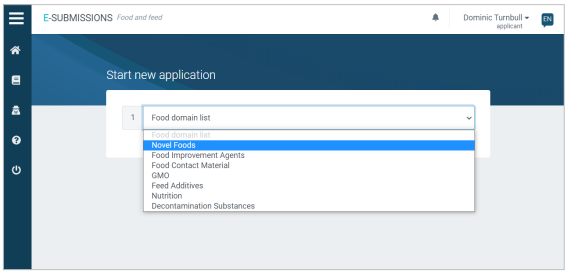
NOTE

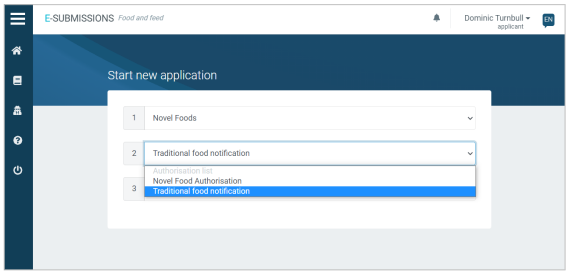
EFSA landing page for Novel Foods Regulations and Guidance documents.

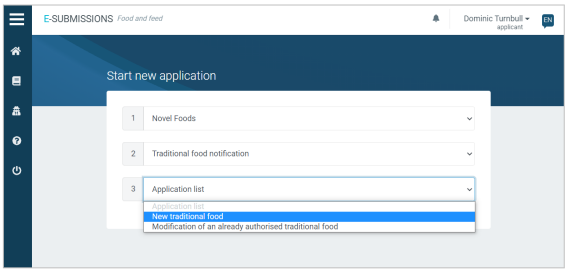
Create a Notification dossier: Traditional Foods

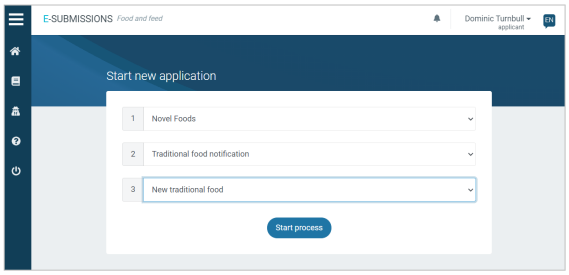


1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **Novel Foods** from the Food domain list. Then choose your Authorisation type **Traditional Foods** and the **Application type** (note that only the 'Notification' option shows, because the 'Application' option is only enabled following a safety objection to the notification), then press '**Start process**'.

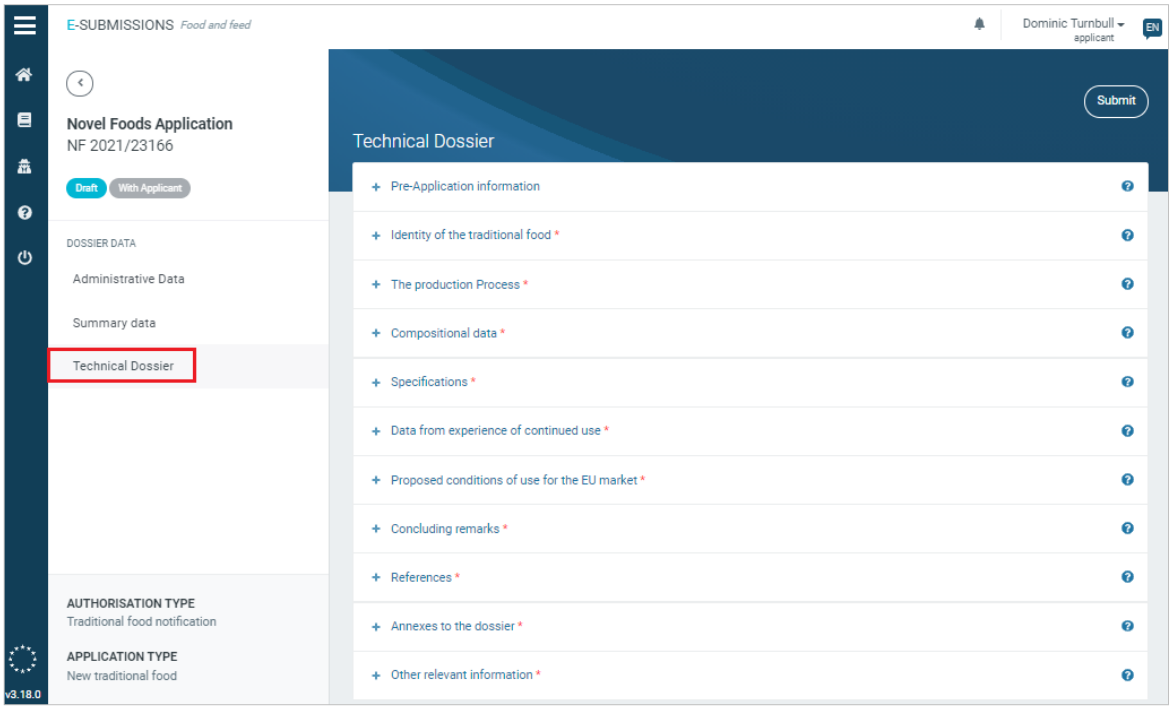




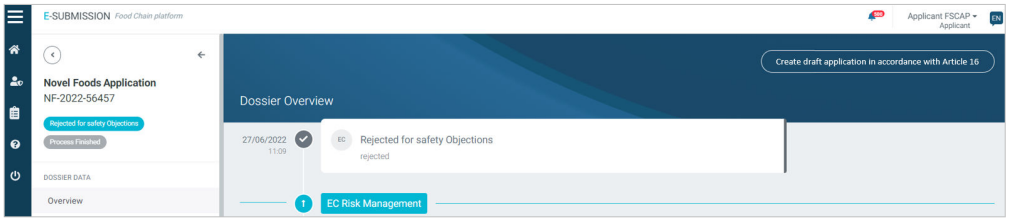




2. The Technical Dossier section is structured according to legislation and unique to each domain.



3. If your notification is rejected due to the safety objection(s), your dossier path has ended. However, by clicking the '**Create draft application in accordance with Article 16**' button which displays, followed by **OK**, the ESFC platform will rebuild the dossier as an Application in draft state, with several extra sections requiring information.



4. You will be notified when the draft dossier is ready for your input.

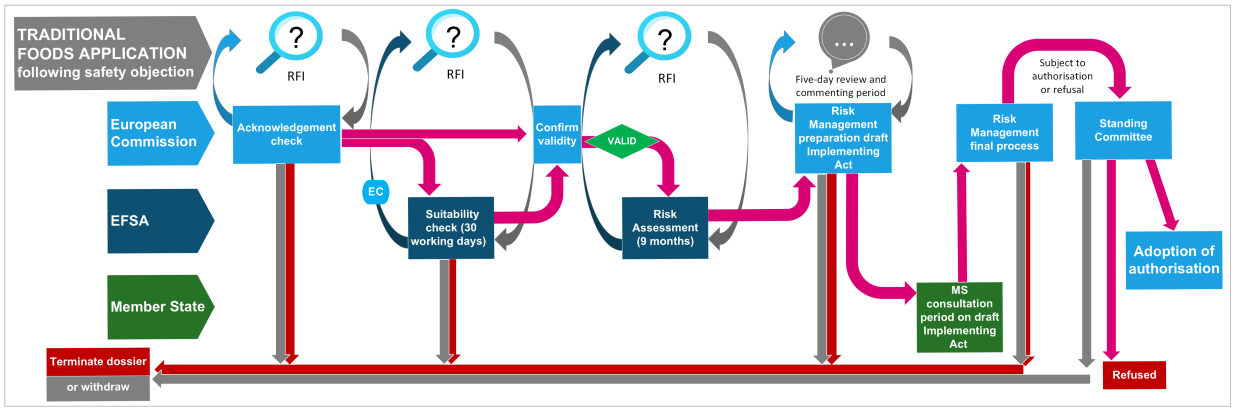
NOTE

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

NOTE

Note EFSA's Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1).

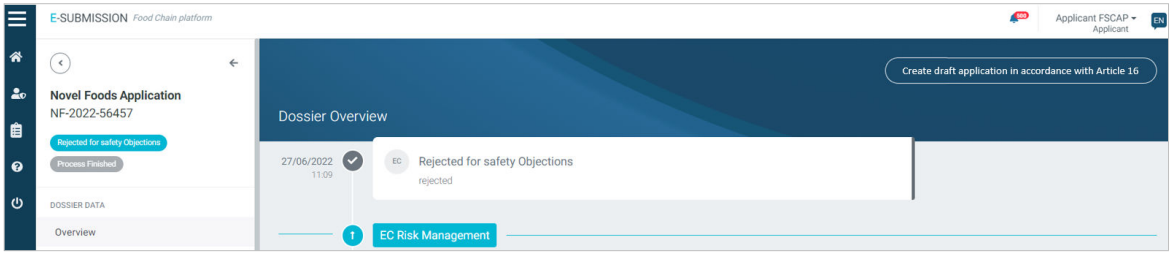
Create an Application: Traditional Foods under Article 16



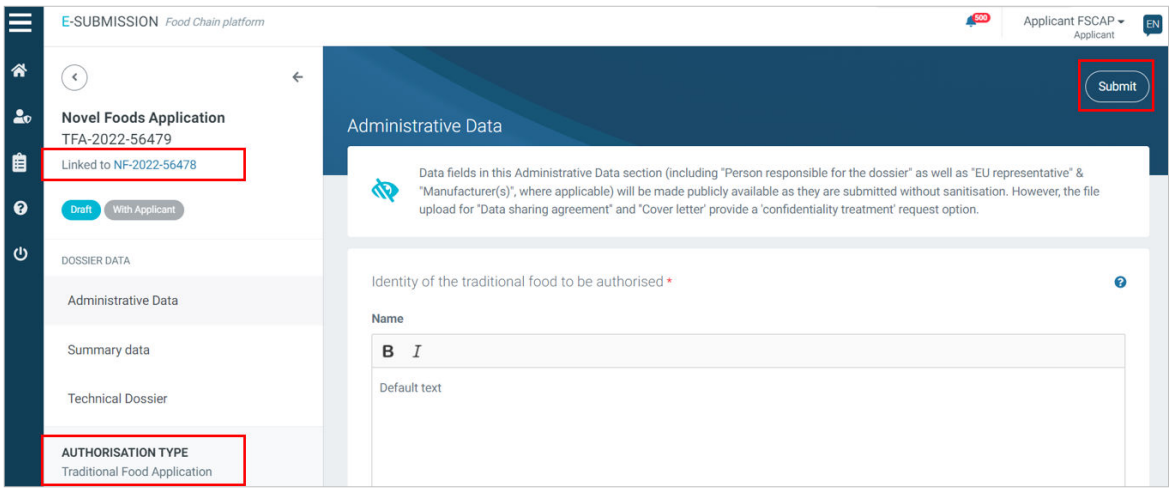
Where duly reasoned safety objections are raised during the evaluation, the **notification** is rejected by EC (via a Commission Decision) and the Applicant is invited to resubmit a Traditional Foods **application** under Article 16 of Regulation (EU) 2015/2283. EFSA will carry out the Risk Assessment, and EFSA will also manage any confidentiality assessments. It is also possible that EC will send a dossier directly for Risk Assessment without the Suitability Check.

Refer to the original (rejected) notification dossier to access the confidentiality dashboard.

1. You are informed about the rejection. Go to the dossier via the dashboard or use the link in the email notification. Click **'Create draft application in accordance with Article 16'**.



2. A new dossier is created containing the notification information and submitted files, in **draft** state. A new application number is assigned, and the dossier type is Traditional Food Application (TFA). A link shows the rejected dossier number. You can click between the two.
   Complete the additional fields in the technical dossier. Click **Submit** to begin the process.



NOTE

The **Traditional Foods application'** option in the ESFC dropdown menu is only visible if the Traditional Foods *notification* has first been rejected for safety reasons. In that instance, the Applicant may resubmit according to the conditions as outlined in Article 16 (EU) 2015/2283.

NOTE

EFSA guidance: Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1).

4.7 GMO authorisations

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

- **Cultivation**
- **Marketing of food and feed and derived products**
- **GMO Part C and Part B**

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.

For renewal of food and feed applications, the dossier is submitted to the EC at least a year before consent expiry. It carries out administrative validity checks before EFSA's scientific validity and confidentiality checks.

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 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	Articles 11 and 23 (EC) 1829/2003 Regulation (EU) 503/2013
Summary notification for the release of GMOs other than higher plants (GMOTHPs)	Summary notification concerning) New release of GMOs other than higher plants Summary notification concerning) Modification of GMOs other than higher plants already released	Directive 2001/18/EC-Part B
Summary notification for the release of GM higher plants (GMHPs)	Summary notification concerning) New release of GM higher plants Summary notification concerning) Modification of GM higher plants already released	Directive 2001/18/EC-Part B
GMO Part C – Deliberate release into the environment of genetically modified higher plants (GMHPs)	Notification concerning new release of genetically modified higher plants Notification concerning renewal of release of genetically modified higher plant	Directive 2001/18/EC-Part C
GMO Part C – Deliberate release into the environment of GMO other than higher plants (OTHPs)	Notification concerning new release of GMOs other than higher plants Notification concerning renewal of release of GMOs other than higher plants	Directive 2001/18/EC-Part C

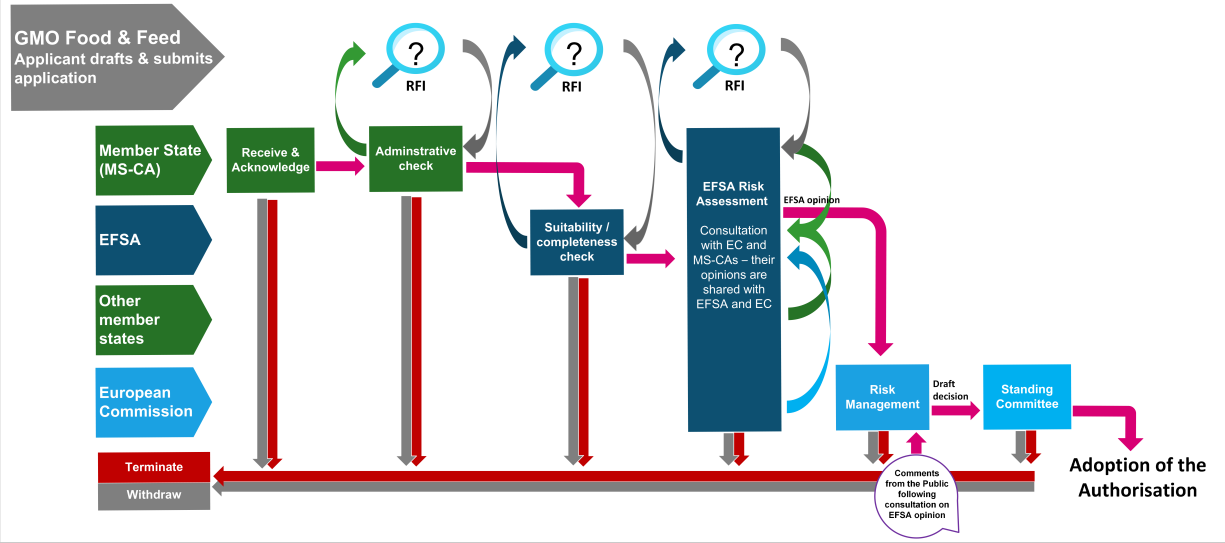
TIP

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.

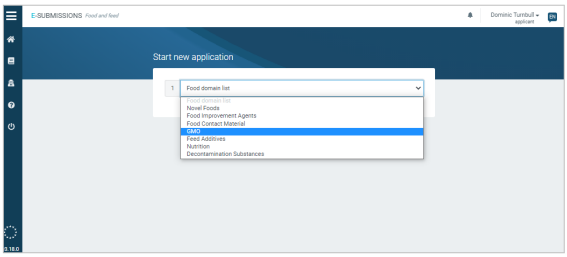
NOTE
EFSA landing page for all GMO procedures Regulations and Guidance documents.

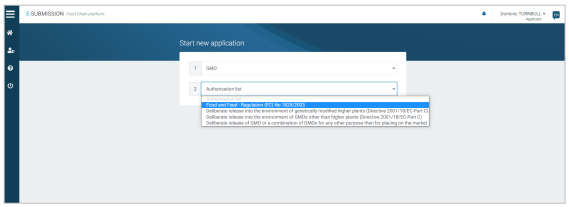
4.7.1 Getting started

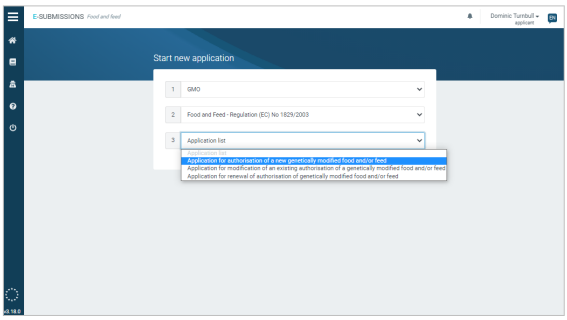
Create a dossier: GMO Food & Feed

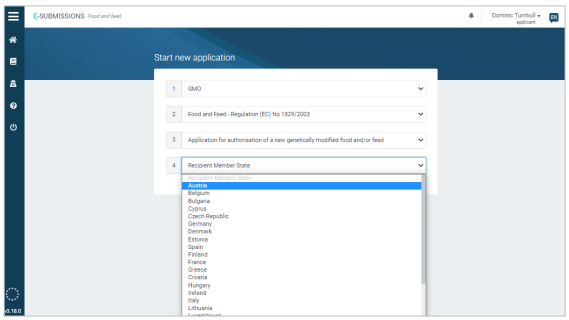


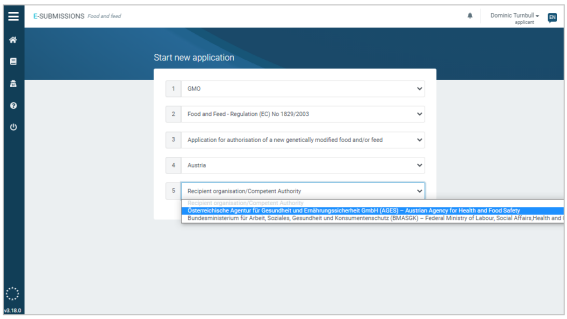
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **GMO** from the Food domain list. Then choose your domain type **GMO Food & Feed**, the **Application type**, the **Recipient Member State** and the appropriate **Competent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

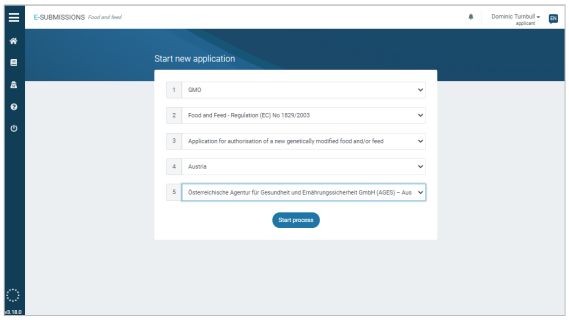




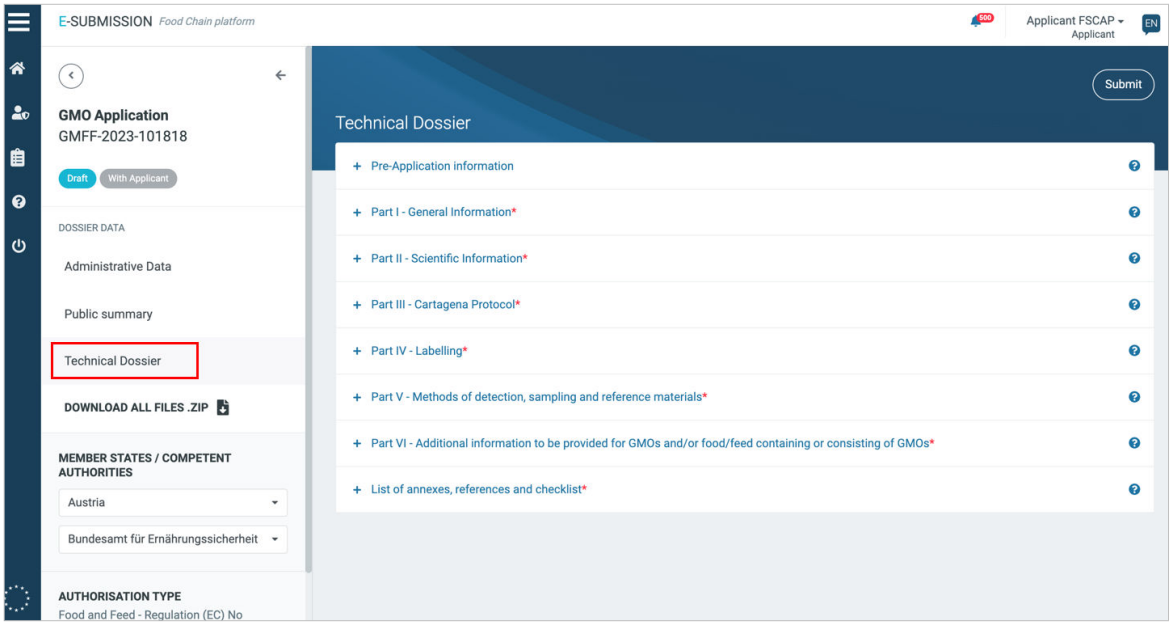








2. The Technical Dossier section is structured according to legislation and unique to each domain.



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 [14], illustrates the process, covering: Administrative Data, Public summary, NOS declaration, Pre-Application IDs, Study IDs, how to manage a section that is 'Not applicable', and how to submit.

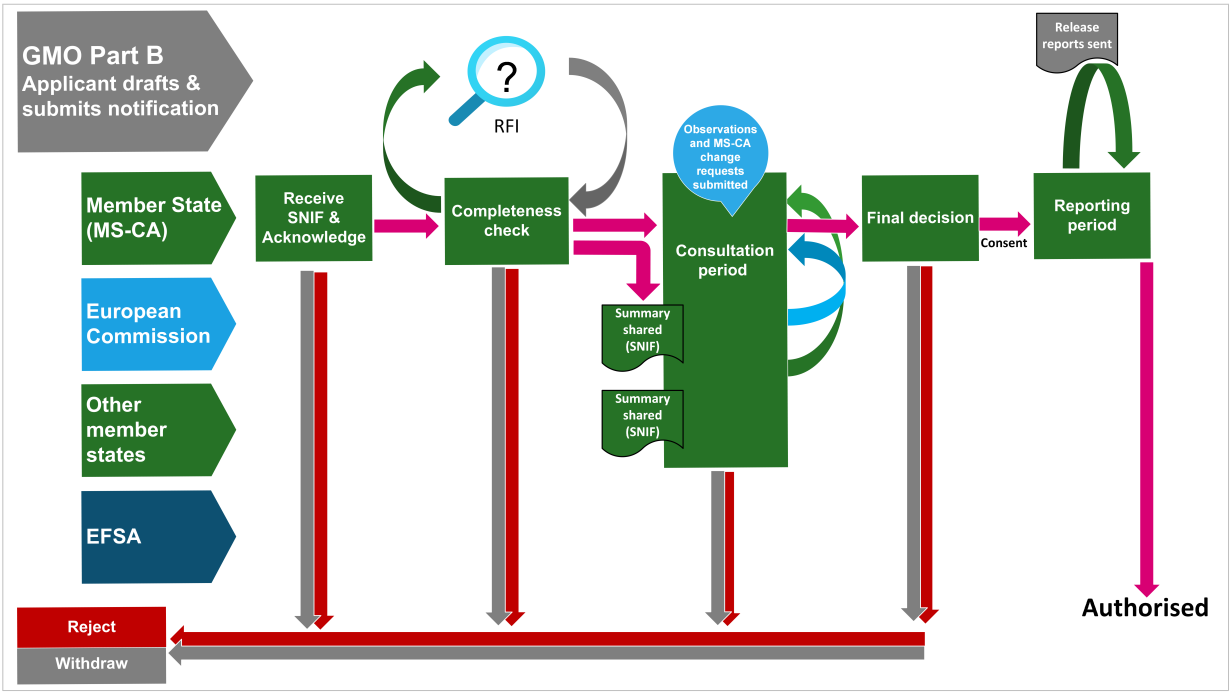
NOTE

Renewal applications are directed to EC rather than the MS-CA, using the same path followed by Food Additives [34].

EFSA landing page for GMO Regulations and Guidance documents.

Create a dossier: GMO Part B

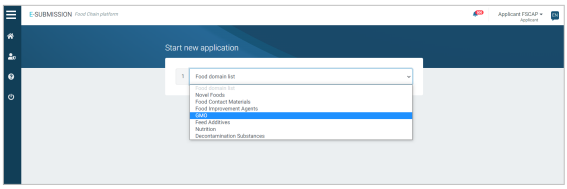
Deliberate release of GMOs for any other purpose than for placing on the market

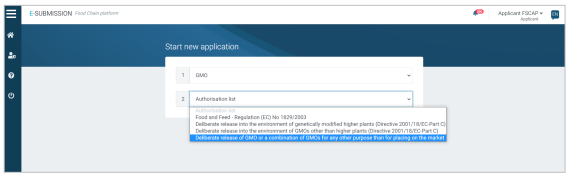


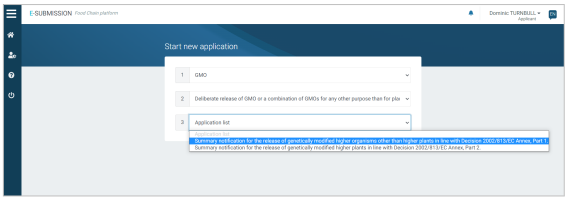
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **GMO** from the Food domain list. Then choose your **Authorisation type** – in this example we select **Deliberate release of GMO or a combination of GMOs for any other purpose than for placing on the market**.

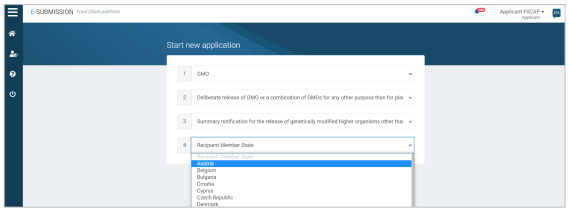
   From the Application list, select the Summary Notification for the release of **genetically modified higher organisms other than higher plants**, or **genetically modified higher plants**. Choose the **Recipient Member State** and the **Recipient Organisation/Competent Authority** (within whose territory the release is to take place). This MS-CA choice can later be changed.

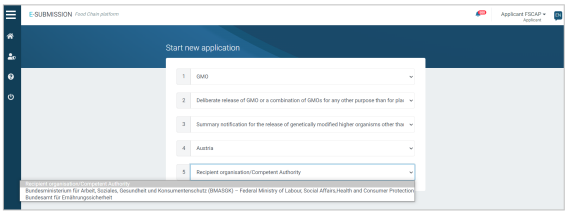
   Click '**Start process**'.

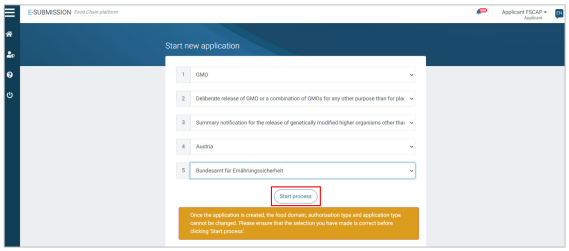




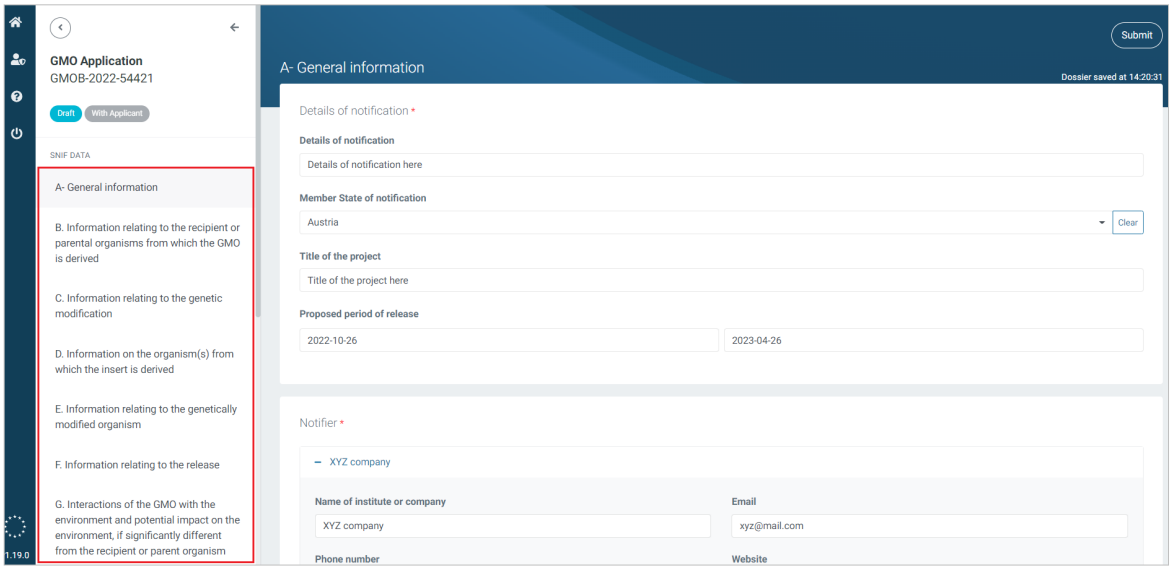




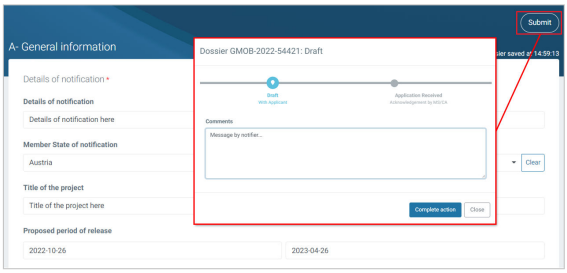


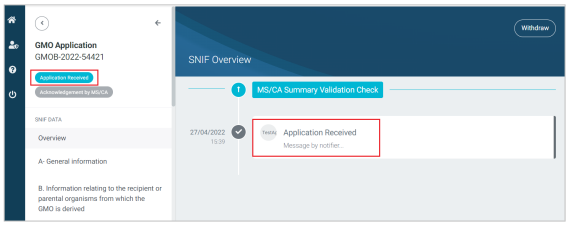


2. The notifier must complete all the sections for the Summary Notification Information Format (SNIF), i.e. from sections A to J, noting the mandatory fields.



3. Once all the information is in place, click **Submit**. You will receive an email and acknowledgement of the date and notification number from the MS-CA. The dashboard and badge show 'Application received'. The notification details are shared with EC and all MS-CAs to enable the 30-day (by calendar) Observation Period. EC **publishes** the summary in the GMO register.

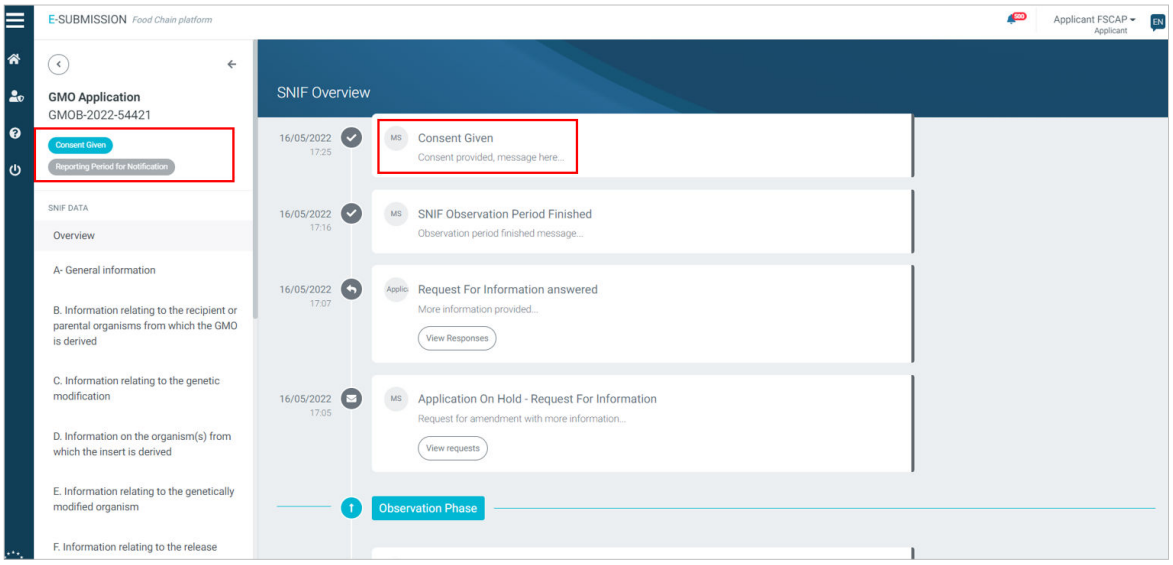




4. The initiating MS-CA manages the observation period, comments and objections. As a result, you may receive Requests for Amendments (in which case see this chapter [96] on RFIs). Note that if parts of the sections or subsections referred to in the RFI remain locked, you can provide additional information **within the RFI message itself**, and/or attach documents, before resubmitting the dossier.

5. Any MS-CA may request the **full notification** (i.e. have access to the full dataset supporting the GMO notification). This takes place outside ESFC.

6. If **approved**, after the release has taken place, the notifier will have to submit the release reports as per Article 10, Directive 2001/18/EC.



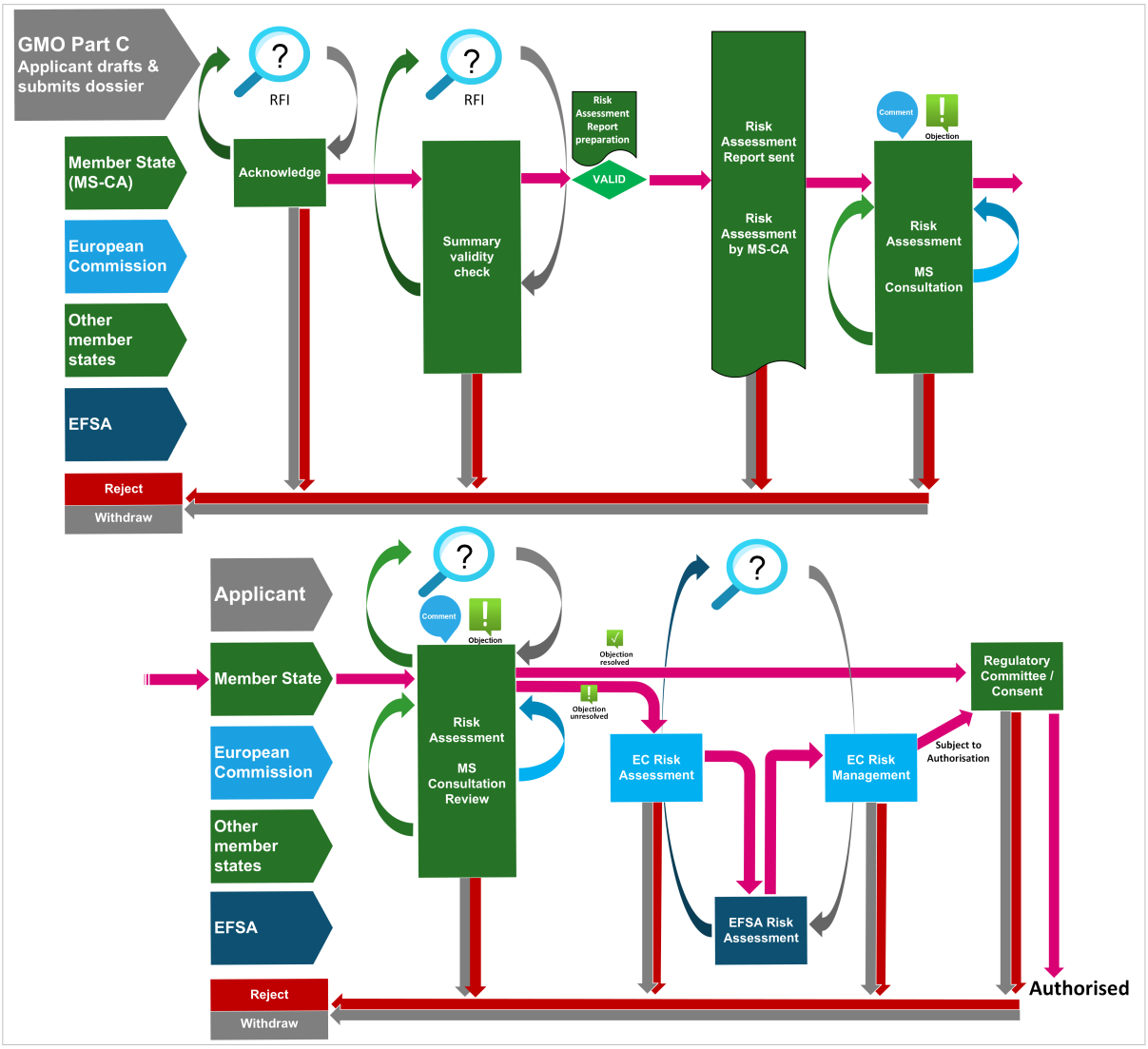
7. If **rejected**, the SNIF remains published in the GMO Register.

NOTE

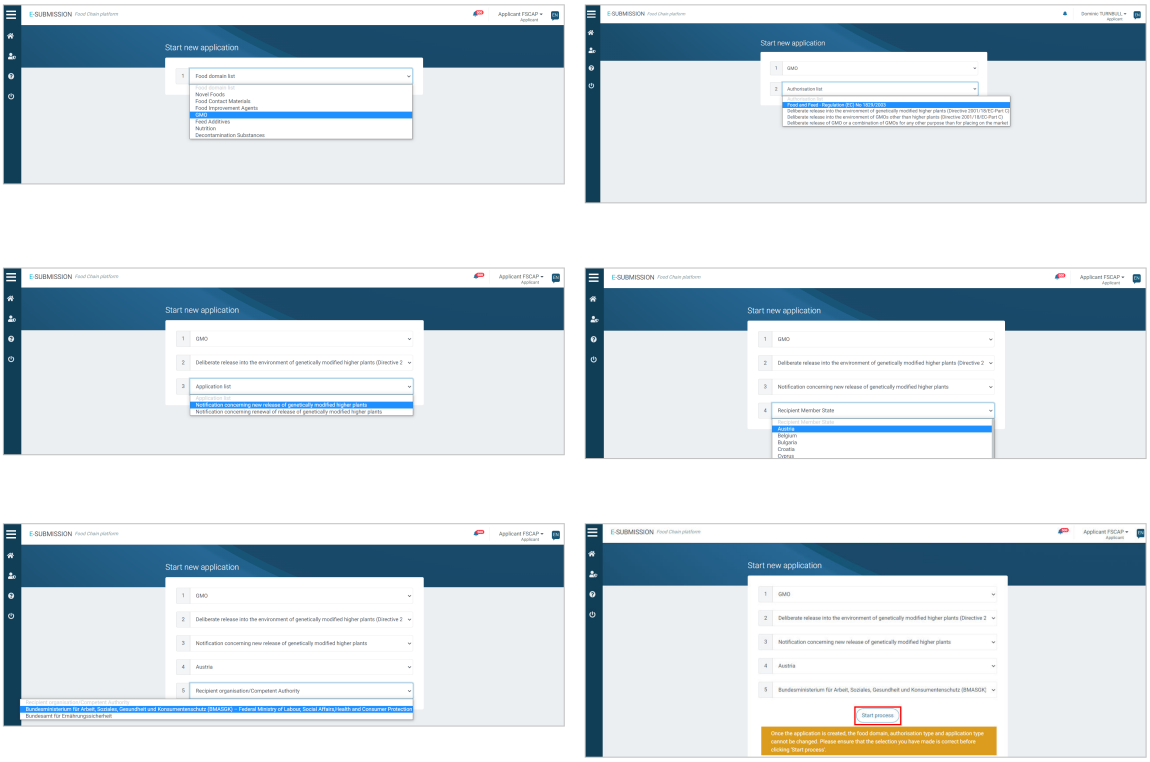
EFSA has **no role** in GMO Part B notifications, and therefore the information provided is not impacted by the Transparency Regulation. However, all MS-CAs are informed of the notification. They have access to the content, and they may raise objections or comment during the consultation, which could lead to RFIs.

Create a dossier: GMO Part C (GMHP & GMOTHP)

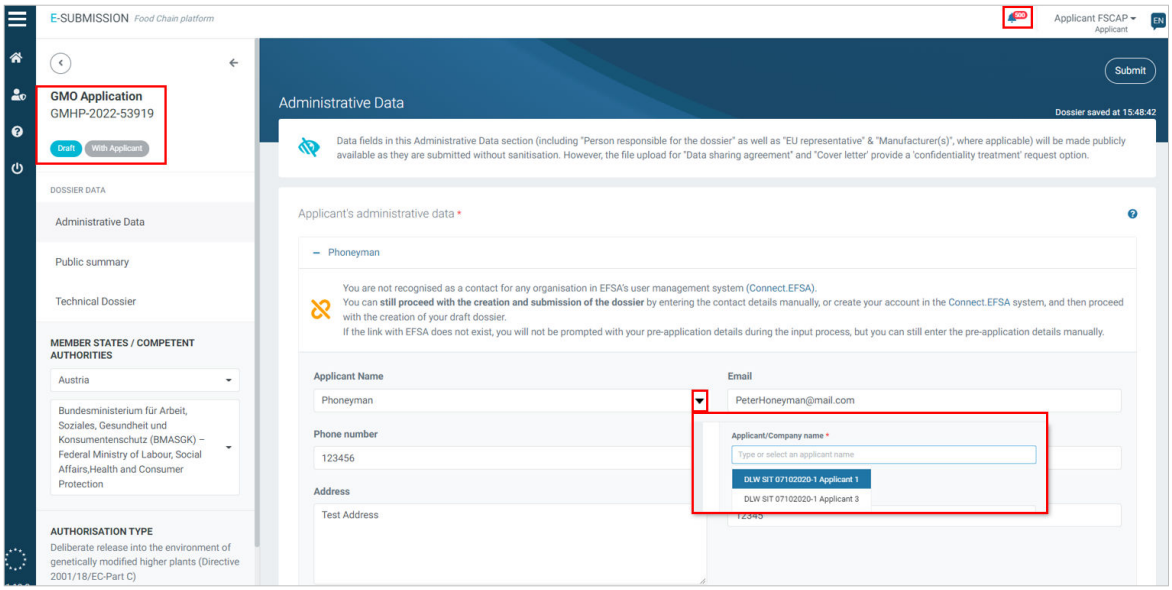
Deliberate release of Genetically Modified Higher Plants (GMHP) / Other Than Higher Plants (GMOTHP)



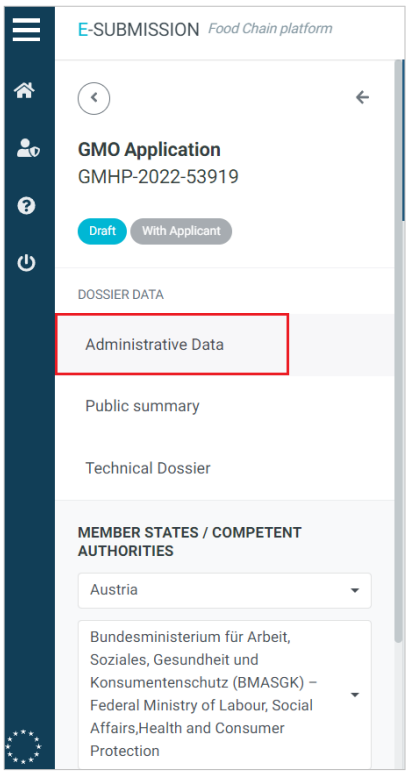
1. According to EFSA guidance and EC regulation, the appropriate domain template will be generated via the following steps. Select **GMO** from the Food domain list. Then choose your **Authorisation type** – in this example we select **Deliberate release into the environment of genetically modified higher plants (Directive 2001/18/EC-Part C)**. The path is the same for GMOTHP.
   Select the **Notification type** as 'New' or 'Renewal', the **Recipient Member State** and the **Recipient Organisation/Competent Authority** from the list provided. This MS-CA choice can later be changed. Note that Renewals must be directed to the same MS-CA to which the original notification was submitted.
   Click '**Start process**'.



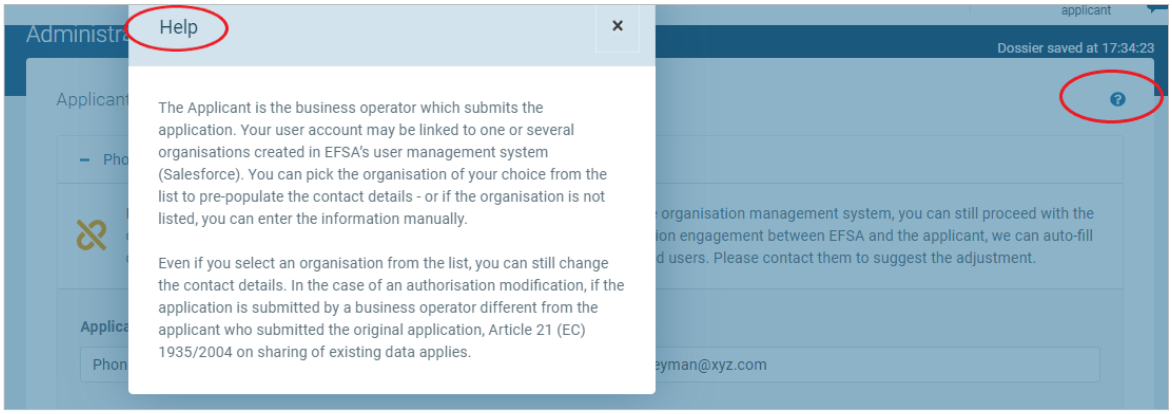
2. Complete the administrative data. Note the mandatory fields (*). Note the message beside the '' icon. If your login email **is associated** with one or more applicants, the '' symbol will appear from which you can select the appropriate Applicant. The top-left dossier number will remain throughout. The top-right notification bell indicates activity.



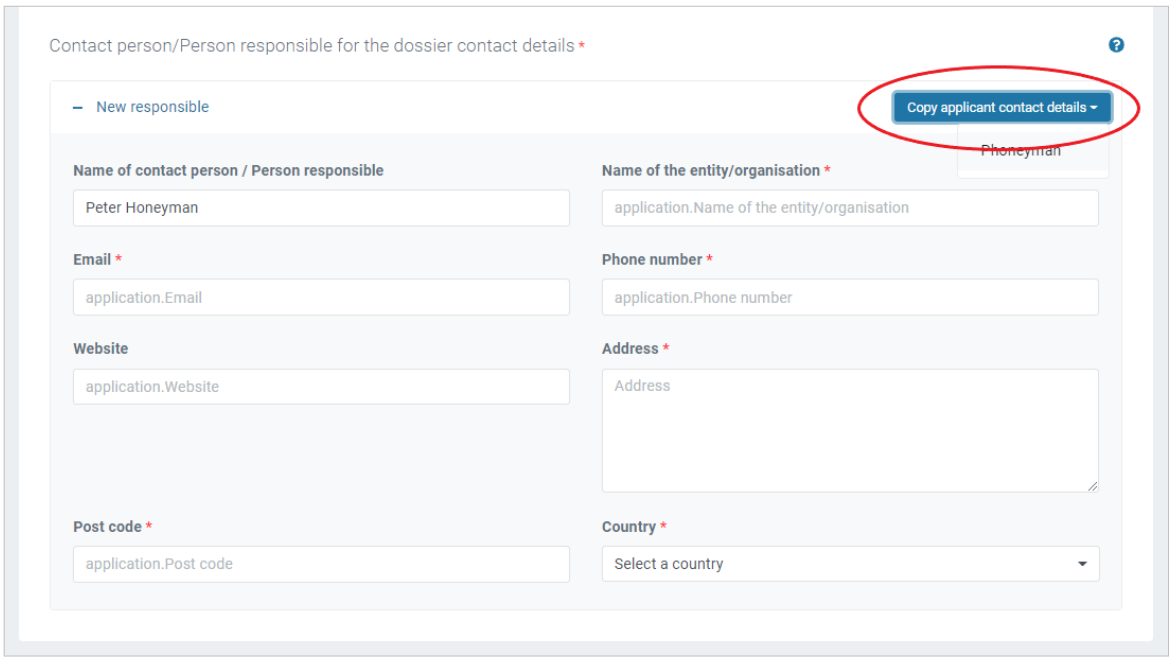
3. The column top shows the dossier status and phase. The three dossier sections remain throughout. The bottom section displays the authorisation and application type.



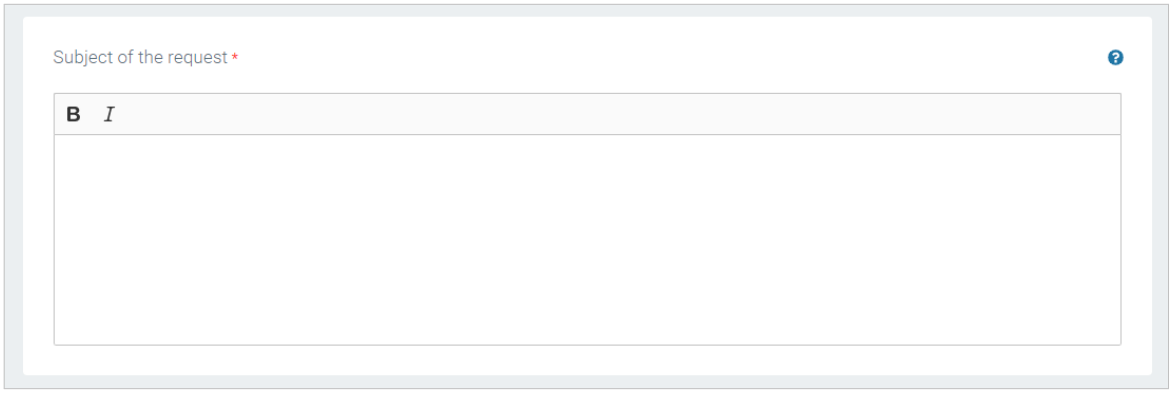
4. Click the '**?**' to see contextual help for the field.



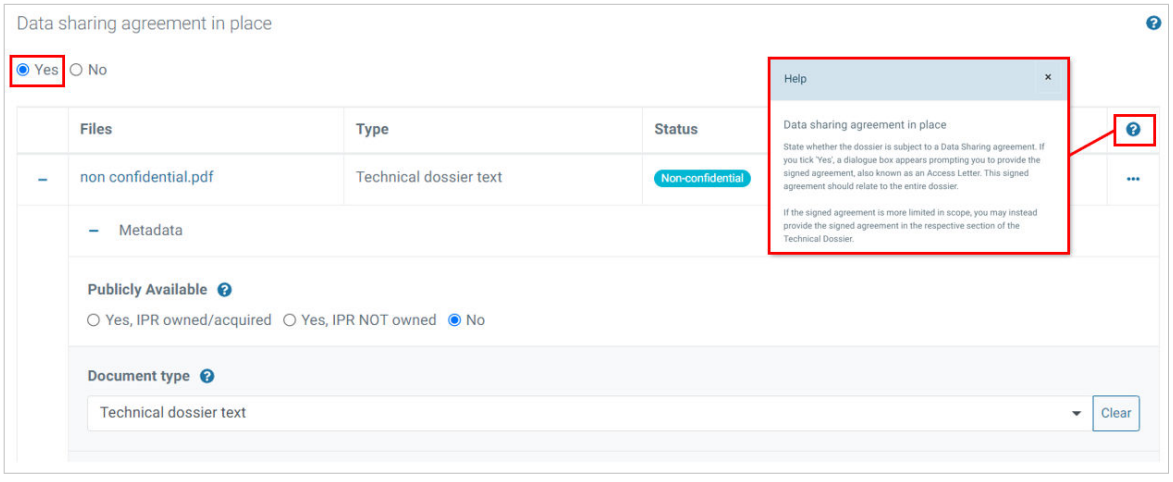
5. Click on '**Copy applicant contact details**' to duplicate the Applicants' data inserted in *Step 2*, in case the person responsible is working in the same company as the Applicant. Fields can be manually overwritten.



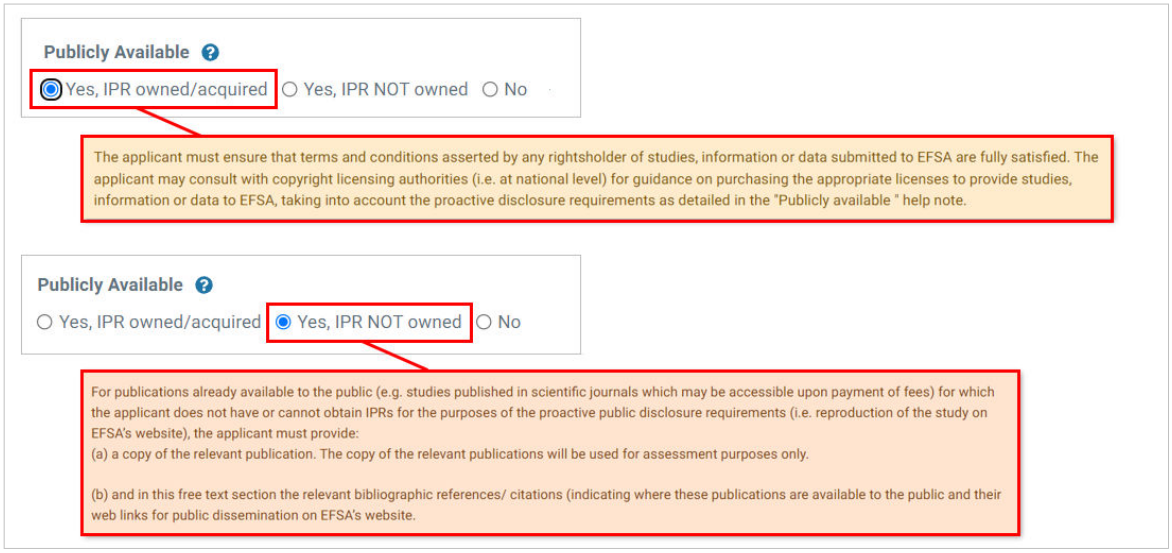
6. Enter the '**Subject of the request**'. You may consult the contextual help note '**?**' for additional information.



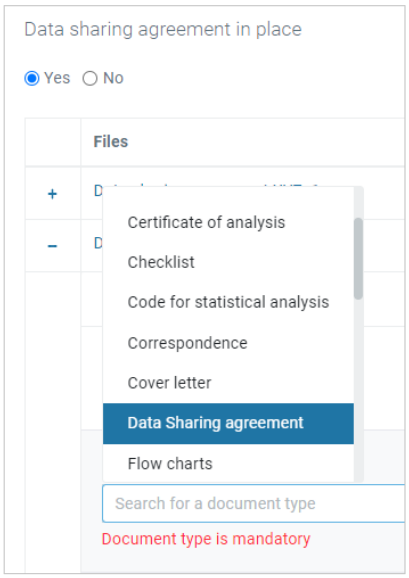
7. If a data-sharing agreement is available, relating to the entire dossier, click the '**Yes**' radial. Click '**Add document**' for multiple agreements. Note the default 'Non-confidential' badge.



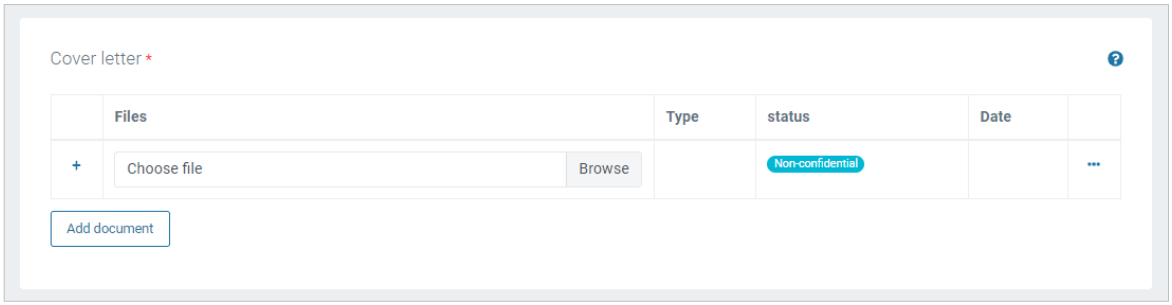
8. Indicate for each document whether it is '**Publicly available**', or whether there are related IPR considerations. The default setting is '**no**'. Publicly available files cannot be claimed as confidential. Confidentiality treatments already requested for this file will be automatically removed. For more information on how IPR impacts disclosure, read the chapter on Intellectual Property Rights [119].



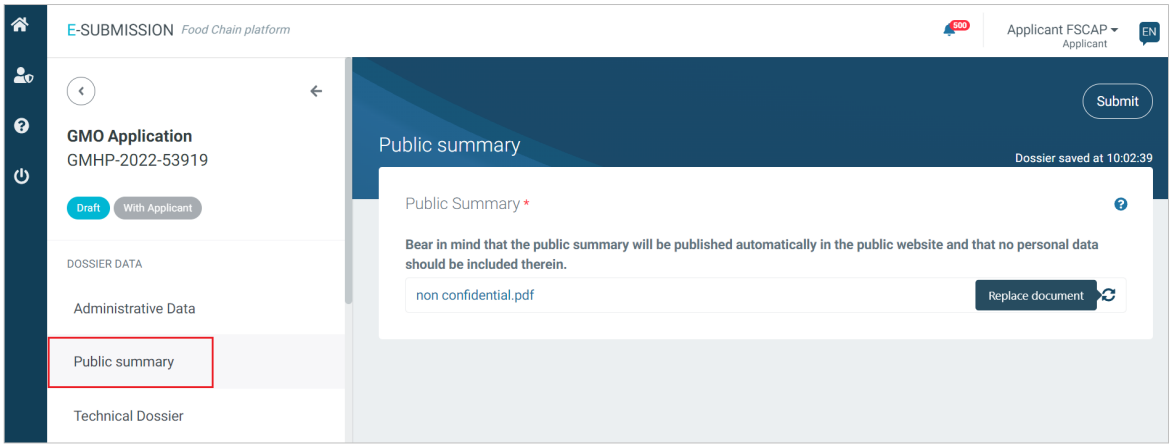
9. Now identify the '**Document type**' via the metadata dropdown menu (see Appendix A [157]). In this instance, we select '**Data Sharing agreement/Access letter**'.



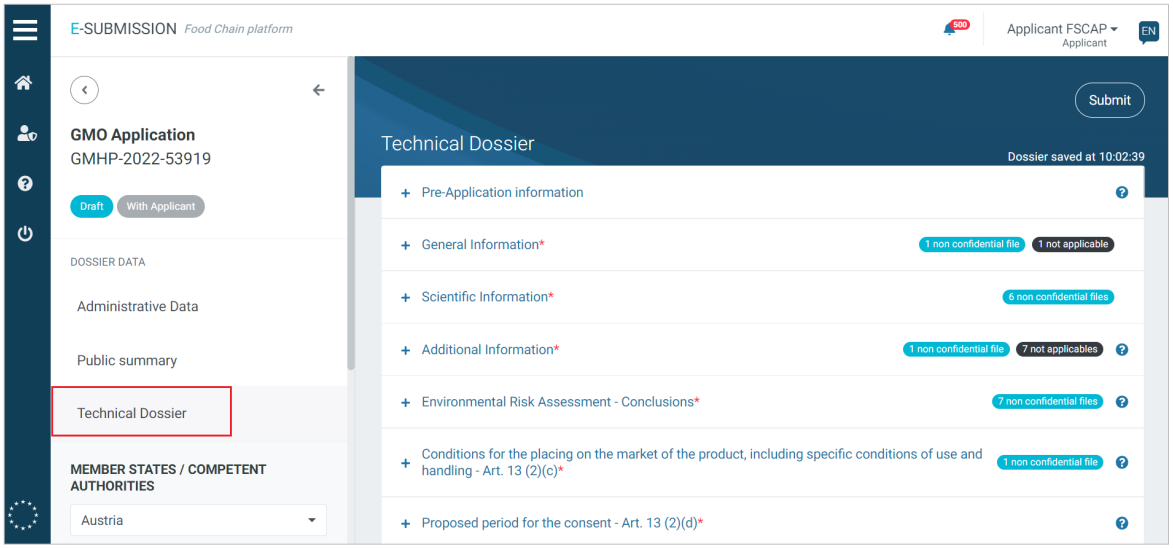
10. Upload the cover letter.



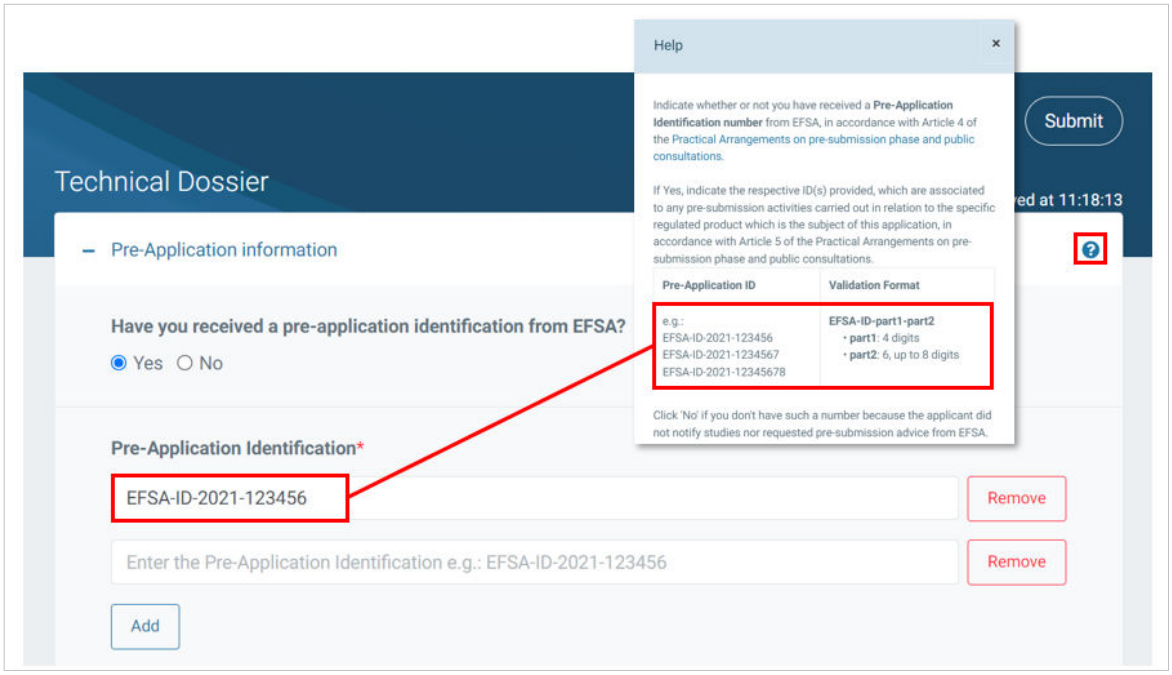
11. Click the '**Public summary**' tab, upload a public summary. The document can be replaced using the '↻' icon.



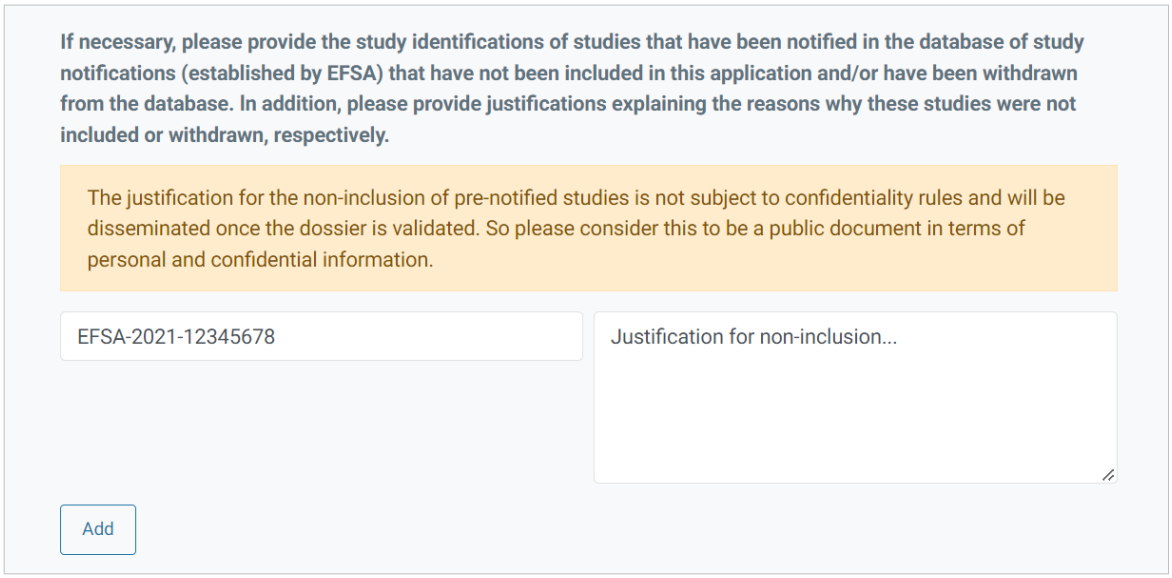
12. Click to the Technical dossier. The full table of contents reflects the sections required by legislation and outlined in EFSA guidance.



13. 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.

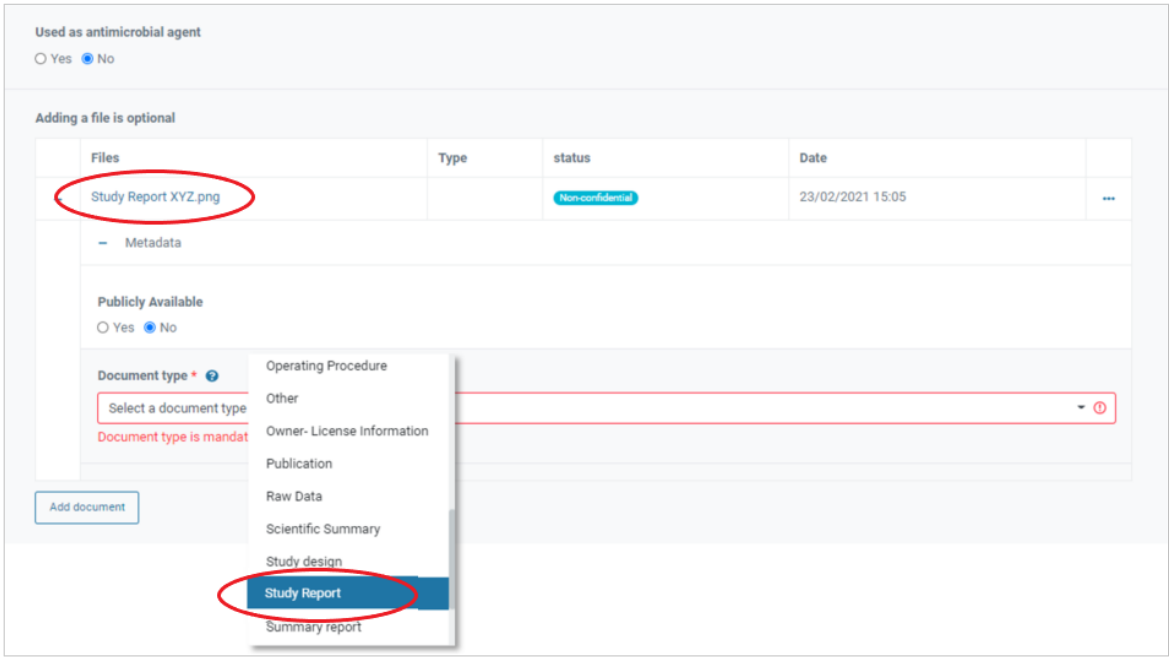


14. If you pre-notified any study which was withdrawn or is otherwise not present within this dossier, input its Pre-Notification ID here, including a justification for why it has been omitted. Click '**Add**' if there are multiple study omissions.

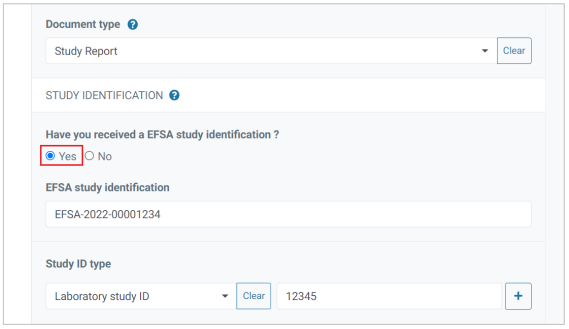


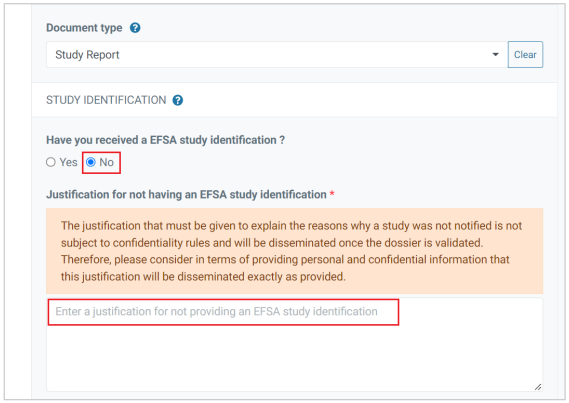
15. Complete the **General Information** section, including Unique Identifier(s) and the scope of the notification.

16. In any section, when you upload a file, 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.)

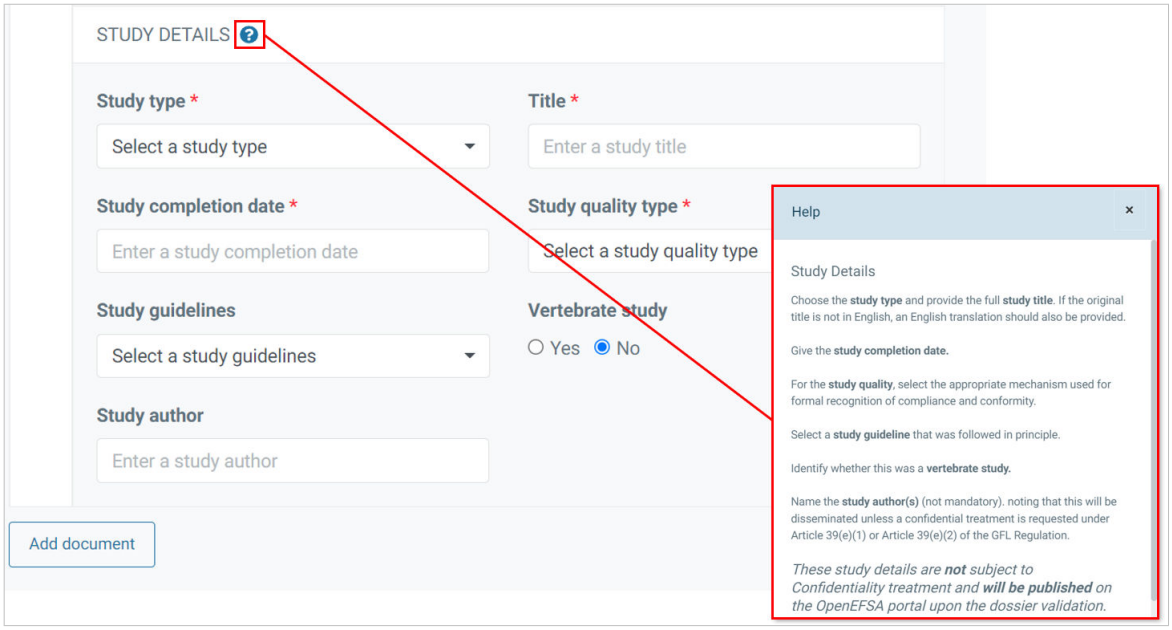


17. If you have a study identification, i.e. the study was pre-notified with EFSA, click **Yes** and input the Study ID. Then complete the study ID type and identifier. If you have no EFSA study ID, click **No** and provide a justification.

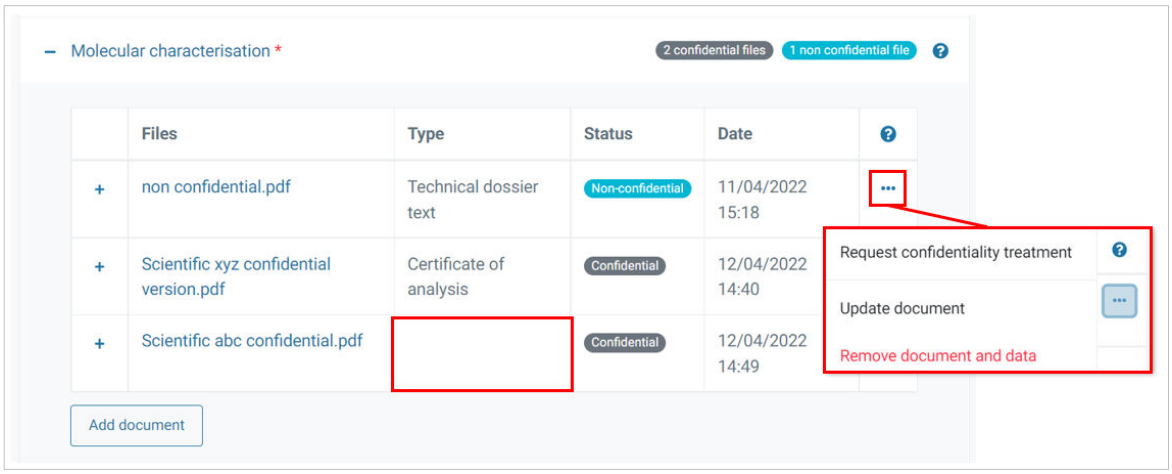




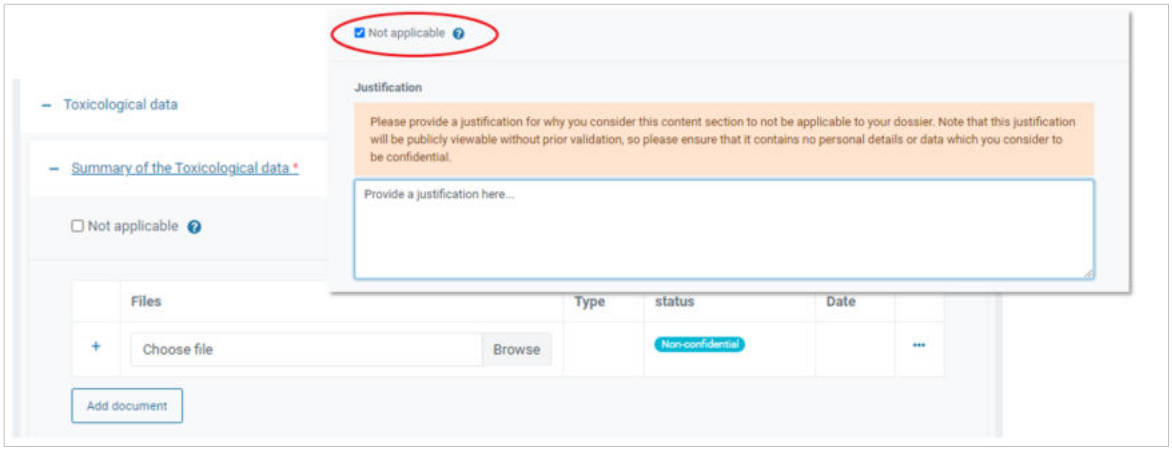
18. Complete the study details fields, with related dates and values. Note that these entries will be published.



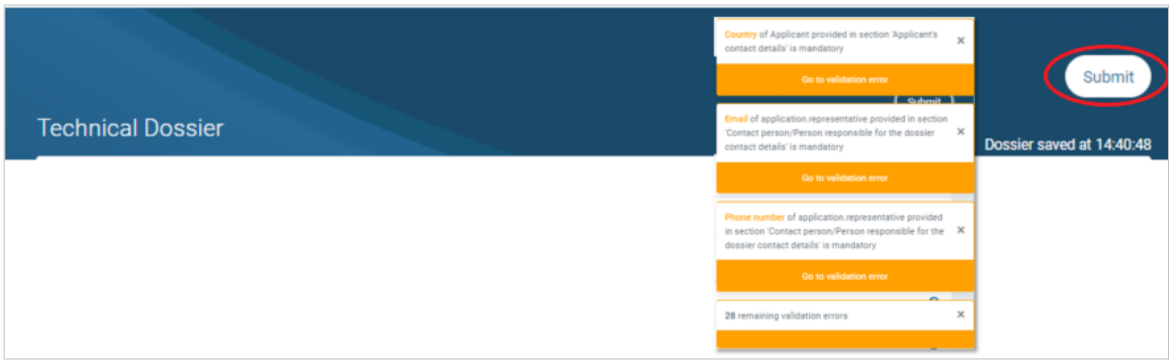
19. You can upload non-confidential files and files containing confidential information. By default, the green badge indicates 'Non confidential'. Click the three dots and select '**Request confidentiality treatment**' once you have uploaded the confidential version. The badge will now indicate 'Confidential'. You can make one, or multiple, requests for confidentiality in a single file. See How the request confidentiality [130] for more details. Note that missing metadata (in this case the file type) is not flagged until the point of submission, triggering a blocking message.



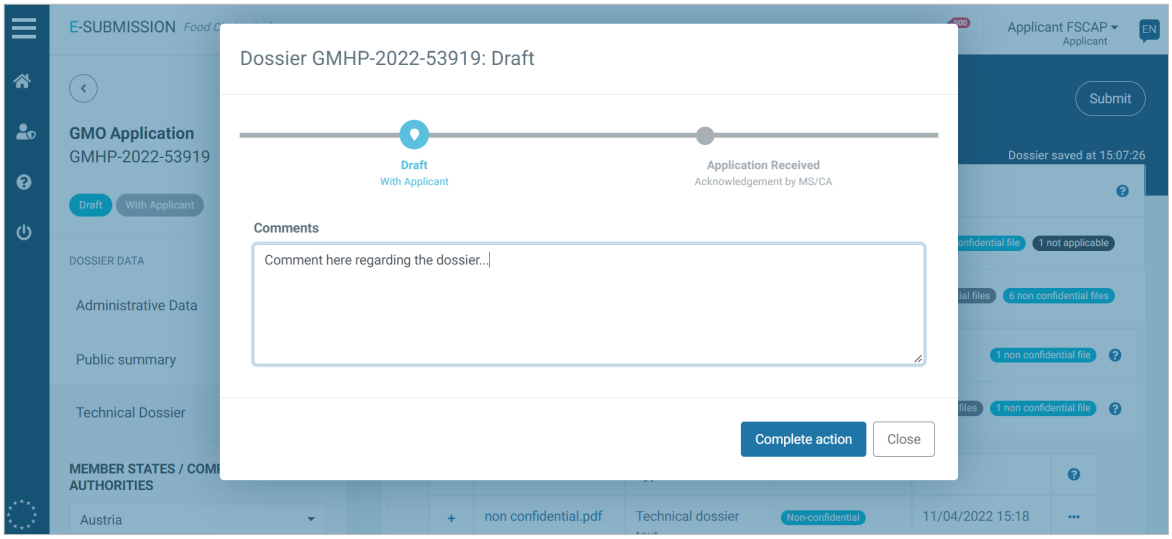
20. If certain mandatory fields do not apply to your dossier, click '**Not applicable**' and provide a justification.



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

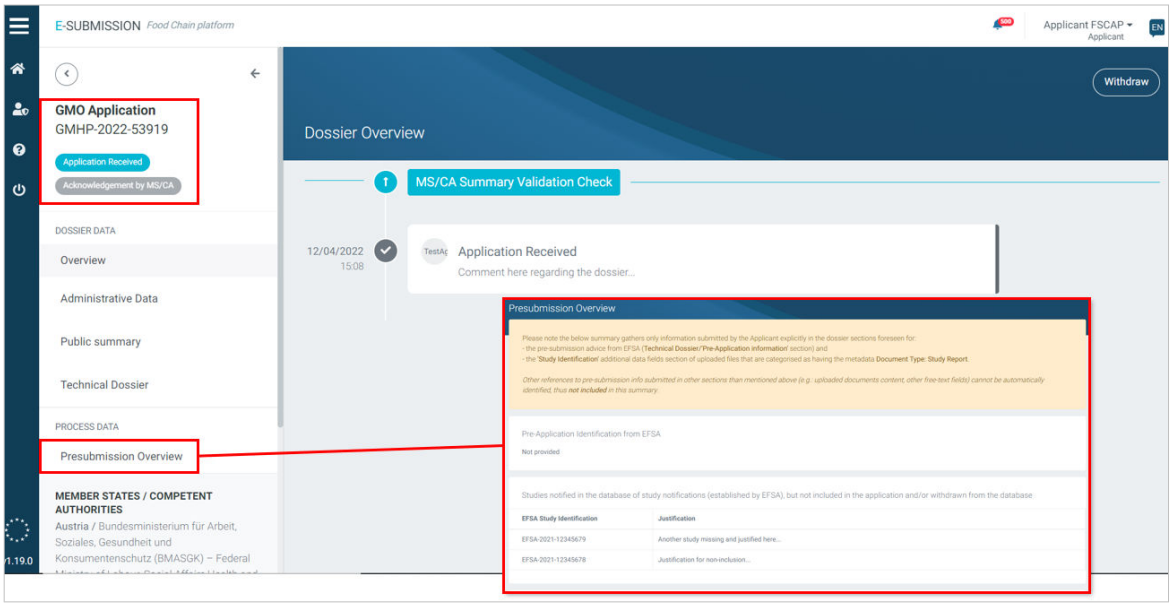


22. Click '**Submit**' and input a final message. Click '**Complete action**' to send. The dossier is sent and cannot now be edited without invitation.



23. 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 inputted, relating to the pre-submission phase. You now need to wait. For any action taken in relation to your dossier, a

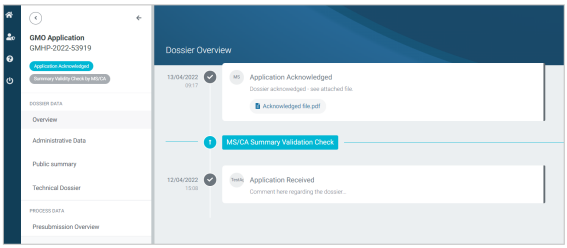
relevant entry will appear in your timeline. If an action is required from you, you will receive a notification.

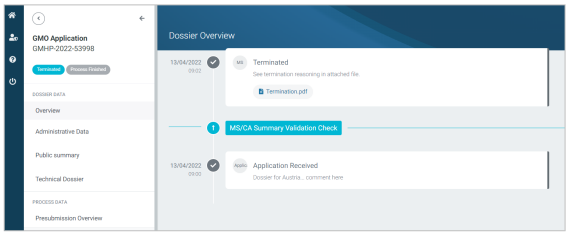


NOTE
The Applicant can withdraw the dossier at each step, and the selected MS-CA can terminate it at each step. If EFSA is involved, EC can terminate the process.

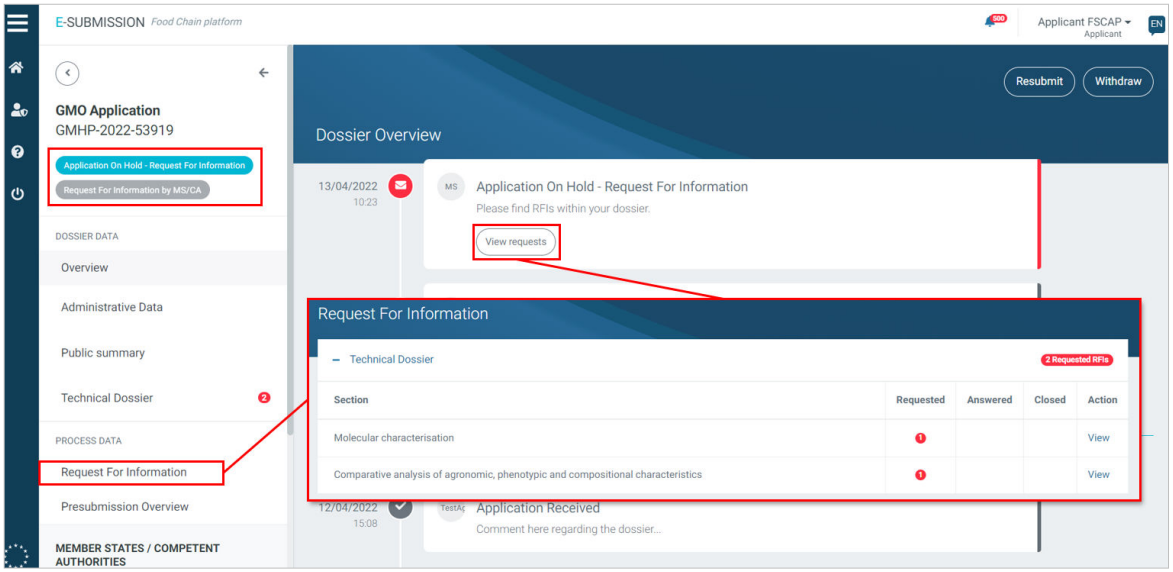
GMO Part C – path after submission

1. 'Application Acknowledged' appears on the dashboard and the 90-day (+/- 15) process begins until the Risk Assessment report is shared. If the dossier is terminated by assessors, the Applicant is notified and this status appears in the dashboard. The left blue badge also shows the status.

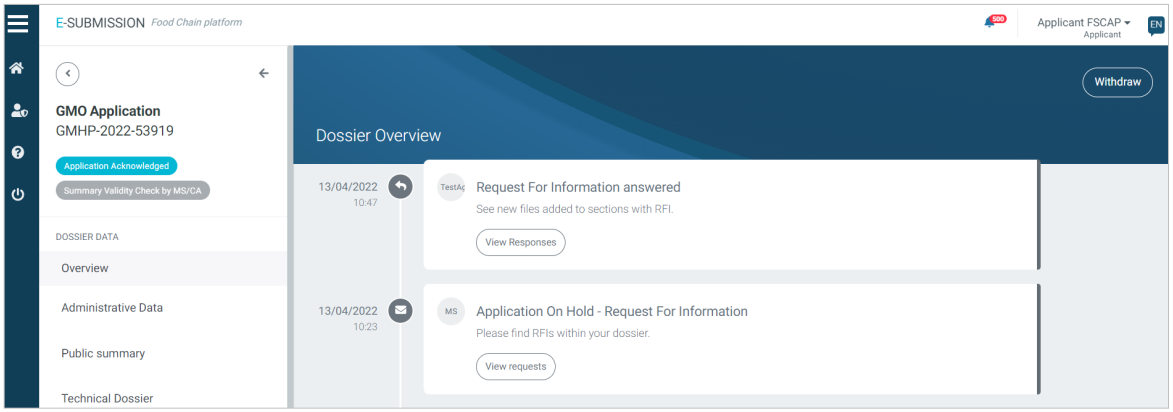




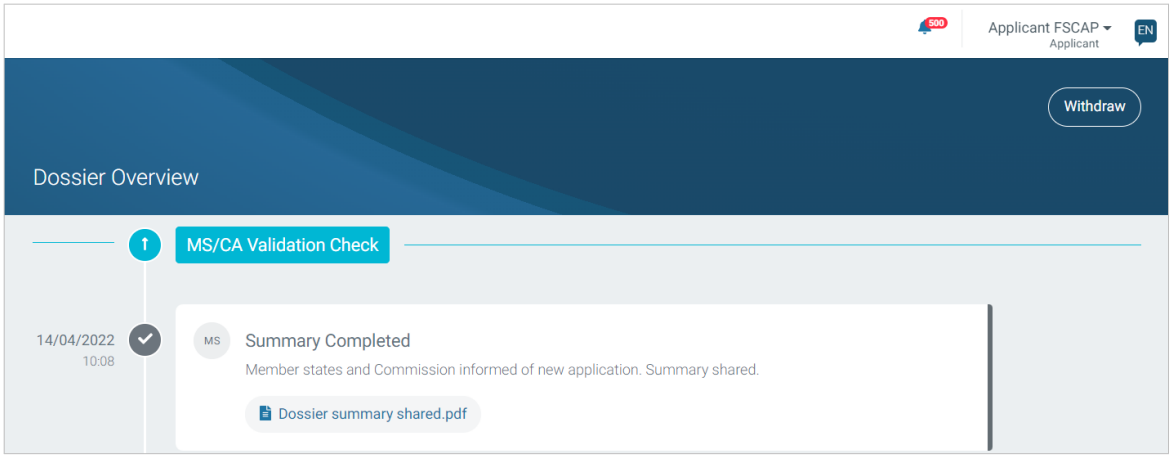
2. If an RFI is received, the dossier goes on hold with no response deadline assigned. Note the new **'Request for Information'** appears (see the RFI chapter [99])



3. Once all RFIs are answered, the dossier process continues.

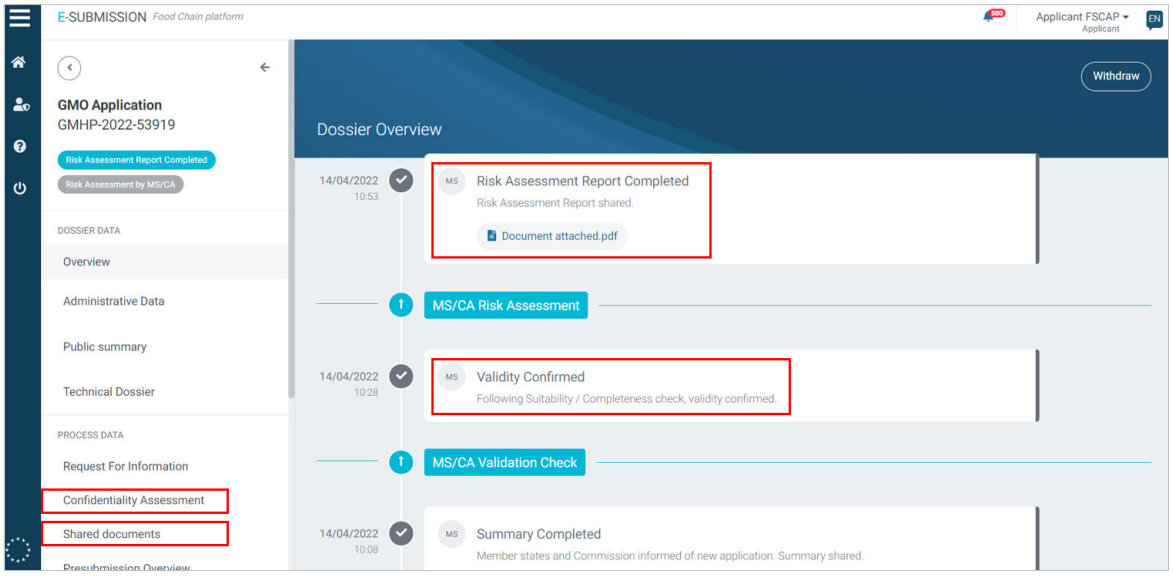


4. During the validation check, the dossier summary is shared with EC and other MS-CAs. EC publishes the summary and any public comments received. **This step does not apply for a notification renewals**, in which no Summary is required.

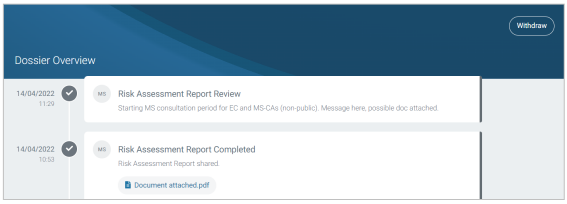


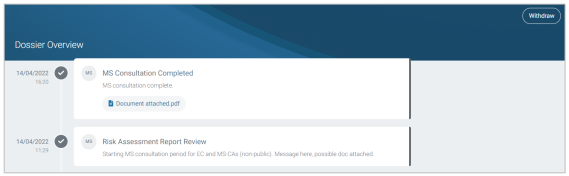
5. Once validity is confirmed, the Risk Assessment Report is shared (see the new '**Shared documents**' tab) and the 105-day Risk Assessment period begins, triggering MS-CA confidentiality assessments. The new '**Confidentiality Assessment**' tab opens the dedicated dashboard. See this section [137] for details about the

confidentiality process. If rejected, the MS-CA informs the Applicant, EC and other MS-CAs, with a reason for the notification rejection.

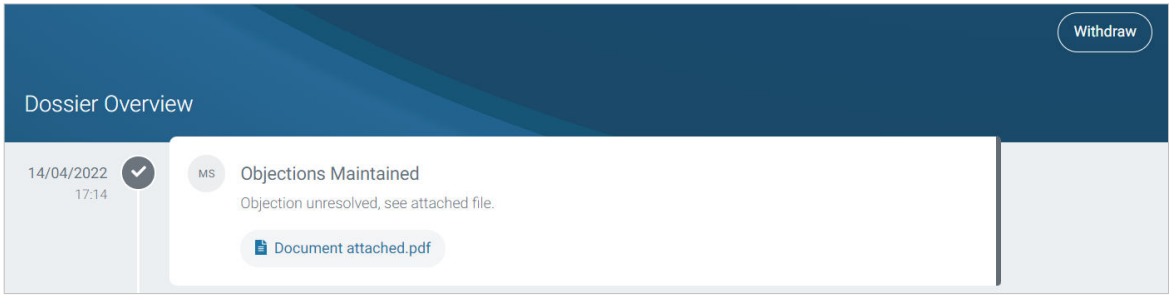


6. All MS-CAs may submit comments or objections to the initiating MS-CA. The initiating MS-CA can send RFIs (which may or may not relate to these consultation interactions), and the Applicant will be notified when the MS consultation is complete. This will be reflected in the dashboard. The dossier moves to authorisation (see *Step 9*).



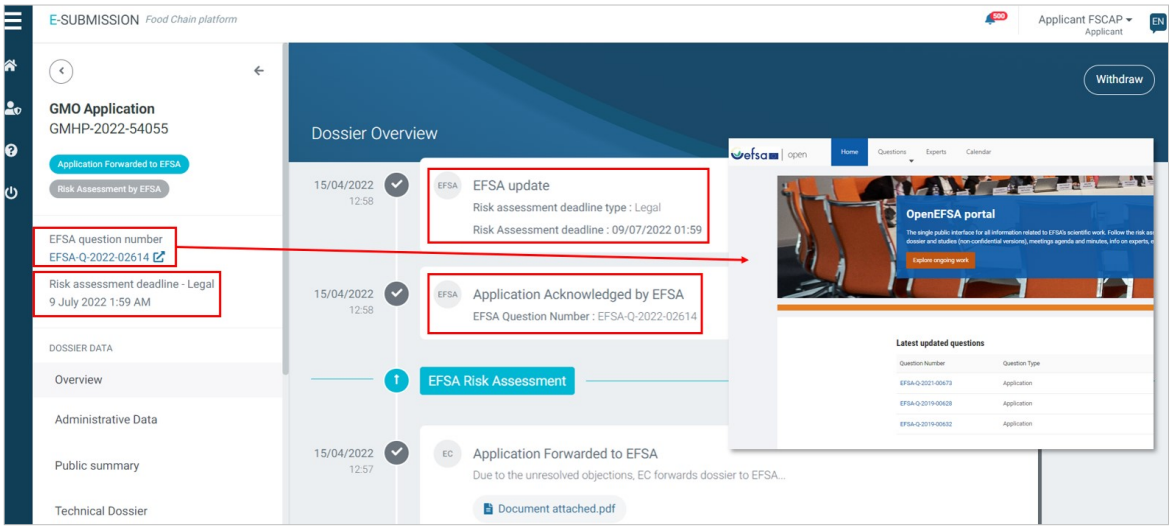


7. However, if MS-CA objections are **not resolved**, the Applicant will be notified. This status will be reflected in the dashboard, and an EC review and EFSA Risk Assessment are now required. The dossier can be withdrawn.

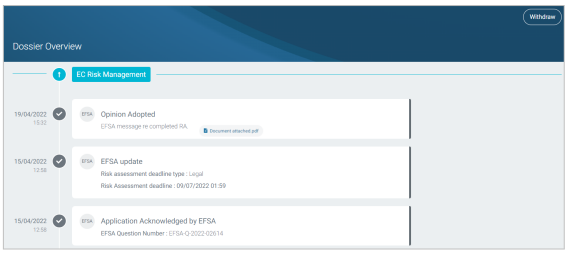


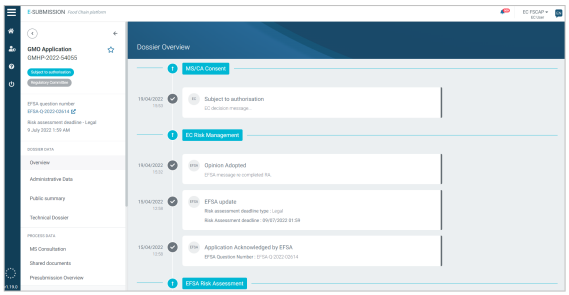
8. The dossier is referred to EC for its 45-day Objections Review, then forwarded to EFSA for Risk Assessment and opinion. For this the dossier goes on hold. EFSA assigns a Question Number which links to the non-confidential dossier content on the Open EFSA dissemination portal. With its involvement, EFSA now has access to the confidential dossier content, as submitted. However, EFSA still has **no access** to the confidentiality dashboard itself. It is informed of decisions regarding confidentiality requests, but not the interactions leading to a decision. The legal deadline for

Risk Assessment completion is displayed. EFSA may send RFIs to obtain more information (see this chapter [99]).

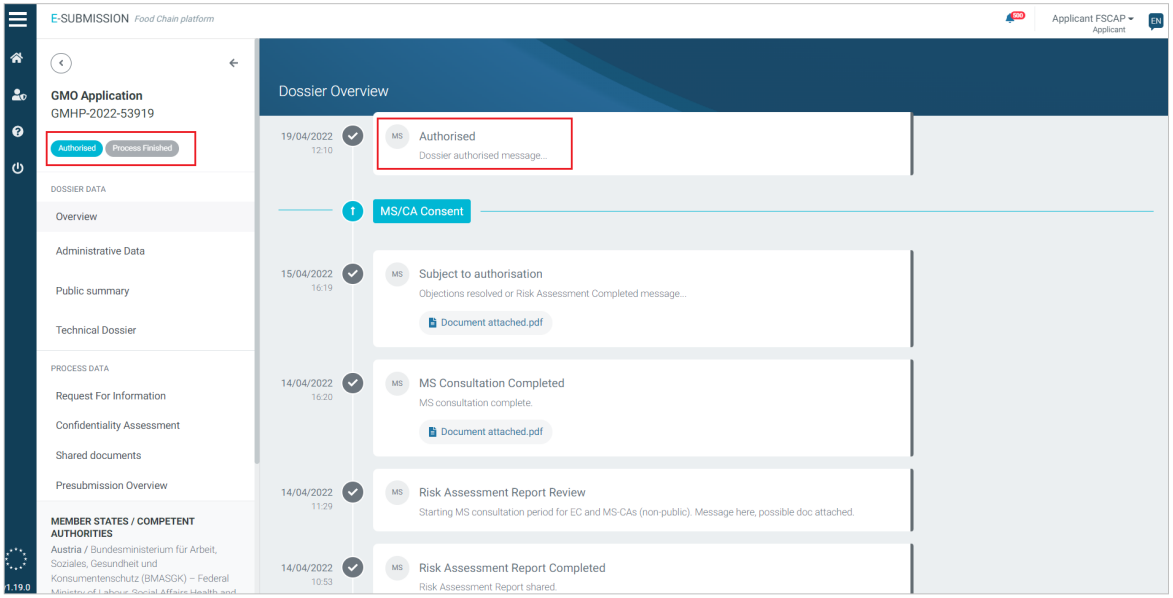


9. EFSA submits its opinion, and EC Risk Management begins. Withdrawal is still an option for the Applicant. The dossier is 'Subject to Authorisation' for 30-days with the MS-CA Regulatory Committee.



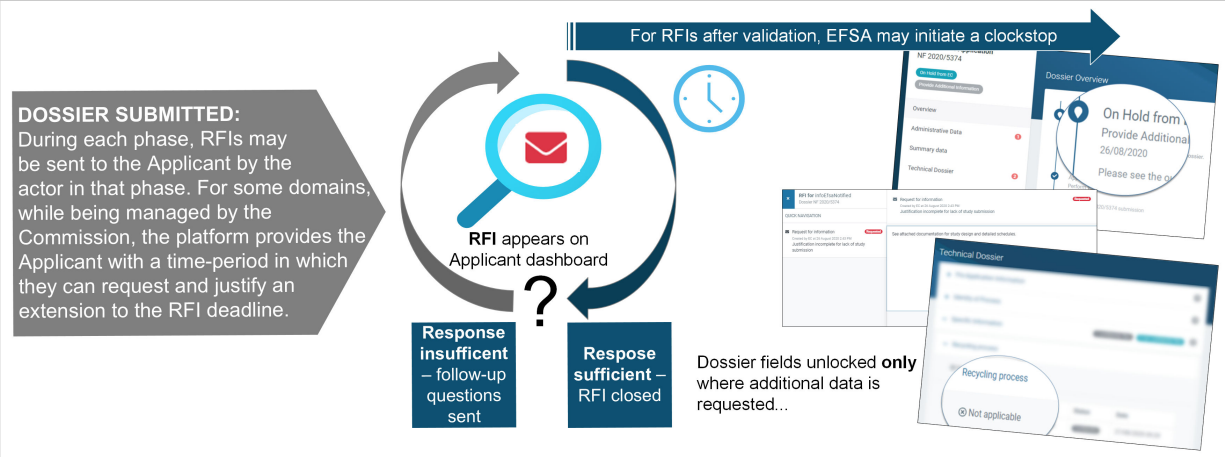


10. Once the dossier is 'Authorised', the process is finished.



NOTE
EFSA landing page for all GMO procedures Regulations and Guidance documents.

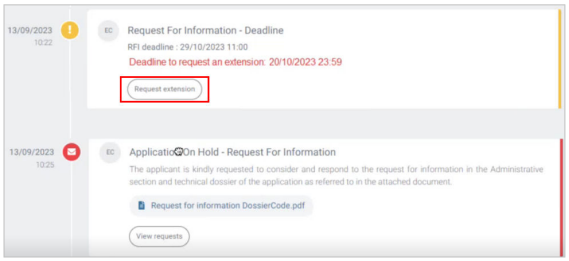
5 Requests for information

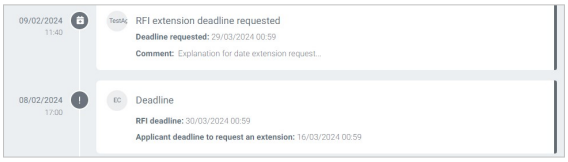


Following the dossier submission, the MS-CA or EC (depending on the domain) may issue Requests for Information (RFI) before forwarding the dossier to EFSA. The Authority then performs the Completeness and/or Suitability check in accordance with the relevant legislation. It may also send RFIs, using its Appian system which integrates with the ESFC platform, to ensure the dossier meets the standards for scientific assessment. An issued RFI switches the dossier to 'On hold'. Novel Foods RFIs contain more legislative details in a PDF attachment.

IMPORTANT
All RFI questions must be suitably responded to for the RFI to be 'closed'. A dossier cannot proceed with an 'open' RFI. For certain domains, the Commission may send a **Reminder** notification as the deadline approaches (see RFI reminder from the Commission [103]).

During this phase, for RFIs raised by the Commission on some domains, Applicants have the option to request an extention to the deadline. However, the time period to make the request is limited – the date appears in red in the overview. The Applicant must provide a preferred RFI deadline and explanation, after which the opportunity passes, and the '**Request extension**' button disappears. The request is considered by the Commission, which may agree with the proposed date or set an alternative (see Step 8, Responding to a Request for Information [99]).



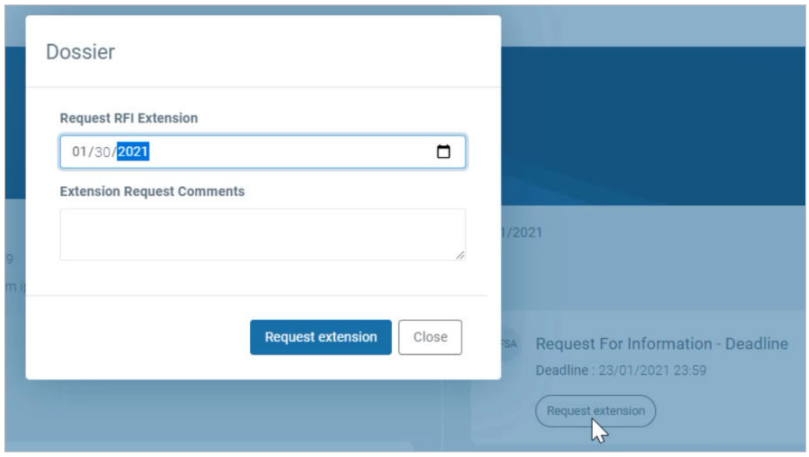


NOTE
The **deadline extension** request is available in the Novel Foods domain.

Once the RFI questions are addressed, **with the information or files added to the unlocked fields,** the Applicant resubmits the updates. The actor involved assesses the response and may seek further information.

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, a clockstop is initiated and an RFI is sent with a response deadline. Through the dashboard, an applicant can **request a deadline extension** at any point, with an explanation. EFSA considers the request, however it may set an alternative date.



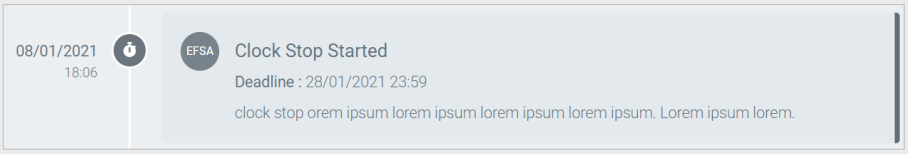
The RFI notification email links to the Applicant's dashboard, with the specific fields unlocked and ready to receive further information. Requests for confidentiality treatment can still be attached to specific information within new document uploads.

However, during the Risk Assessment phase, any existing documents containing confidentiality request information (i.e. the grounds, justifications, related non-confidential versions, etc) are locked. There is no 'Update' option, **so if changes are required, the file must be deleted and re-uploaded as if new**.

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

NOTE
EFSA may choose to initiate its 'clockstop' 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. You will see the clockstop status on the dashboard overview section, as below. It will impact the risk assessment deadline displayed on the top left of the screen.

See the chapter on Clockstop logic [124].

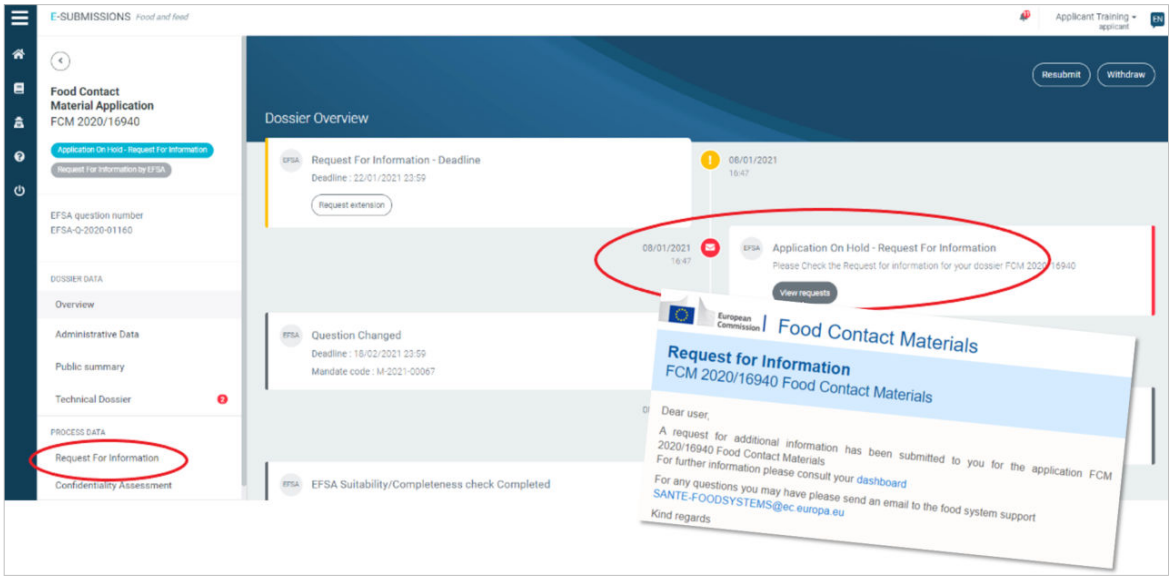


TIP
Swift and complete turnaround for RFIs: Once the Applicant has fully responded and resubmitted the dossier updates during a clockstop, EFSA assesses the reply and manually restarts the clock. If questions remain for the RFI, the clock is reset for that request until a suitable answer is delivered. Refer to EFSA's Administrative Guidance for more detail on the "stop-the-clock" procedure and timing.

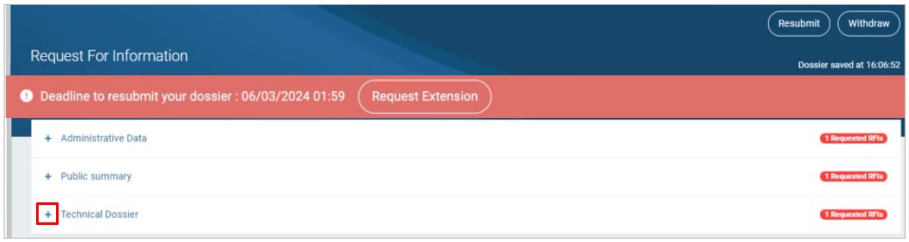
WARNING
The written exchanges which take place during the RFI procedure **are disclosed**, so all actors must ensure they include no personal or confidential information.

5.1 Responding to a Request for Information

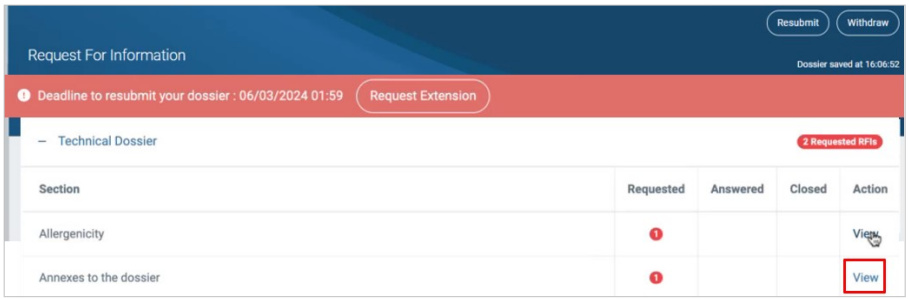
1. The notification bell 39 on the top right of the screen indicates activity on your dashboard. A '**Request for Information**' (RFI) tab appears on the left, red outstanding RFI questions are number-flagged next to their section, and in the dashboard you see the RFI entry. Click the '**Request for Information**' tab in the Process Data area to display the overview screen.



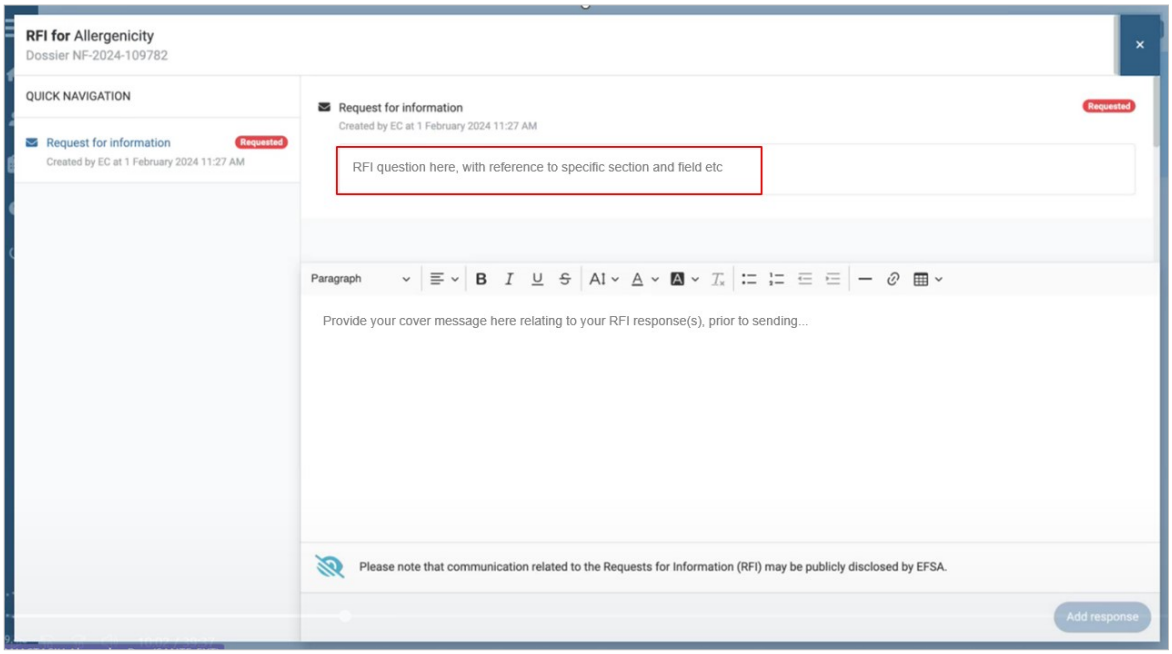
2. RFIs (and Additional Data Requests) can arrive during any assessment phase. The label shows how many RFI questions apply to which section. Note that the **Request Extension** button applies to all questions posed in the RFI bundle.
   Open a section '**+**'.



3. Click on '**View**' to read the question(s) sent for this section of the RFI.

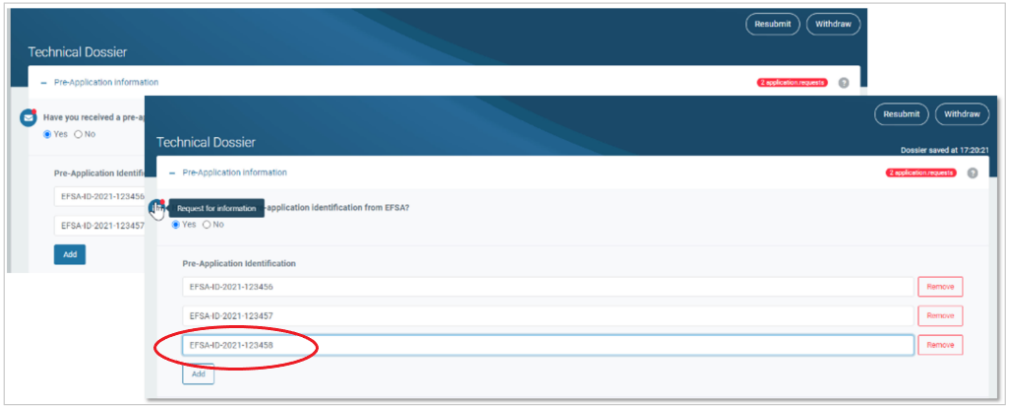


4. The question, with a possible document attachment, relates to a specific field in which more information is needed.

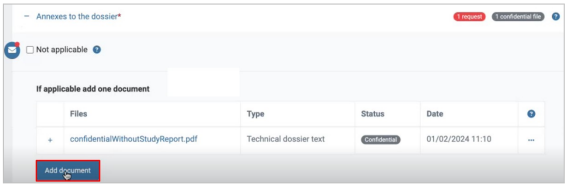


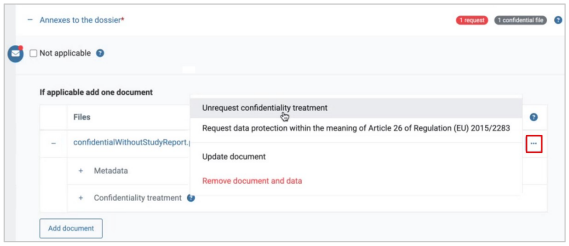
IMPORTANT
Do not reply to the RFI question here – the text field is only for your cover message, explaining how you responded to that specific question, if necessary.

5. Now scroll through the section (i.e. Overview, Administrative Data or Technical Dossier) which contains the RFI question(s) until you see a red email icon , then supply the extra information in the unlocked field. Here, for example, an additional Pre-Application ID has been requested.

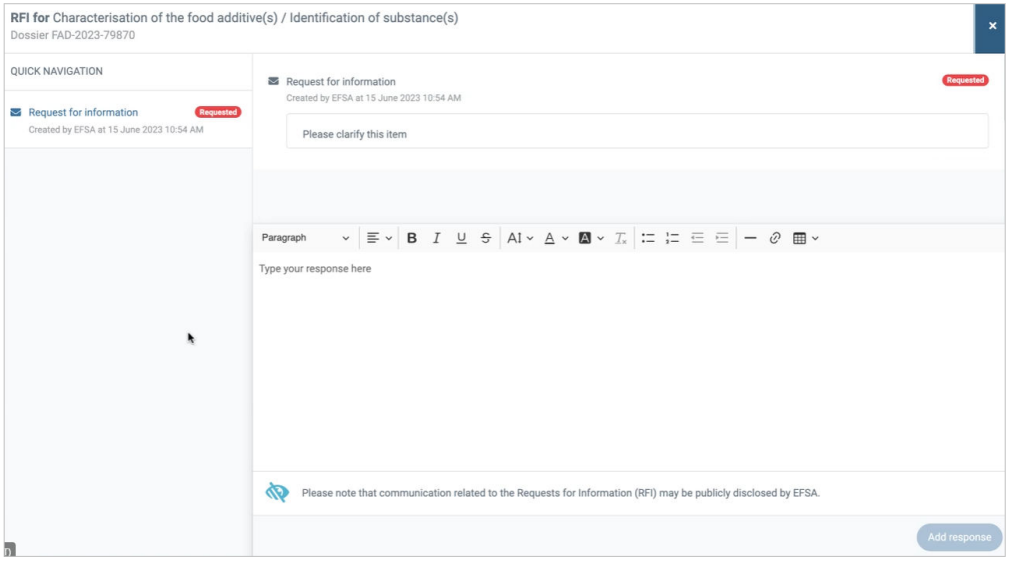


6. And here, for example, an additional document is required (or an alteration to the existing document).
   Go to the section and field. Click **Add document**, then provide the background metadata and confidentiality information. Alternatively, click on the elipse to adapt or delete the existing document. During the Suitability phase, you can update an existing document, however, during Risk Assessment you can only delete an existing document or add a new one – no update is possible.

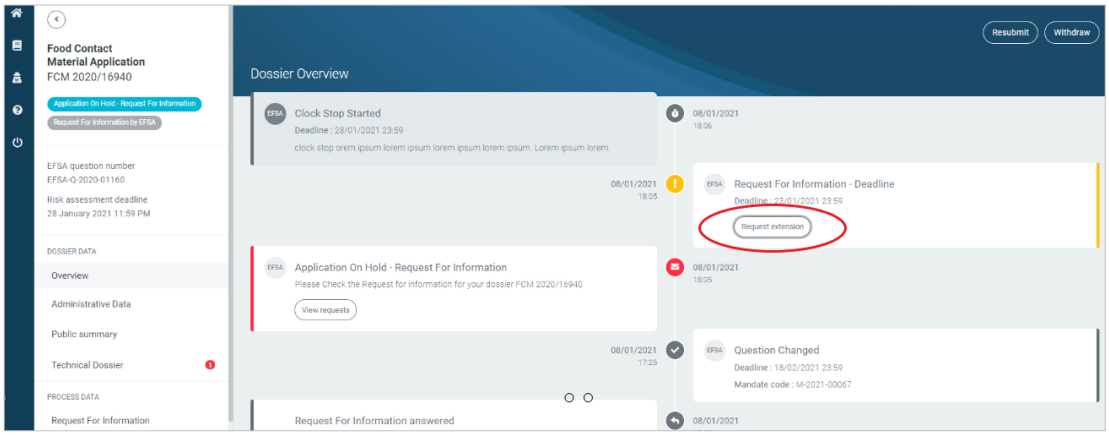




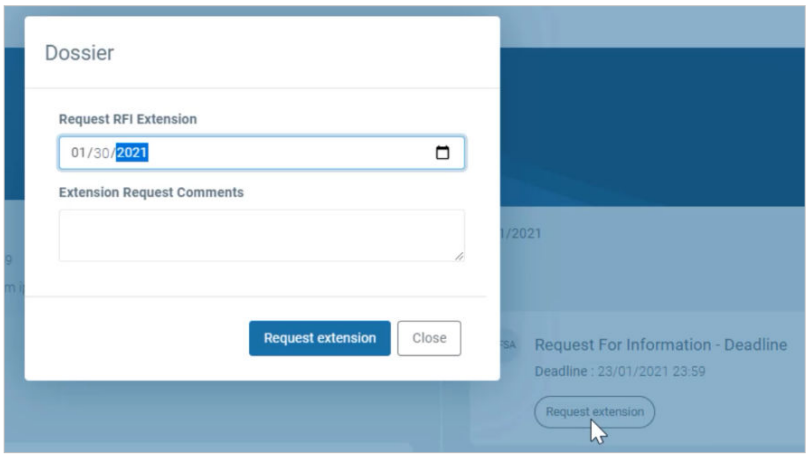
7. Once complete, provide the cover message (up to 20,000 characters in length) to outline how you addressed this specific RFI question.
   Various formatting options are available to allow you to clearly give details on files provided or fields changed, or why any of the information requested was not provided. Please apply the formatting directly in ESFC rather than copy-paste formatted content from Word.
   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 you are able to resubmit the dossier.



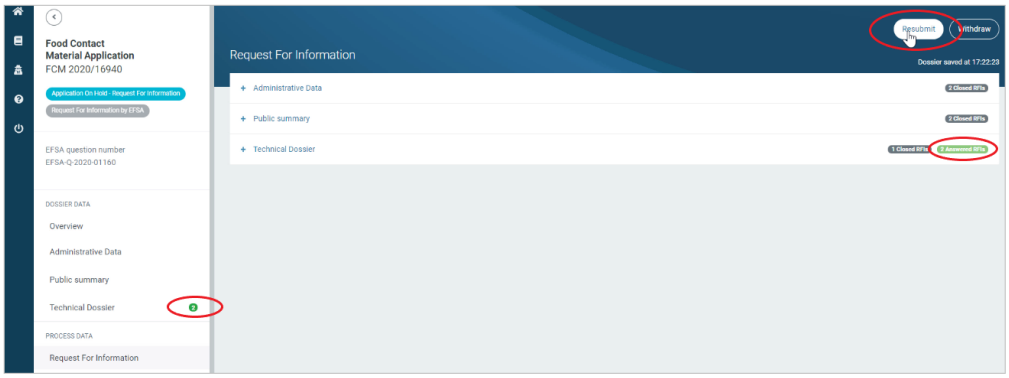
8. If a deadline extension is needed for addressing any of the RFI questions, the dashboard also provides the deadline extension facility (for some domains) for RFIs arriving during the Suitability, and all domains during Risk Assessment phases. Note that for RFIs raised by the Commission, the extension request is available for a limited time period. Click '**Request extension**'.



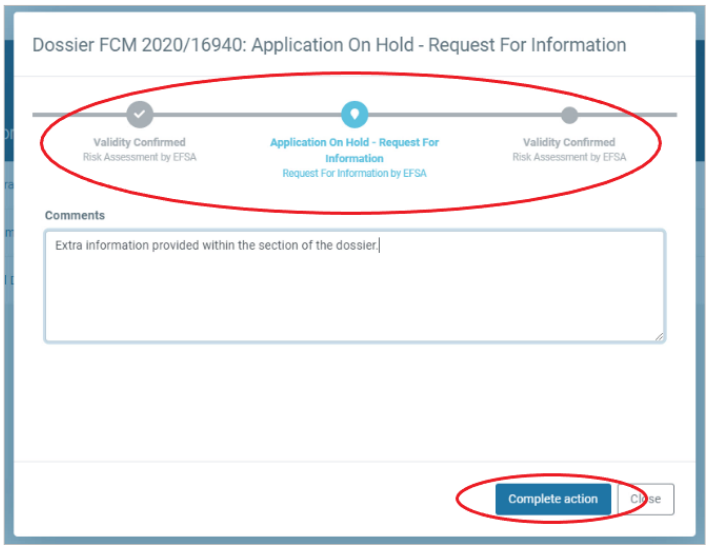
Set your preferred date for EFSA or the Commission to consider, with a supporting explanation. Click '**Request extension**'. The revised deadline (or an alternative date) will appear on the dashboard once the request has been assessed.



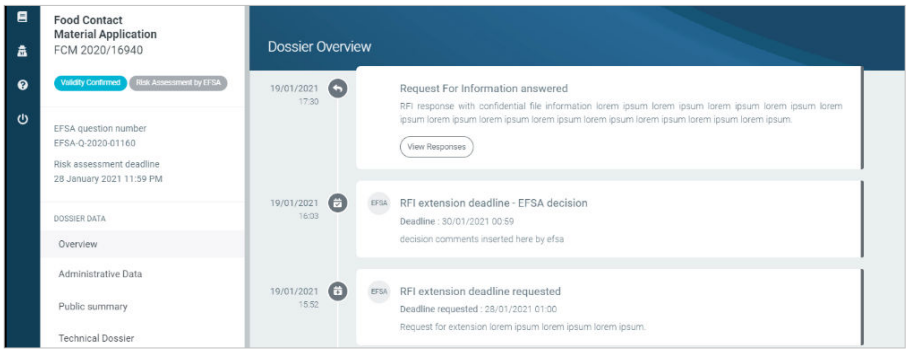
9. The RFI overview screen also shows the total number of completed RFI questions (in green), as well those not yet addressed (in red). When all are replied to, click '**Resubmit**'.



10. A box appears in which you can provide a general cover message relating to your response to the RFI package of questions. This also shows the dossier status path. Click '**Complete action**'. The dossier is resubmitted.



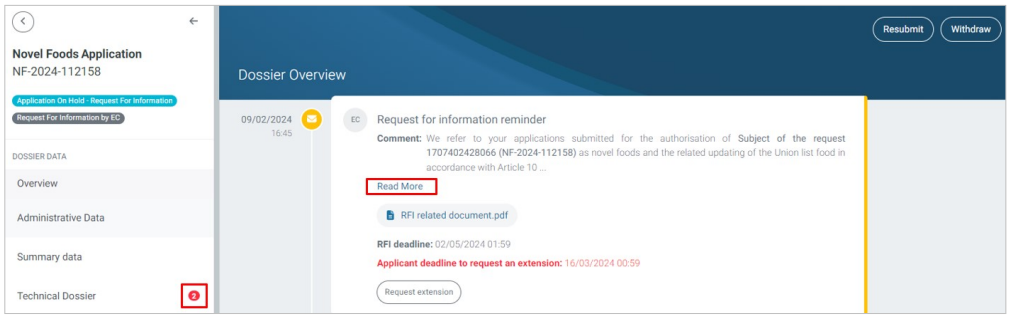
11. Your response to the RFI is reflected in the dashboard.



5.2 RFI reminder from the Commission

As the RFI deadline approaches, the Commission may issue a reminder notification. If RFI questions remain unaddressed, the dossier cannot proceed and may be terminated.

Click '**Read more**' to view the full legal message, containing relevant deadlines and other legal aspects to the dossier. In this example, there are two outstanding questions and there is still time to request an extension.



NOTE
The RFI deadline reminder functionality currently applies to Novel Foods Authorisations only.

6 Communications channel

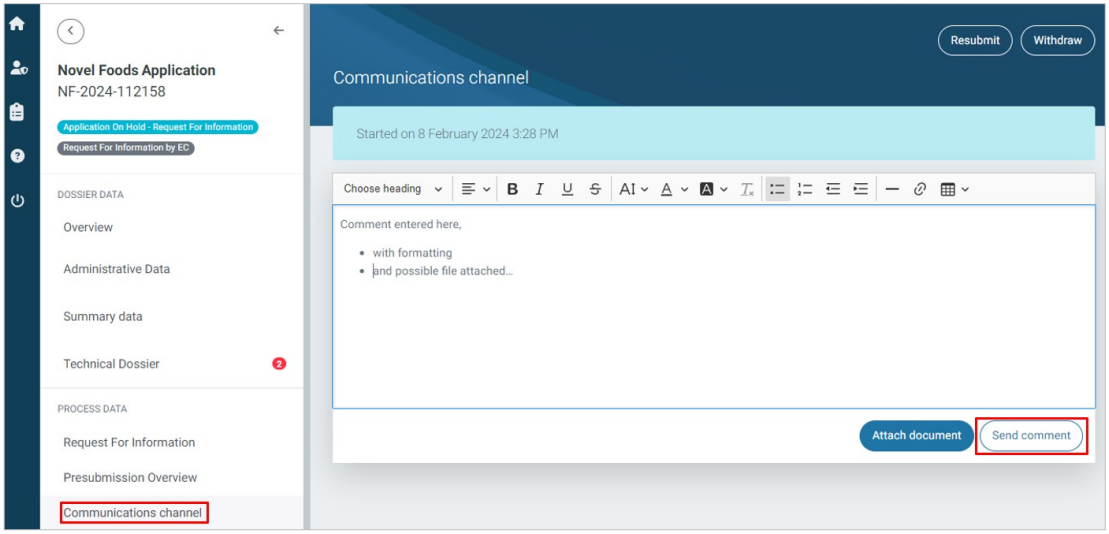
At any time, the Applicant can place comments and questions for the attention of the Commission in the Communication channel. The Commission or Member States can also initiate the communication flow. The comments, responses and files are not published or shared with EFSA, however they are **archived with the dossier for future reference**.

IMPORTANT
Note that comments are **not part of the RFI process**. However they may, for example, relate to an RFI if an explanation is necessary or an observation needs to be shared. These should be business comments only, not for technical problems. They do not replace the RFI interaction in any way, and documents do not enter the dossier structure.

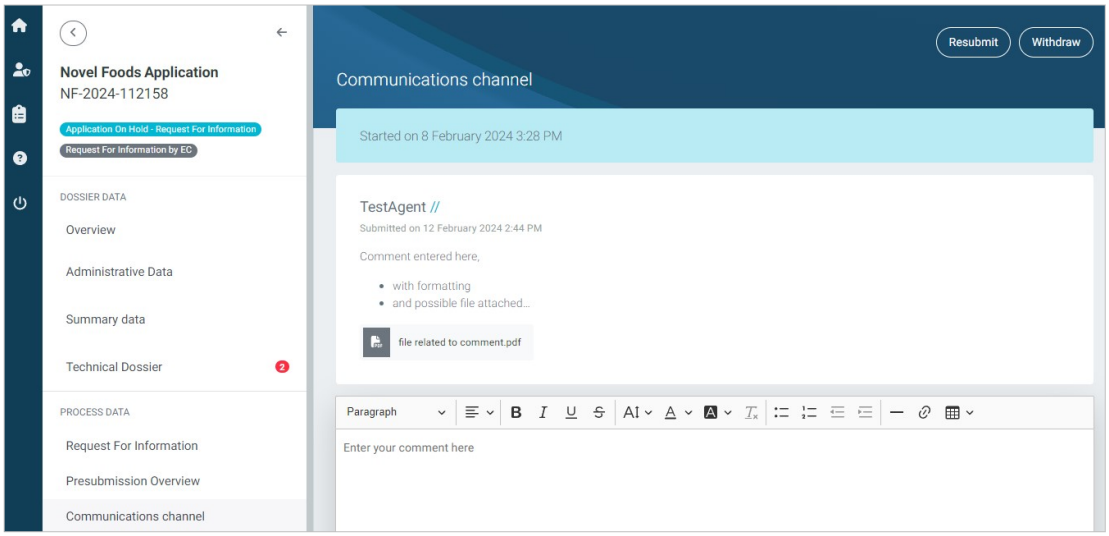
The communication channel may be used by any actor at any time, and a response is **not time-limited or mandatory**. It is currently available on the Novel Foods, Feed Additives, GMO and Food Improvement Agents.

1. Click the '**Communications channel**' tab on the left pane.

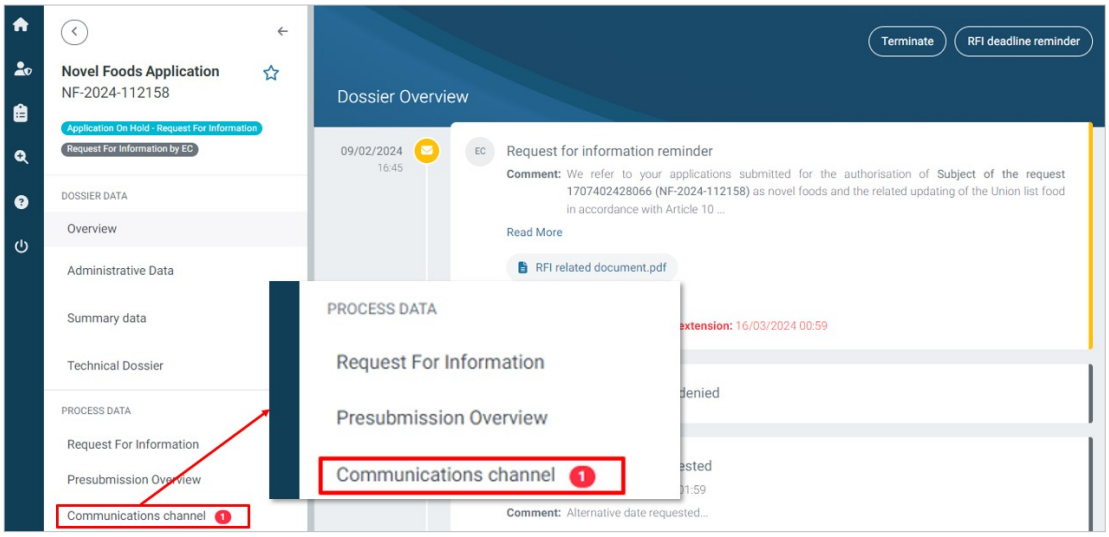
2. Enter your comment, with formatting for clarity, and you may attach a file. Click '**Send comment**'.



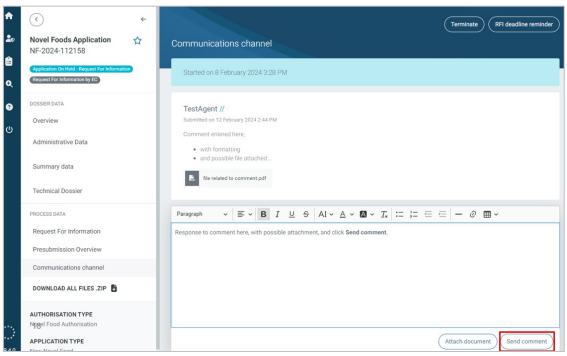
3. The comment is sent, the recipient is notified, and you may immediately send a follow-up comment.

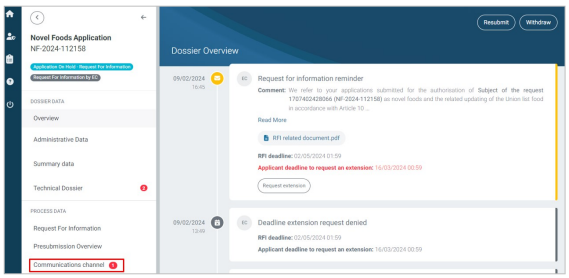


4. The comment is received. The communication channel flags the number of unread comments. Once opened, the flag (i.e. the '1' marker) disappears.



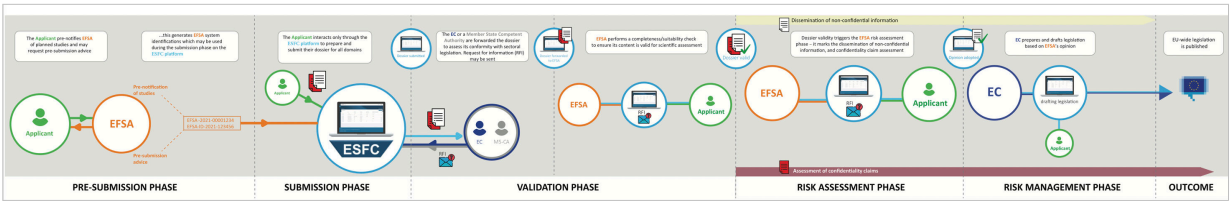
5. Respond to the comment in the same way. The recipient is notified and the comment marker now appears on their dashboard.





WARNING
After the first user associated with a dossier clicks on the communications channel to read a comment, the marker disappears. While all users receive individual email notifications for each comment added, it is advised that the user checks the channel occasionally to ensure nothing has been overlooked.

7 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. The above authorisation process diagram is laid out here [159].

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 [152].

Who receives the application?

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

1. **Dossiers routed to the Member State Competent Authority (MS-CA) for which risk assessment is carried out 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.

2. **Dossiers routed to the MS-CA for which risk assessment may be carried out by EFSA**: GMO (Part C) is managed by the MS-CA, and transparency rules only apply when they seek EFSA's opinion.

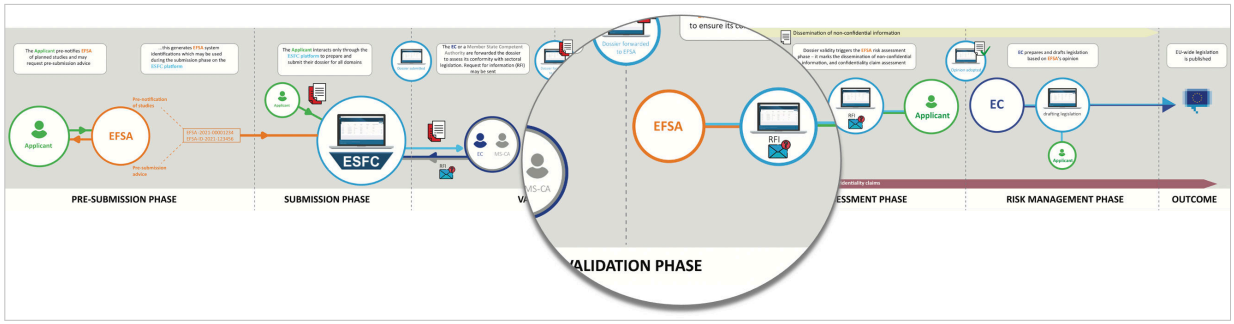
3. **Dossiers routed to the European Commission:** Food Improvement Agents, Novel/ Traditional Foods, Feed Additives, GM Food & Feed (renewals), Smoke Flavourings (renewals).

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

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

7.1 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 validation phase that follows determines whether the dossier contains the correct information components and studies, and whether it complies with the Notification of Studies (NOS) requirements.

For Novel Foods and FIA domains where EFSA carries out the suitability check, EC, based on EFSA's suitability outcome, may determine a dossier to be 'Non valid' due to '**NOS non-compliance**' or '**Other reasons**'. The EC decision on the non-validity will appear in the overview together with the reason. For all other domains, EFSA's outcome decision will appear directly on the overview.

Such a NOS failure will result in a 'non-valid' status and a six-month delay until the authorisation process will commence on the resubmitted dossier[3], (in this case, see Resubmission following NOS non-compliance [111] for the resubmission steps).

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 Requests for Information [96].

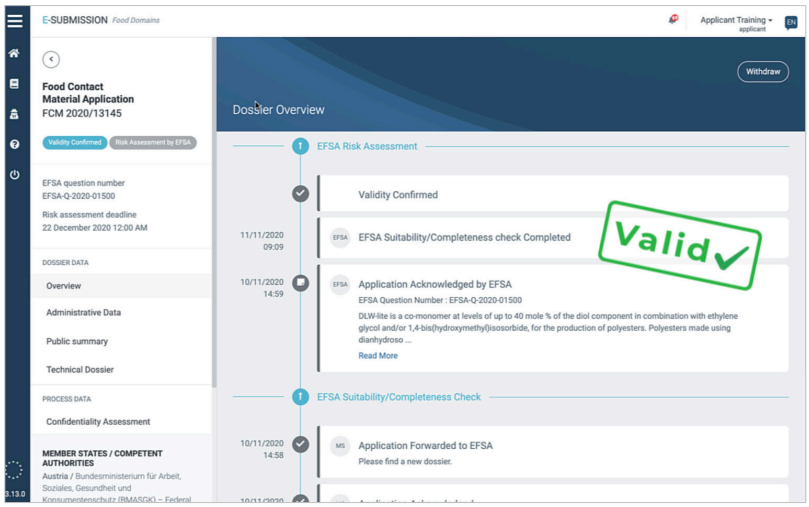
NOTE
From an applicant's perspective, all dossier interactions focus on the **ESFC timeline** irrespective of which body is assessing validation, confidentiality or risk assessment.

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

[3]See Regulation (EC) No 178/2002, Article 32b

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 on the regulatory framework) may begin the assessment of the confidentiality requests.



WARNING

Validation triggers public dissemination: Information that is not subject to a confidentiality request 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.

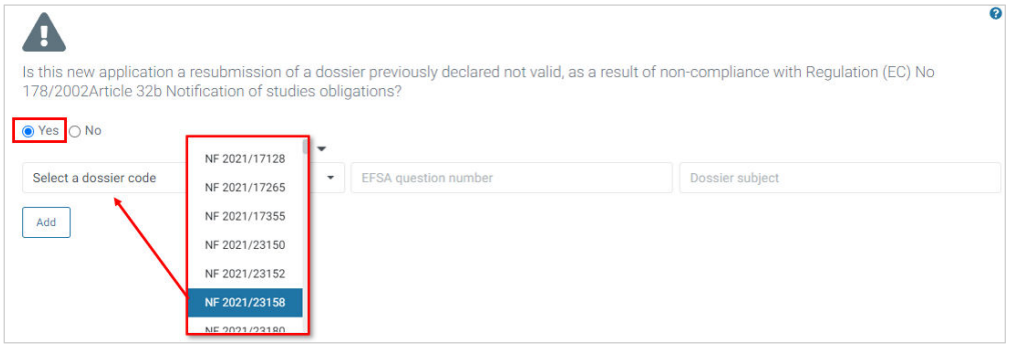
7.2 Resubmission following NOS non-compliance

If a dossier is determined to be 'non-valid' by EFSA due to Notification of Studies (NOS) non-compliance, the Applicant is informed. The process ends.

He/she may rebuild and resubmit a new dossier at any point thereafter, with sufficient NOS information to meet requirements, but it will not enter the authorisation process before a six-month blocking period has passed following the resubmission of the dossier. The new dossier must be linked to the previously **Not valid** submission(s).

1. In the Administrative Data section, you must declare if the original dossier was given a 'non-valid' status due to NOS non-compliance.

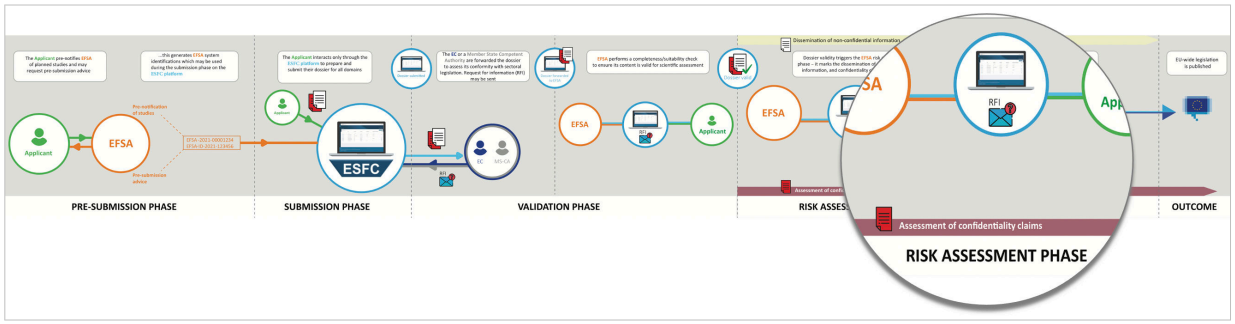
2. If yes, you must then link the new dossier to the original 'non-valid' due to NOS non-compliance dossier. If several were submitted and failed, each non-valid attempt must be linked to the not valid dossier(s) submitted on the same novel food and by the same applicant. The drop-down list displays possible dossiers filtered by the status **Withdrawn**, **Not valid** and **Terminated**.



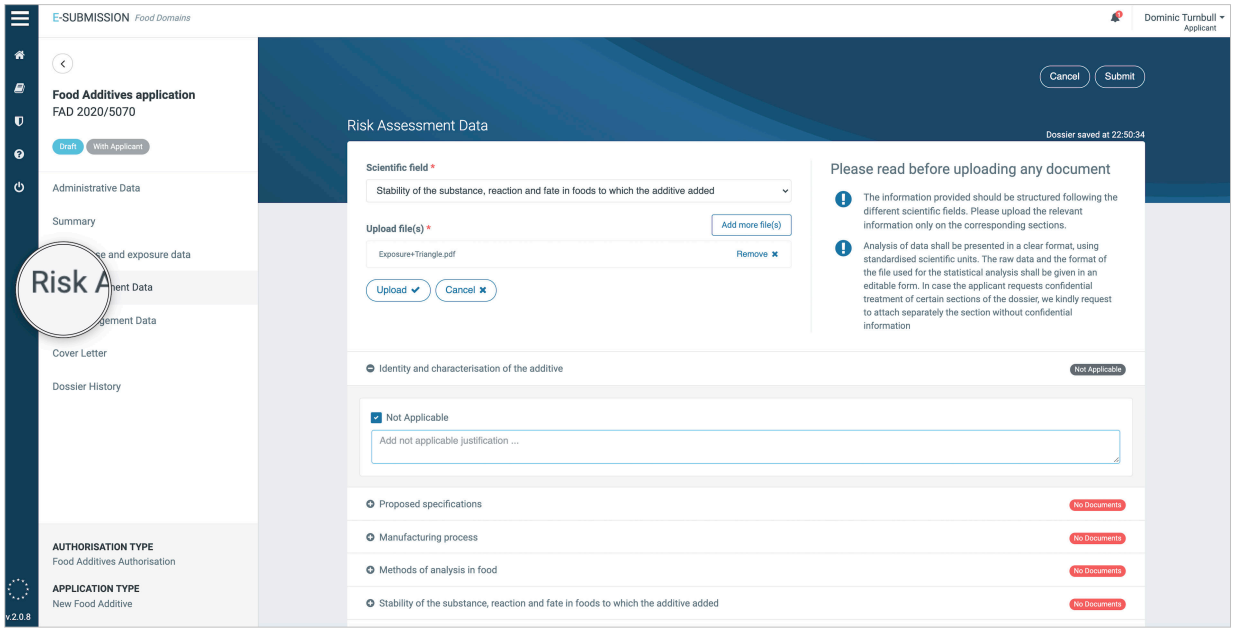
3. If the original dossier does not appear in the list (based on Question Number and subject), the details can be manually entered. This may occur if the Applicant contact details or ownership have changed in the meantime.

NOTE
All new dossiers are checked against non-valid dossiers during validation (i.e. those blocked due to NOS non-compliance) and the six-month blocking period will be imposed if there is an undeclared match.

7.3 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.



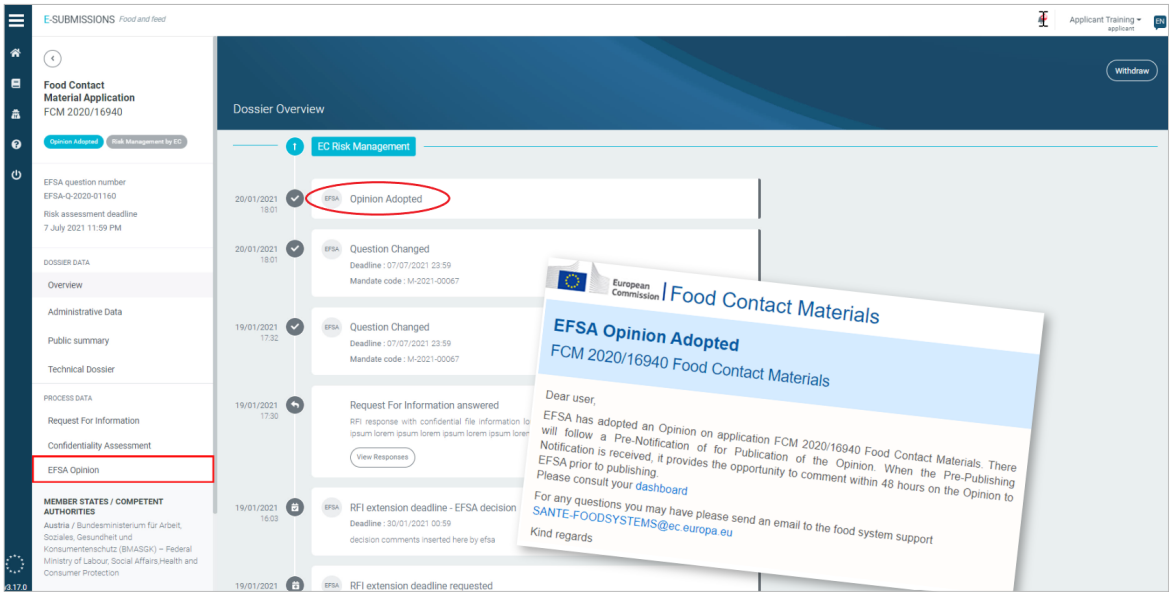
Timeframe for risk assessment

From the moment of dossier 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 clockstop procedure when extra information is requested which may extend the process. Deadline and dossier status are displayed in the ESFC dashboard.

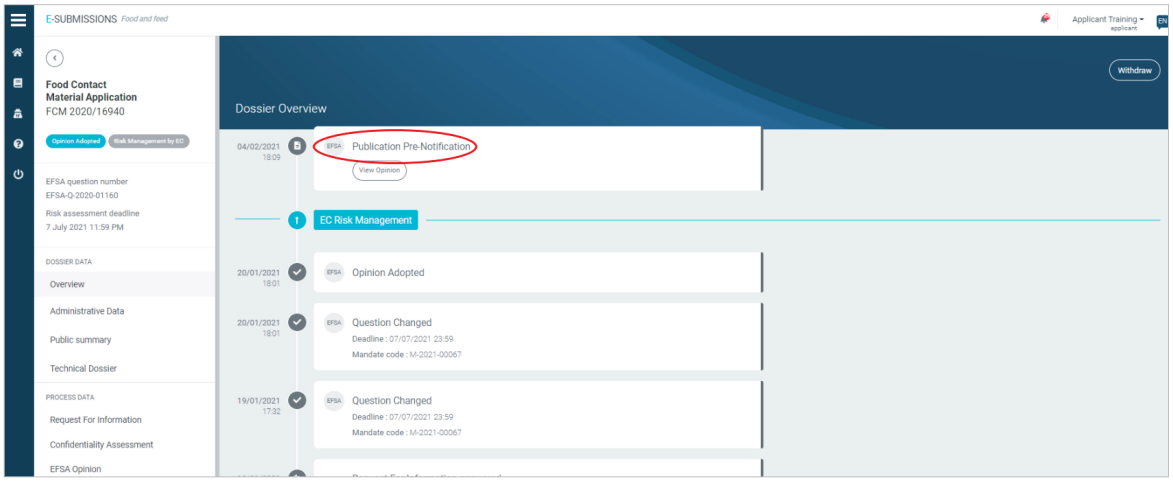
For more information, go to the Administrative guidance for the processing of applications for regulated products (update 2021).

7.4 Opinion outcome

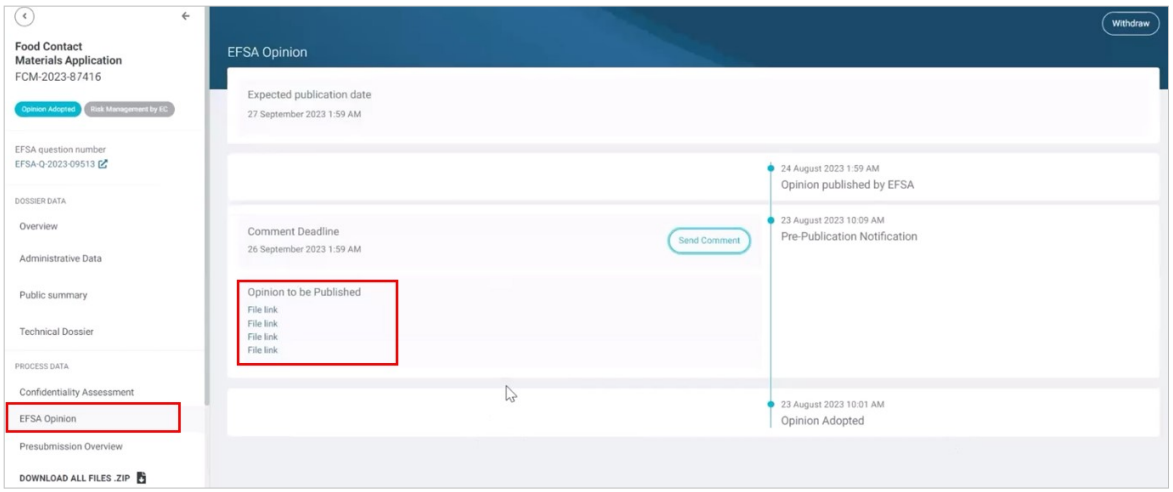
1. An email arrives to inform the user that EFSA has adopted an opinion. The dashboard displays a new '**EFSA Opinion**' tab in the lower left pane.



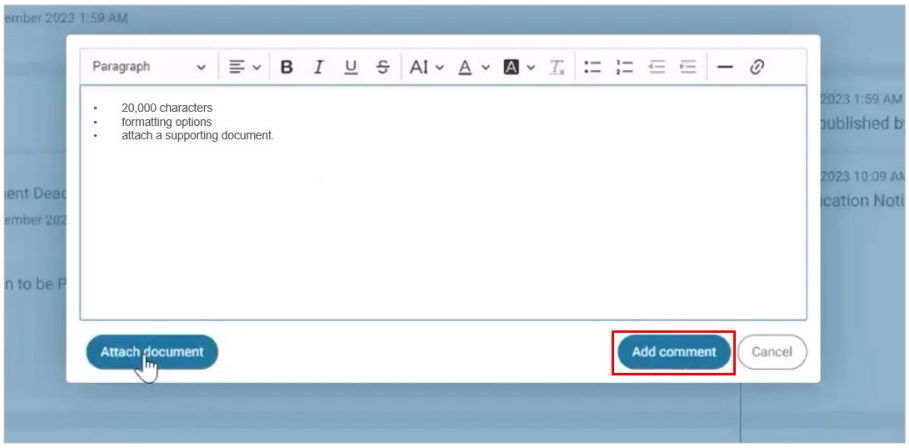
2. A pre-publication notification arrives, offering the Applicant a preview of the EFSA position and its exact wording.



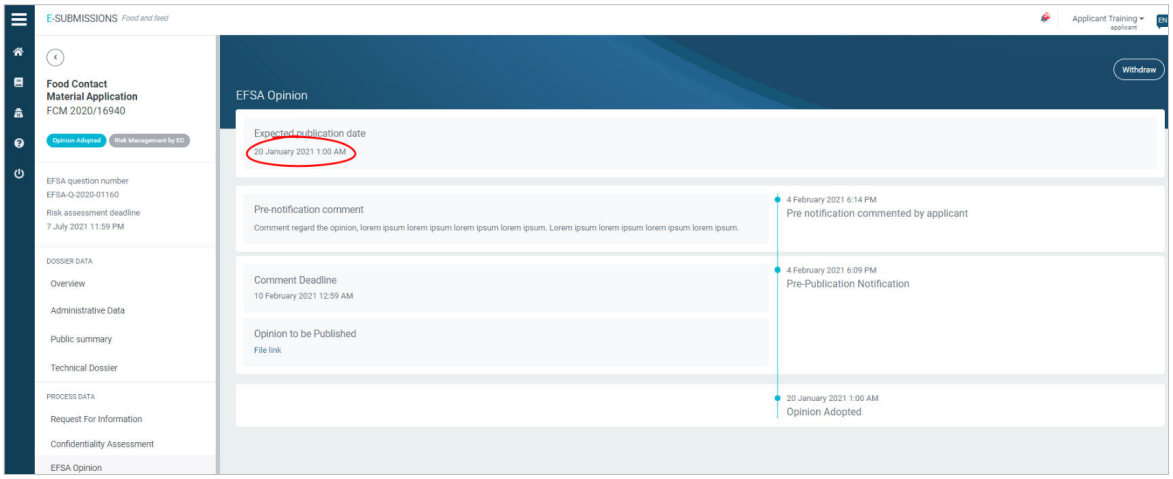
3. Click the '**EFSA Opinion**' tab. The opinion to be published may cover multiple files provided by EFSA. To read/download, click the '**File link**'. Note the 'Comment deadline' and the 'Expected publication deadline'.
   You have an option to comment on the general wording of the opinion, prior to the deadline. Click '**Send comment**'.



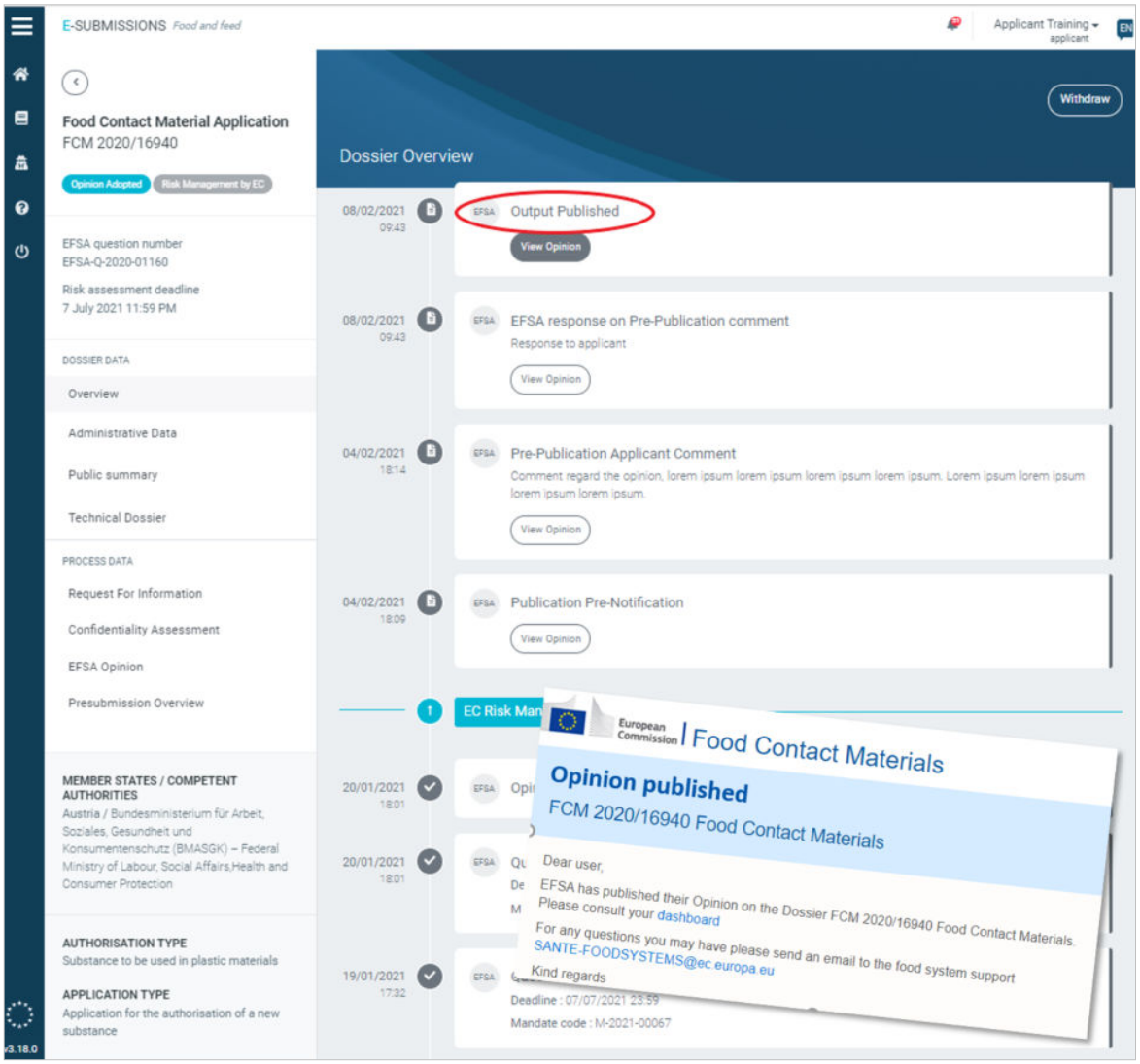
4. Type your comment (using up to 20,000 characters and formatting to improve clarity). You may upload a supporting document, which remains private. Click '**Add comment**'. The comment is sent and EFSA is informed. Note that once the deadline has passed, the **Add comment** button disappears.



5. Comments appear on the dashboard. Now wait for EFSA's reaction.



6. The opinion is published. You are informed, and Risk Management begins. Now you need to wait for the next step.



7.5 Authorisation procedure result

The risk management conclusion will be:

- **Authorisation (new/modification/renewal) granted**. You will be informed.
- **Authorisation rejected**. You will be informed with an explanation. A generic reason will also be published.
- **EFSA Inconclusive Opinion**. Upon request from EC, the Applicant can be invited to submit complementary information in order to complete the assessment.

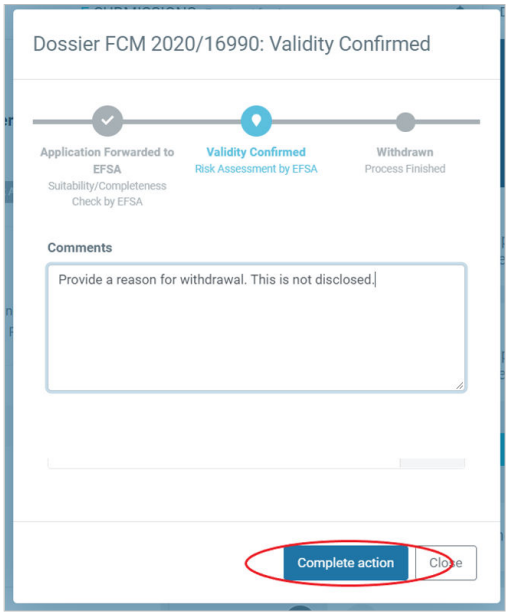
7.6 Withdraw dossier

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.

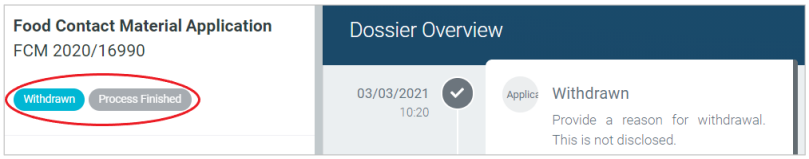
How to withdraw your dossier

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.



8 Intellectual Property Rights

8.1 How to accommodate IPR not owned by the Applicant

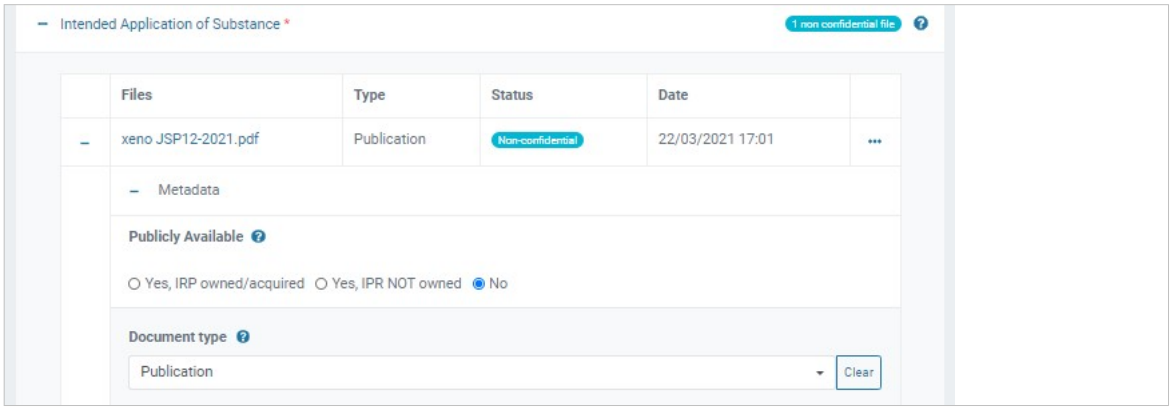
The new provisions of the Transparency Regulation, amending among others the General Food Law Regulation, provide for the proactive public disclosure by EFSA on its website of all scientific studies that support any request addressed to the European Food Safety Authority (EFSA) for scientific output,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

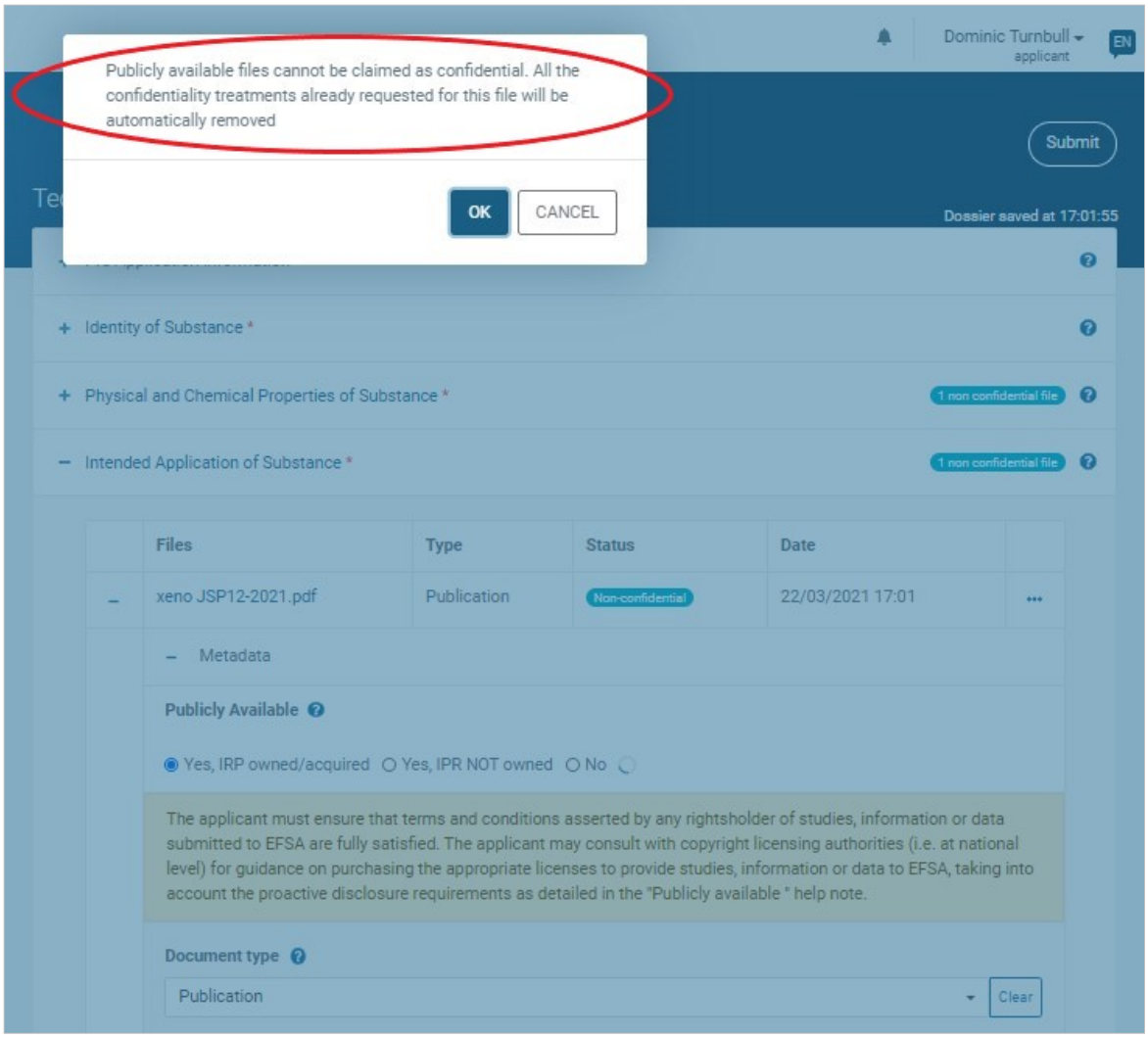
- Where the Applicant supports its applications by invoking published studies, the Applicant would need to provide risk assessors with the copies of those studies for the purposes of the risk assessment, namely to facilitate the scientific assessment. For the submission of these copies for EFSA risk 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.

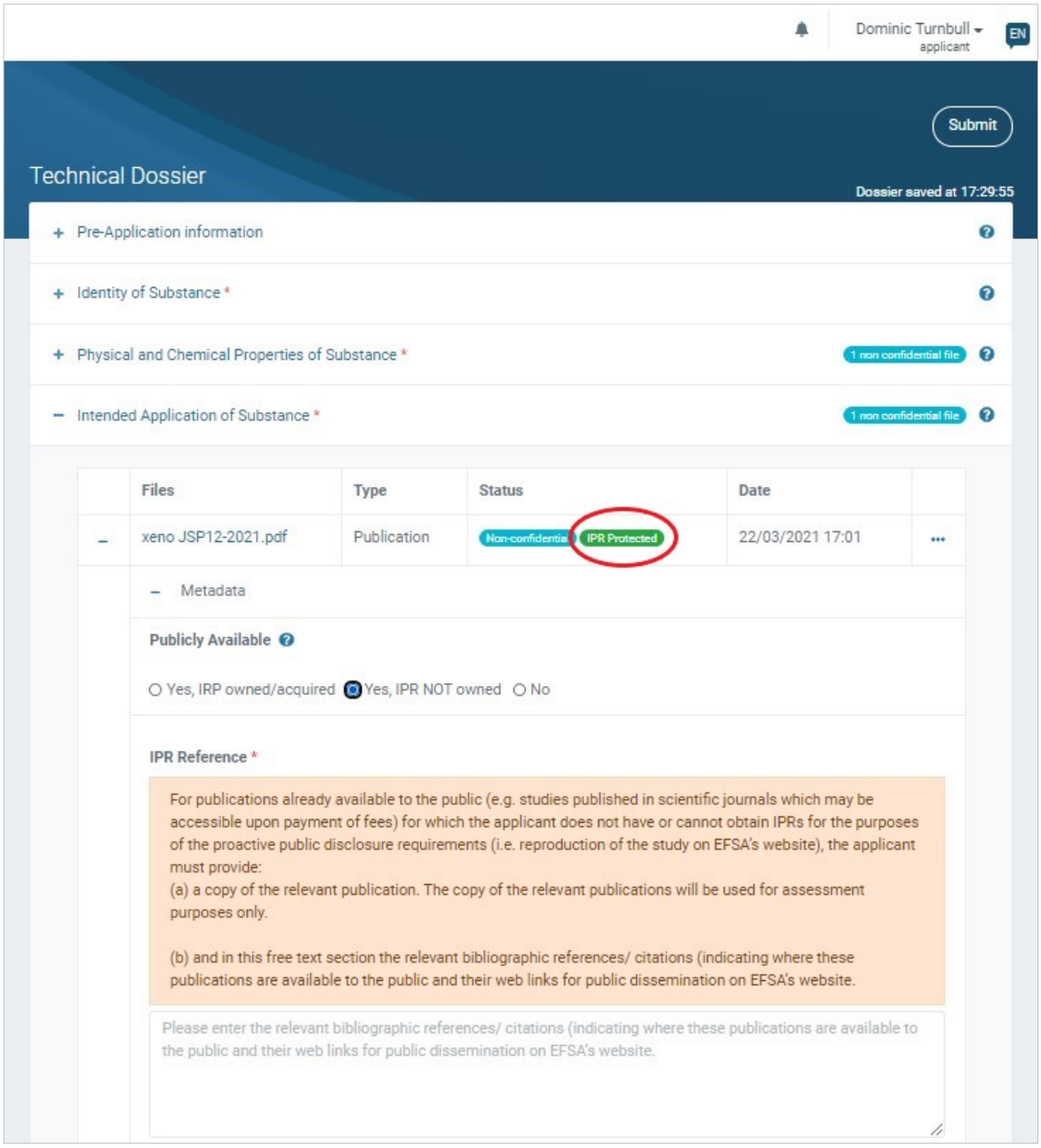
1. By default, 'Publicly Available' is set to '**No**'.



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



3. 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.



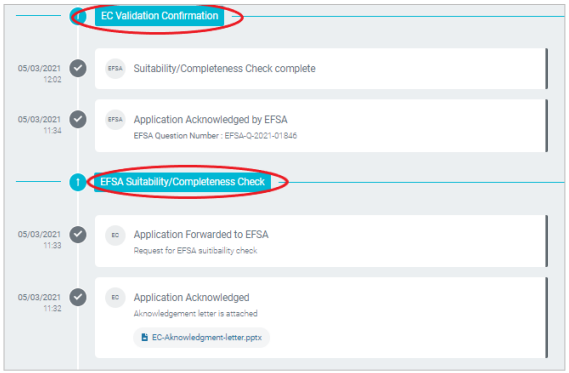
TIP
See the tutorial video here, which contains a section on meeting Intellectual Property Rights requirements.

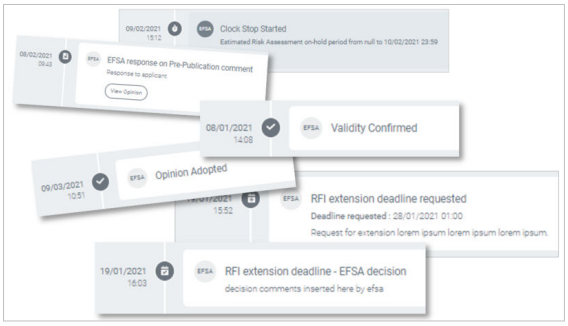
9 ESFC dossier tracking

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, intensions to disclose, sanitised file uploads, pre-publication notifications of the outcome, status changes, clockstops, 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.



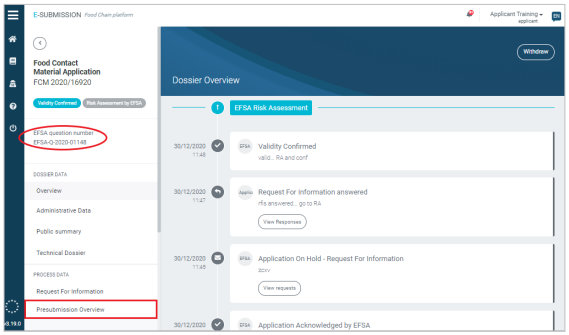


WARNING

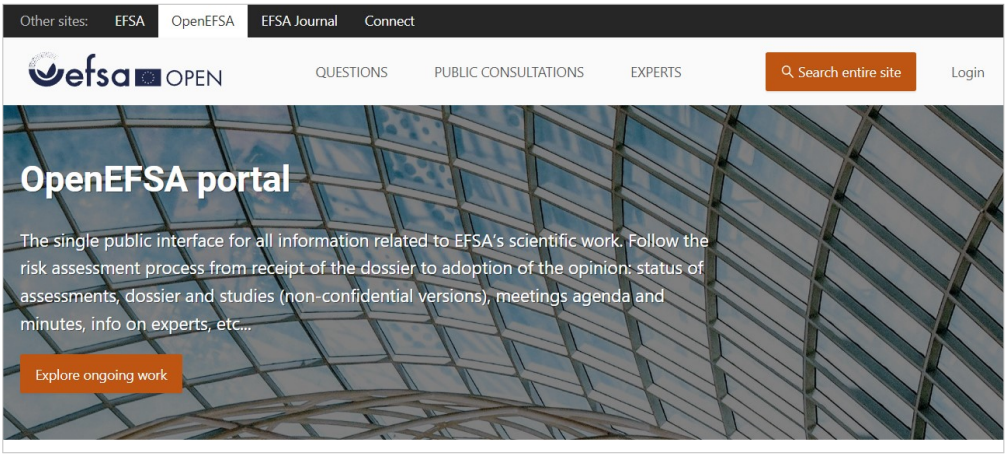
As the Applicant/Notifier, you should be aware that once an actor (i.e, EC, MS-CA and EFSA) is logged into the platform, they will see the activity timeline showing the history and current phase of any dossier. If the dossier phase is with them, that actor can interact via RFI. The content will also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

9.1 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.



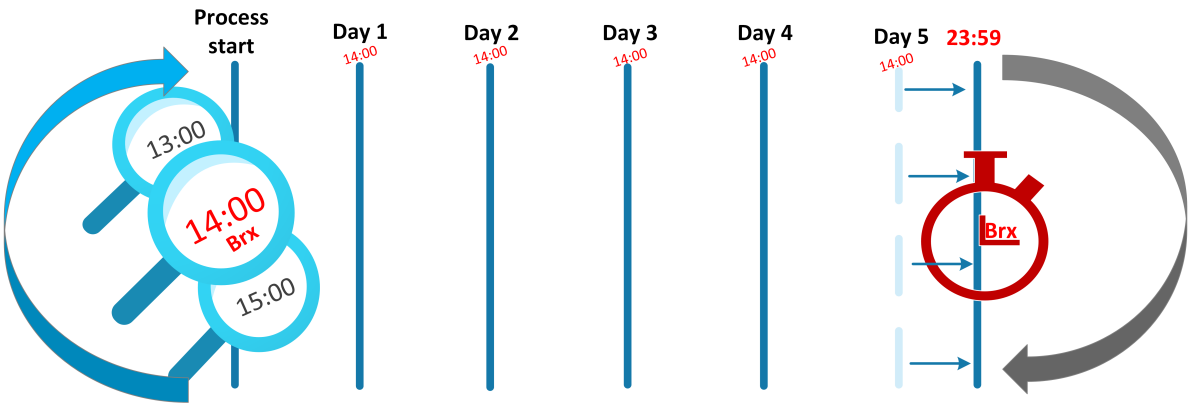
Through the **OpenEFSA** portal, the Applicant or the general public can track dossier progress.



9.2 Timezone logic

We use Zulu time as our programming logic for deadlines, which is a digitised form of Greenwich Mean Time (GMT), but we base the timing calculation to CET (i.e. Brussels time). In this way, we include the timings set by EFSA for RFI deadlines, for example, or for confidentiality request draft decision comments etc.

We set the end point of the deadline/period to midnight of the ending day. **The timings that you see displayed on the ESFC platform are then converted to your local time.**



The initiation-of-process time is calculated to Brussels time.
Whatever the period – working days or calendar month – it ends at 23:59 on the final day, by Brussels time.

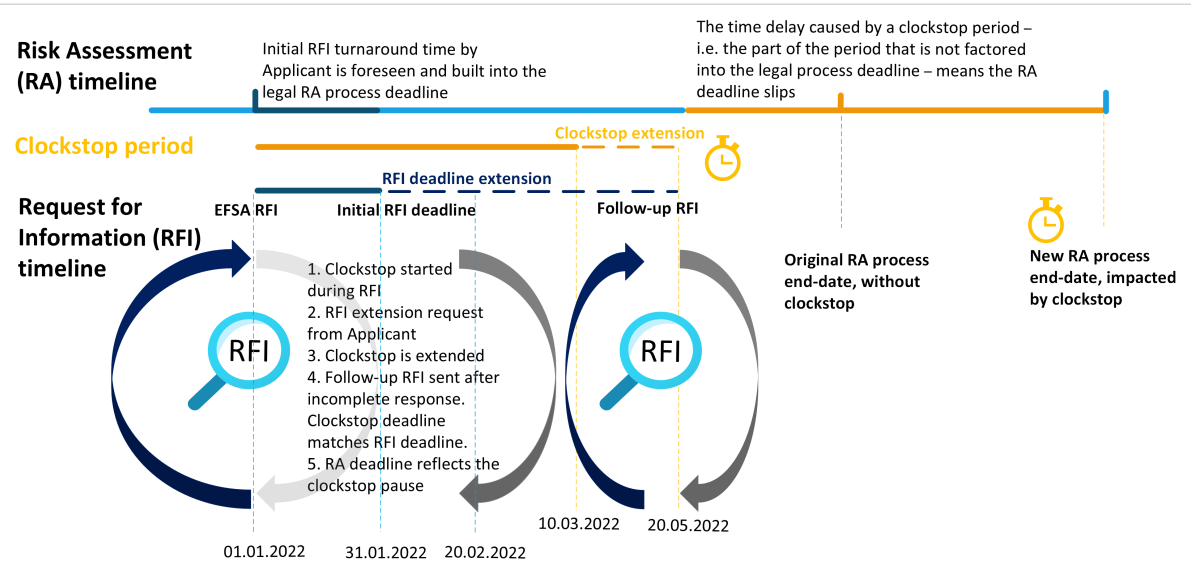
Evaluation period in Traditional Foods – four calendar months from when the TFN is validated, ending midnight set to (CET) Brussels time of the ending day:

- **Brussels**: 01 May, 09:00 – 01 September, **23.59**
- **Bucharest**: 01 May, 10:00 – 02 September, 00.59

Draft implementing Act comment in Novel and Traditional Foods – five working days, ending midnight set to (CET) Brussels time:

- **Brussels**: Friday 06 August, 15:00 – 12 August, **23.59**
- **Lisbon**: Friday 06 August, 14:00 – 12 August, 22.59 (note that an EFSA or EC bank holiday would not be calculated as a 'working day')

9.3 EFSA's clockstop logic



Timeline for clockstop graphic

Initial RFI deadline: 31.01.2022

- During the Risk Assessment (RA) phase, the clock-stop starts upon submission of the RFI.
- Clockstop end-date is initially set at 10.03.2022.
- The applicant requests a deadline extension to reply to the RFI (if needed).
- EFSA checks the Applicant response to the RFI:
  - if it is complete, the **clockstop is ended from the date of submission of the RFI reply** and the risk assessment process is resumed;
  - if it is not complete, EFSA submits a follow-up RFI for clarification on the incomplete reply, and the clock remains stopped. The clockstop deadline is extended as needed in order to match the deadline for the follow-up RFI
- EFSA send a follow-up RFI with a ten-day deadline, still within the extended clockstop.
- Once the applicant provides a complete reply to the RFI the clock stop ends from the date of submission of the reply. The RA process is resumed and the RA deadline is recalculated on the basis of the on-hold period, and the related regulation.

For most areas (except for Health Claims), the approach would be:

- RA Legal DL: e.g. five months
- An RFI is sent and the clock is stopped after two months – three months remain of the RA DL
- A complete RFI reply is provided after one month and the clockstop can be ended.
- The RA deadline will be recalculated considering the on-hold period, i.e. adding to the clock restart date the three months that were remaining for RA.

Background to the process

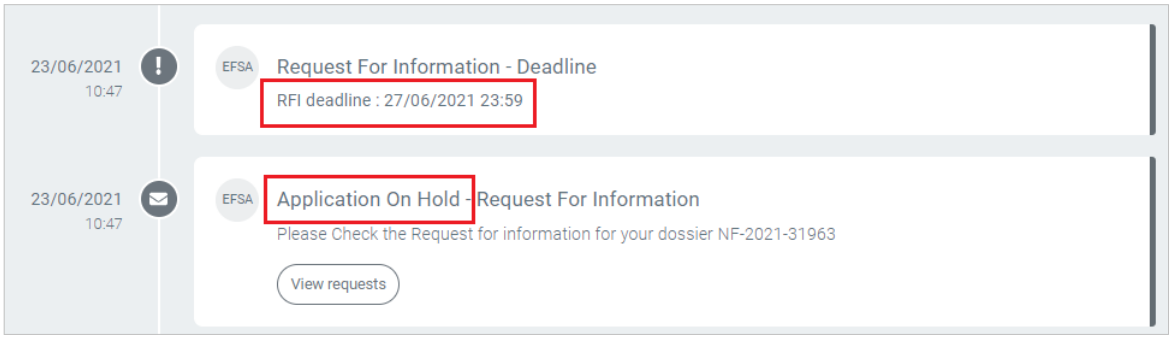
EFSA's clockstop procedure takes place when EFSA manage an **RFI** (or **ADR** during Risk Assessment).

The initial RFI deadline that appears on the ESFC timeline does not impact the overall RA process deadline, because the need for RFIs is accounted for within the 'legal deadline' – i.e. the nine-month period stated in legislation for Novel Foods does not slip due to an RFI. When an RFI is issued, the application just goes '**On hold**'.

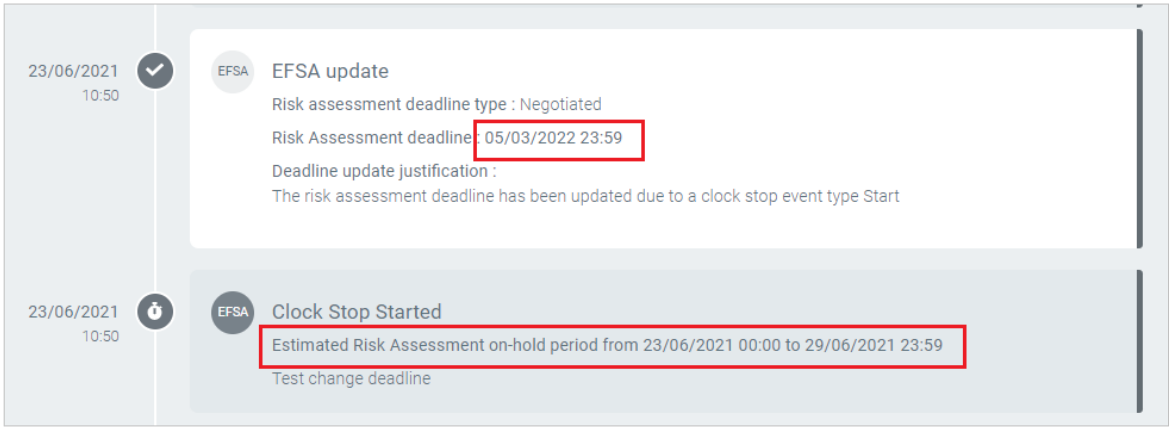
There will be a legal impact, however, on the overall RA deadline if EFSA start a clockstop procedure. The situation could be such that EFSA consider that a follow-up RFI is needed, or that there are clear gaps in the data that would take time to resolve. EFSA provides a justification.

The RA process deadline slips, recalculated to take into account the on-hold period and the remaining RA time based on the legal deadline. A clockstop can be extended for duly justified reasons (e.g. deadline for RFI reply extended; to align with follow-up RFI). It can also be ended earlier, if needed (e.g. complete RFI reply provided, and RA process resumed). It does not automatically end once the RFI is closed.

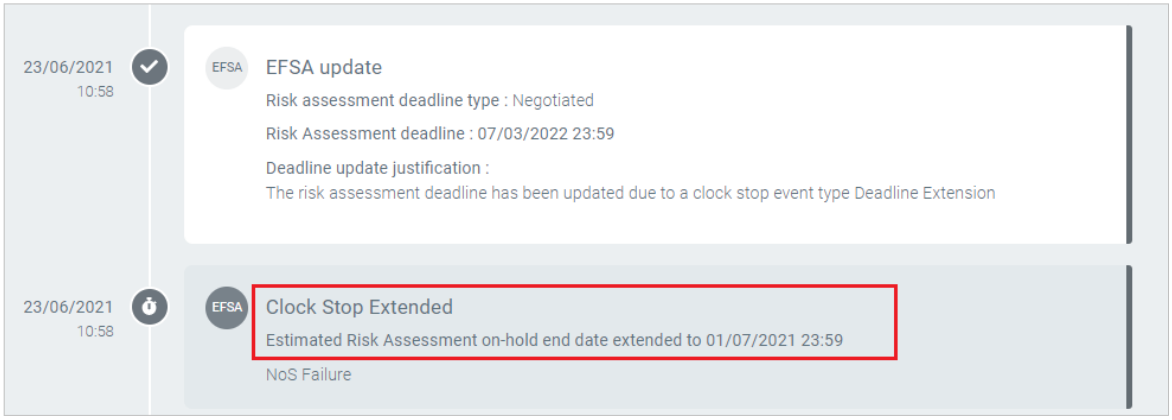
1. An RFI is issued by EFSA.



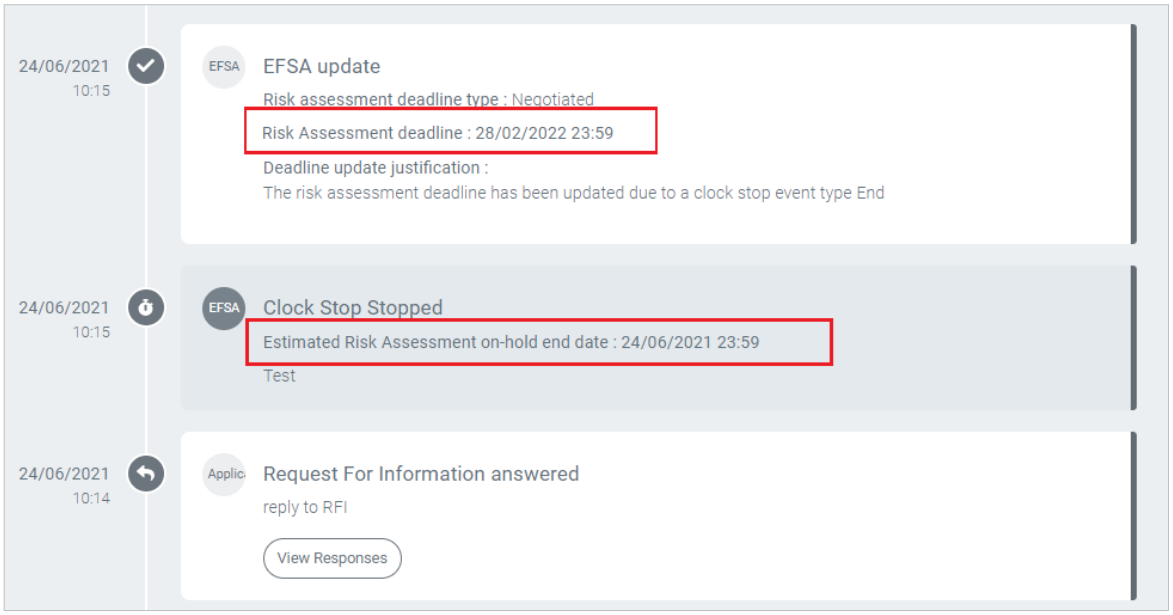
2. EFSA **start a clockstop**. A reason is provided, and the estimated delay is added (manually) to the overall risk assessment process deadline, which is now displayed as a 'negotiated' rather than 'legal' deadline.



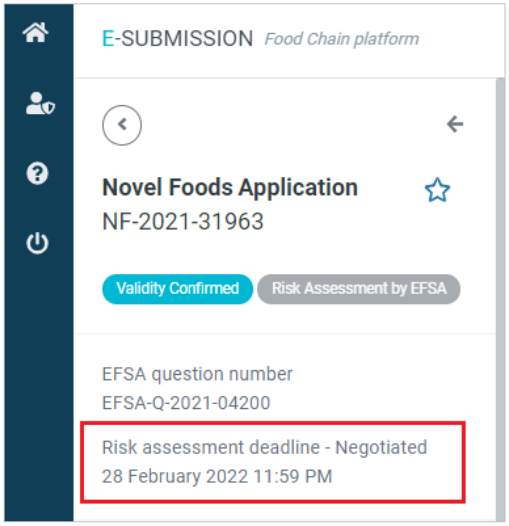
3. EFSA can **extend the clockstop**, and this extra delay is reflected in the RA process deadline. A justification is provided. The Applicant can also request an extension to the RFI deadline, and EFSA may accept this date or set an alternative date within the clockstop period.



4. If, after consideration, an RFI response is acceptable, the **clockstop can be ended** by EFSA, even if earlier/before its set deadline. The RA process is resumed and the RA deadline is recalculated on the basis of the on-hold period and the remaining RA time.



5. The clockstop causes a delay to the overall risk assessment completion date, which now is labelled as 'Negotiated' rather than 'Legal'.

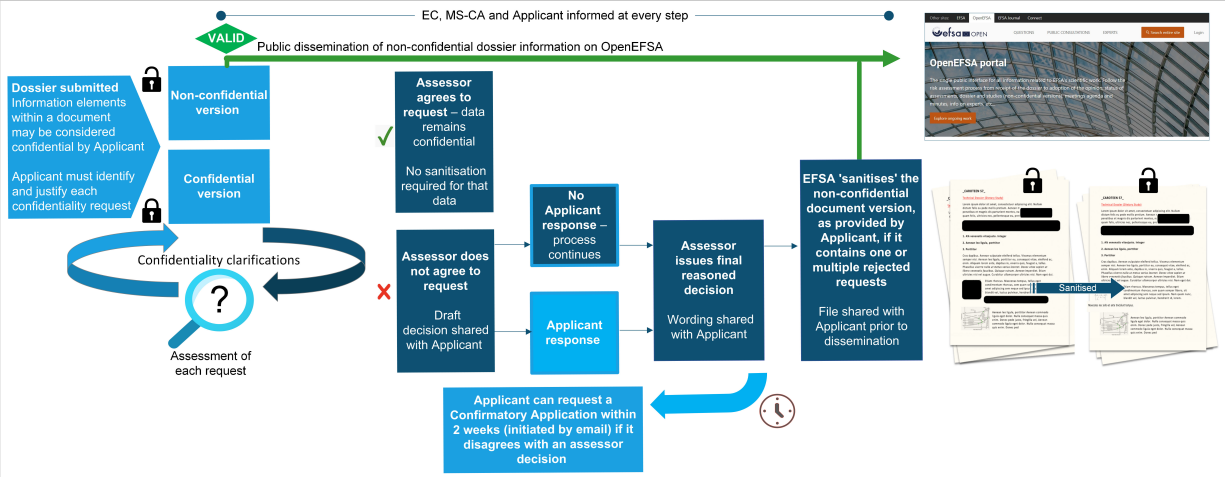


NOTE
During a clockstop, the RFI deadline is an 'indicator' for the Applicant to respond in a timely manner.

NOTE
Currently, EFSA cannot proceed with a dossier assessment until all RFIs are 'closed' – i.e. responded to satisfactorily and so not requiring follow-up RFIs. If an Applicant does not respond, or fails to see the notification email, the process is effectively blocked.

IMPORTANT
EFSA calculate and update the Risk Assessment process deadline. See the Timezone logic [123] section with regards to deadline display.

10 Dossier confidentiality



The Applicant needs to provide a confidential version of the dossier, where all scientific data and other supplementary information supporting the application are readable/accessible to assessors. Even in the confidential version of the application, the information for which confidentiality is required should be identified (e.g. earmarked).

The Applicant also needs to provide a non-confidential version of the dossier, where all data and information claimed to be confidential are marked as confidential (blackened). However, according to the Transparency Regulation, the Applicant can request confidentiality treatment at the lowest level of granularity possible, in order to ensure compliance with the principle that transparency is the rule, and confidentiality the exception to the rule.

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 Articles 39(2,3) and 39a of Regulation (EC) No 178/2002, as amended by the Transparency Regulation.

The confidentiality assessment is generally carried out by EFSA, but there are some exceptions in which EC or MS Competent Authorities carry out the assessments.

- **EC**: Novel Foods (in some cases). Re-evaluation of food additives, enzymes or flavourings (removing a substance from the Community list, adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list), if the updates in question are not liable to have an effect on human health.

- **MS-CA**: GMOs (release into the environment),

For a comprehensive description of applicable provision and procedures, refer to EFSA's Practical Arrangements concerning transparency and confidentiality available here, on

which EFSA has provided additional guidance in the form of a **Q&A document** available here. Click here [130] for details on how to submit a confidentiality request.

Note that a blanket request for confidentiality (for instance, covering "The entire document") is not compliant with the applicable legal framework and EFSA's Practical Arrangements, and will not be accepted.

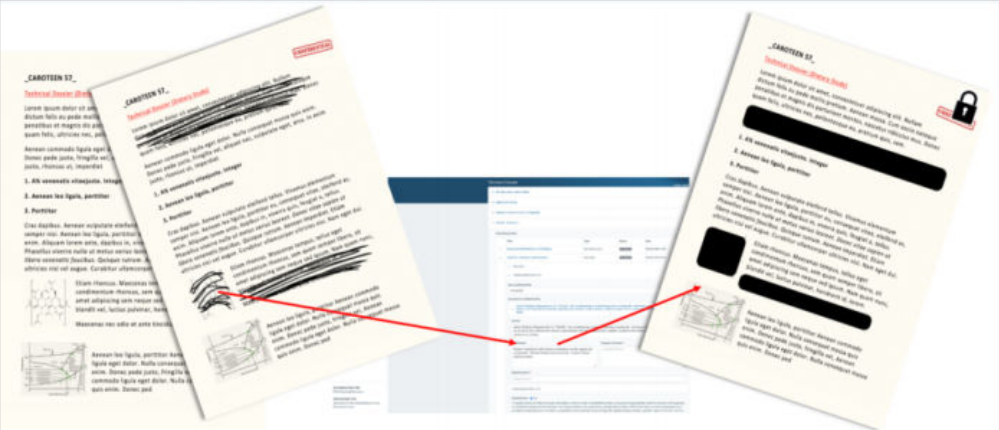
The following pages offer a practical guide to requesting confidentiality and responding to clarification requests from assessors.

TIP
View the tutorial video here that outlines the confidentiality process and the separate requirements surrounding Intellectual Property Rights.

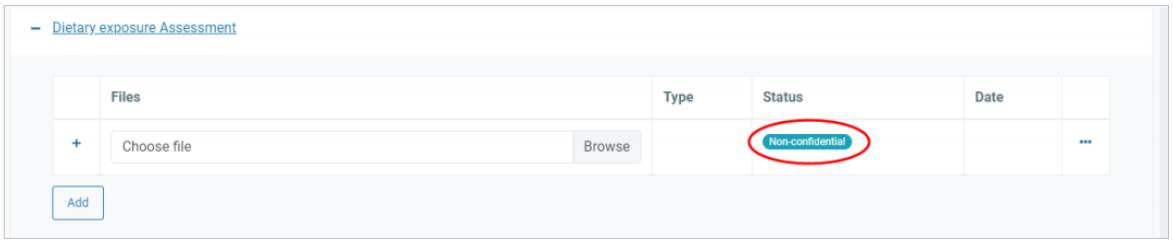
Also visit EFSA's Confidentiality and sanitisation webpages.

10.1 How to request confidentiality

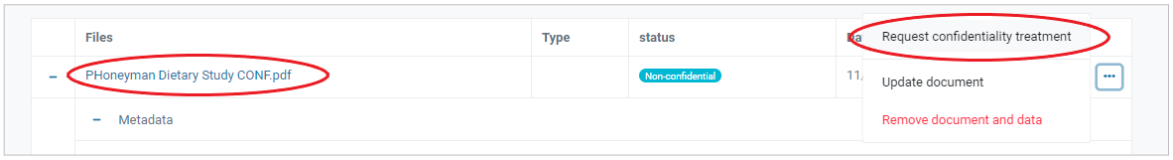
Identify all confidential elements within your documents, then establish which legal ground underpins each request and prepare its justification. Redact a duplicate file to create the 'non-confidential version' – digitally and permanently black out content for which you are requesting confidentiality.



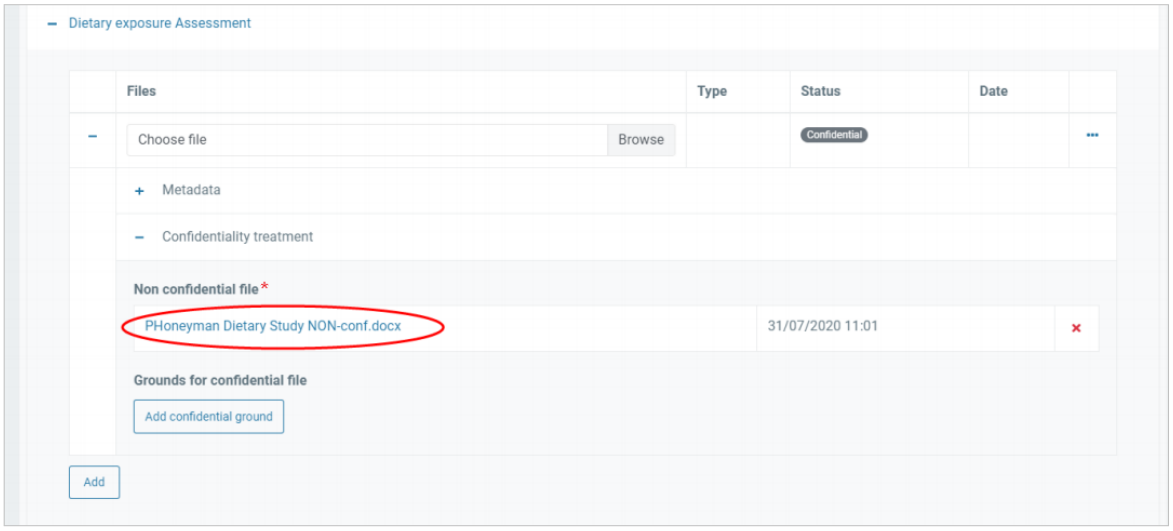
1. In the file upload fields, notice that the badge by default invites **non-confidential** documents. Browse to and upload each non-confidential document. Define the document using the metadata '**Document type**' – see Appendix A [157]. Be sure that the document is not the 'non-confidential version' of a document which contains confidentiality requests, as these should be submitted together according to the following steps.



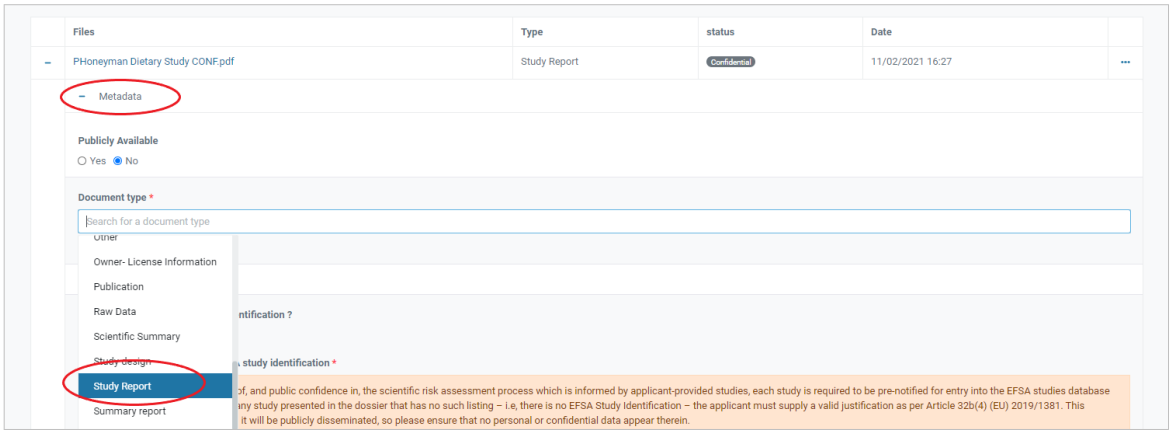
2. If you have a document which contains at least one confidentiality request, upload it here, unredacted but earmarked, and click the three dots to select '**Request confidentiality treatment**'. The badge changes to '**Confidential**'. If you choose '**Update document**' and you upload a new version, all the metadata and confidentiality treatment information will disappear.



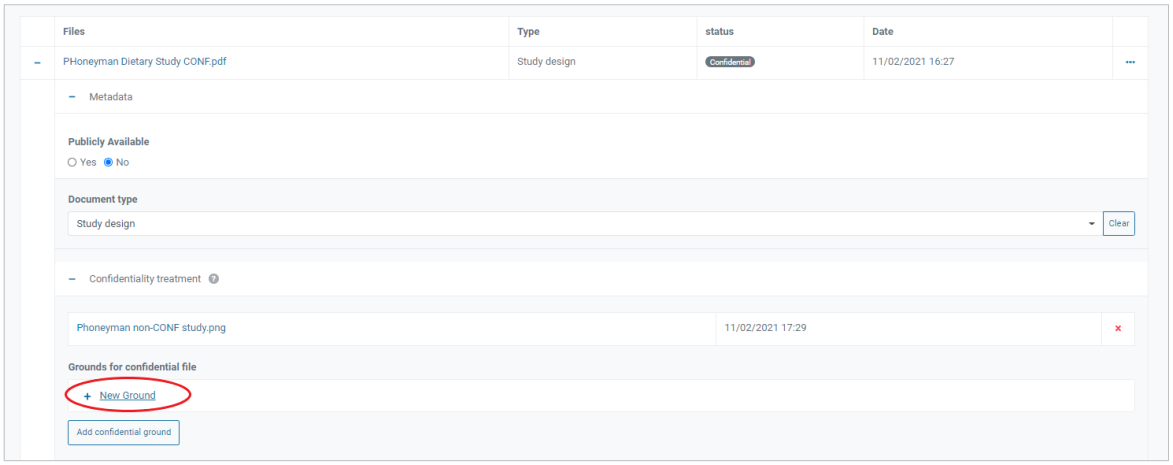
3. Upload its non-confidential version. This will be proactively disseminated once your dossier has been validated. You can carry out this step at any point – but note that it is mandatory as a follow-up to *Step 2*.



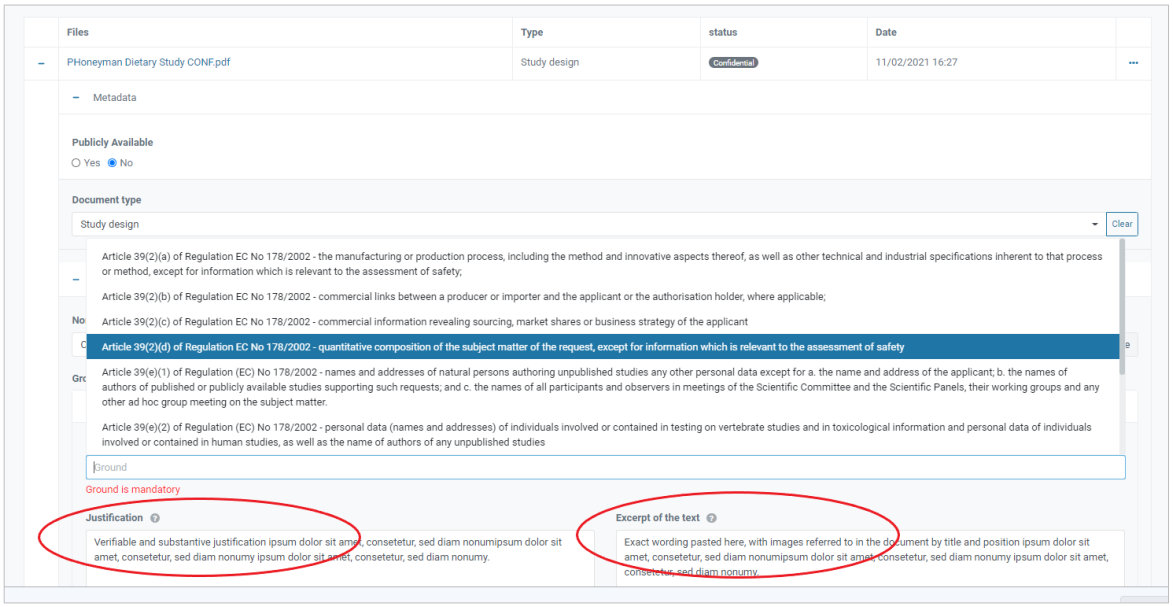
4. Define your confidential document from the '**Document type**' list, see Appendix A [157]. Please note that if the document type selected is '**Study report**', '**Certificate of Analysis**', '**Raw data**', or '**Other supporting document**', then additional NOS elements apply, as illustrated in *Steps 18-21* of this dossier build [34].



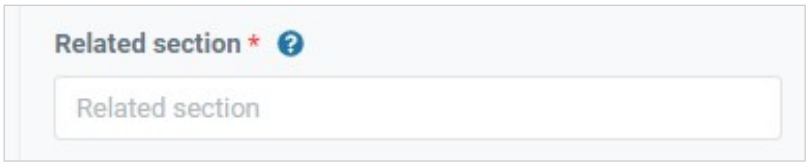
5. Select one ground for each confidentiality request. There may be multiple requests for the same document.



6. 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 in the **Excerpt** box paste the exact wording. This is a text-only field, so any graphic/table should be referred to by its title and position in the file.

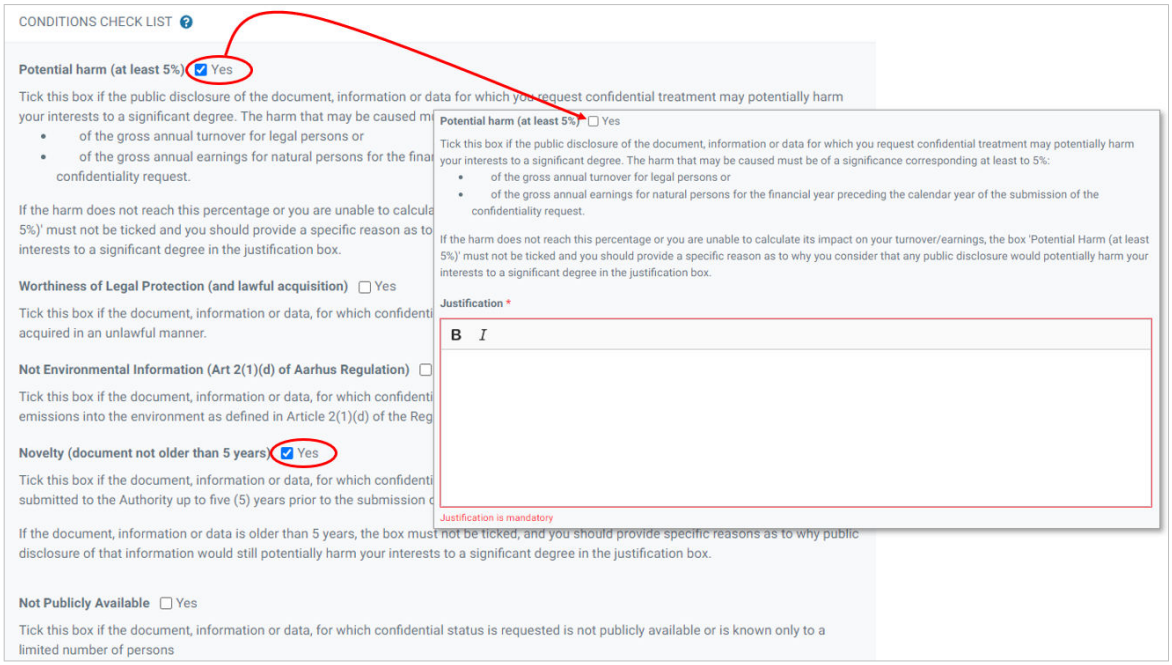


7. In the '**Related section**' field, identify the exact position of the content for which you are requesting confidentiality treatment – by page/section number, column, paragraph, line, or word if necessary. Provide this document position in a sufficiently precise manner to exclude any information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

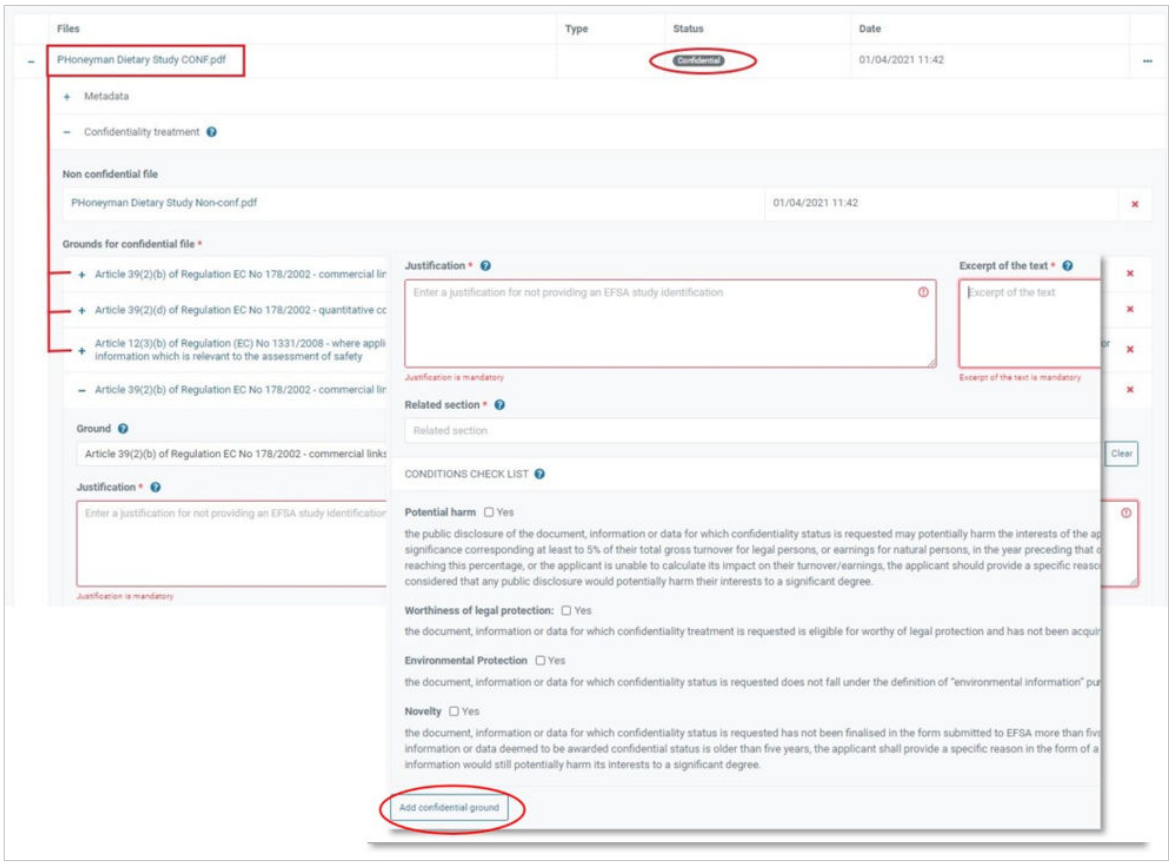


8. In the ‘conditions check list’ section, click the condition boxes that you deem as satisfied for your confidentiality request. Kindly note that such condition boxes mirror the substantive requirements listed in Article 10(b) of EFSA Practical Arrangements on Transparency and Confidentiality, which, as stated therein, have to be cumulatively met.

   If the requirements related to the conditions “Potential harm” and/or “Novelty” are satisfied for your confidentiality request, click **'Yes'** in the respective condition boxes. If the requirements are not satisfied, you **must provide** a specific reason as to why you consider that any public disclosure would potentially harm your interests to a significant degree in the justification box related to the relevant condition box. The completion of the justification box is mandatory for the “Potential harm” and the “Novelty” condition in case the boxes are not selected.

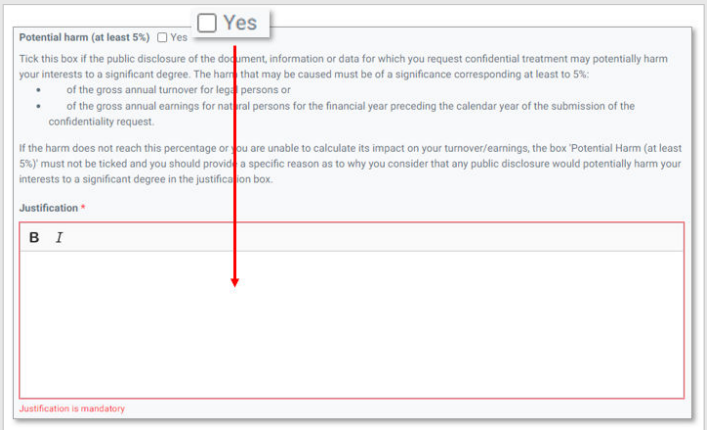


9. If you have multiple requests per document, a new request can be created by clicking '**Add confidential ground**'. The new request may refer to the same ground or the same document, but they should be introduced separately.



CAUTION

If the requirements for 'Potential harm' or 'Novelty' conditions are not satisfied, do not click '**Yes**'. However, you must provide an explanation as to why you consider that any public disclosure would potentially harm your interests to a significant degree in the justification box.

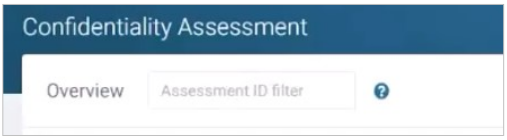


NOTE
For more details on the confidentiality process, visit EFSA's 'Transparency Regulation: Practical Arrangements' page. Also visit EFSA's webpage on confidentiality and sanitisation.

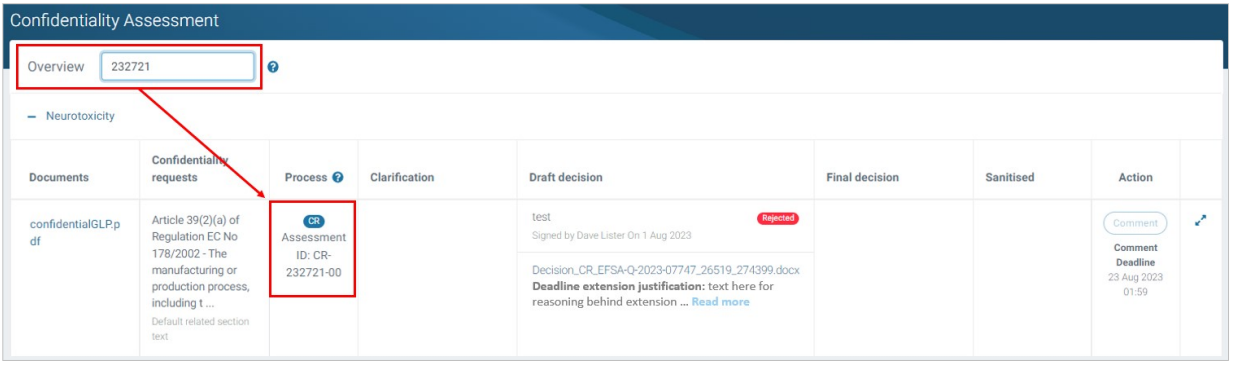
WARNING
Future confidentiality assessments may be triggered by the availability of new information or new scientific understanding (see Article 39c of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381).

10.2 Tracking confidentiality requests

EFSA issues an **Assessment ID** for each confidentiality request (CR). The **Overview** filter enables the user to search and display a specific CR using the Assessment ID.



The ID appears in the 'Process' column with a badge [150] indicating the assessment phase. EFSA will refer to it for clarity during interactions with the applicant regarding specific CRs.

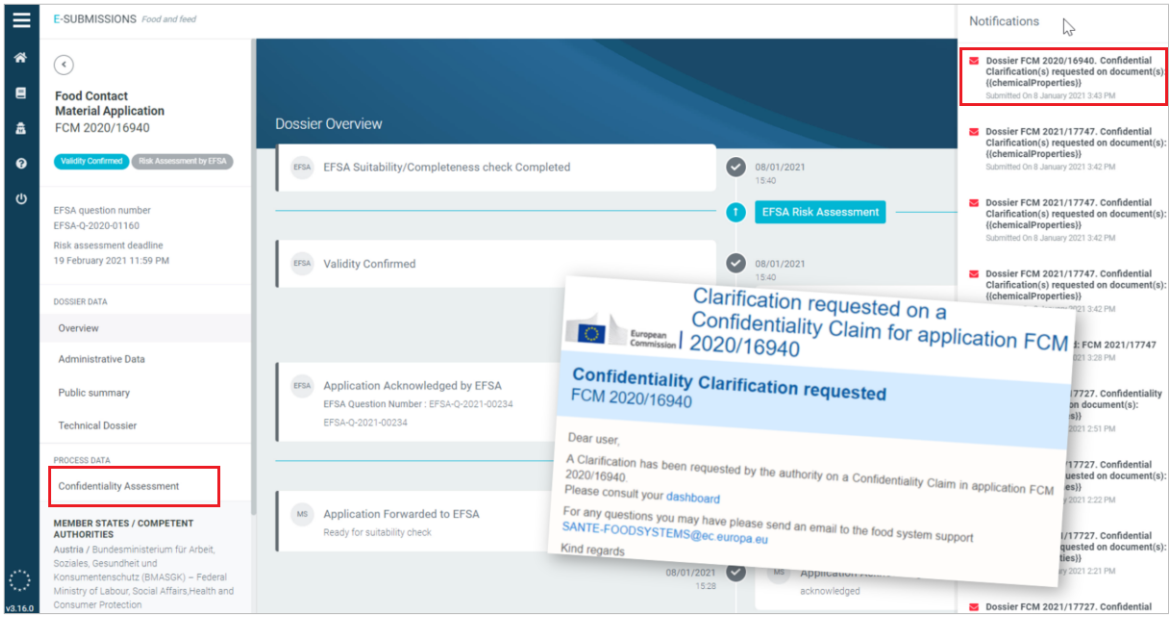


In the above example, '*232721*' is the Assessment ID. The following number sequence '*-00*' relates to the cycle of that particular CR (i.e. in the case of multiple re-assessments).

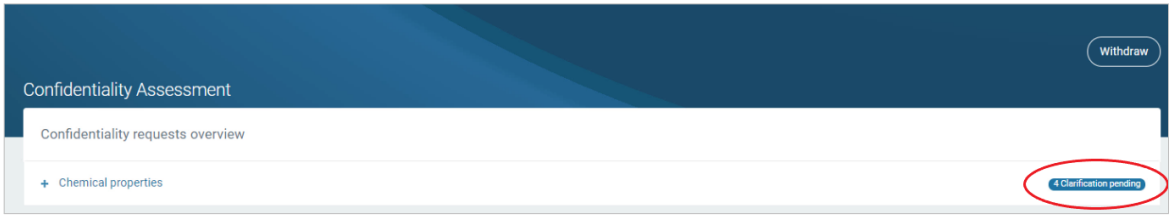
10.3 Responding to confidentiality clarifications

We advise you to respond to clarifications requests as soon as possible. The process will continue if you do not respond within the deadline.

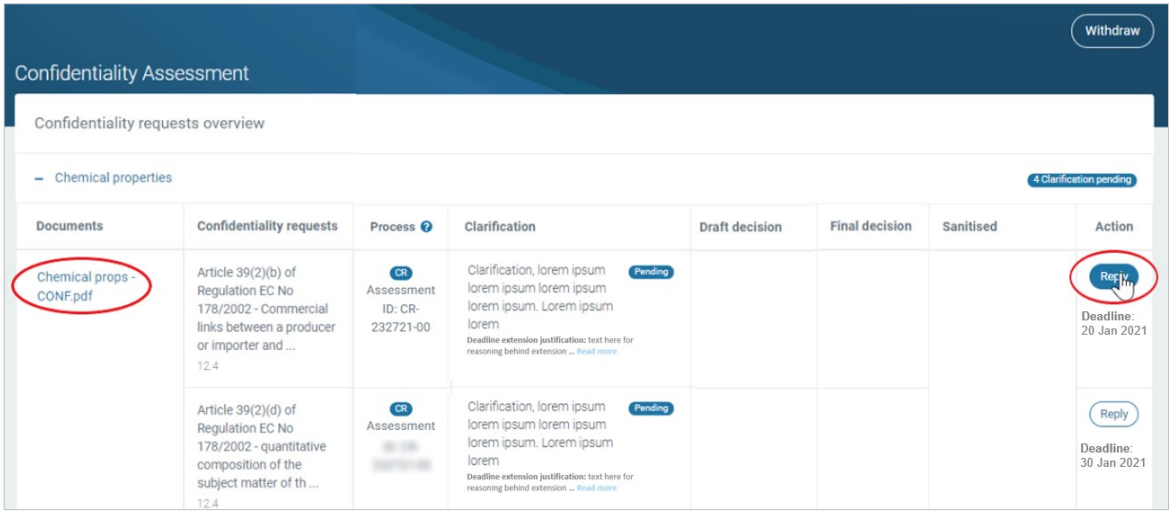
1. After dossier validation, you will notice the new **Confidentiality Assessment** tab on the left pane. If there are clarification requests, you will receive an email. Also the request will appear under the notifications bell top-right.



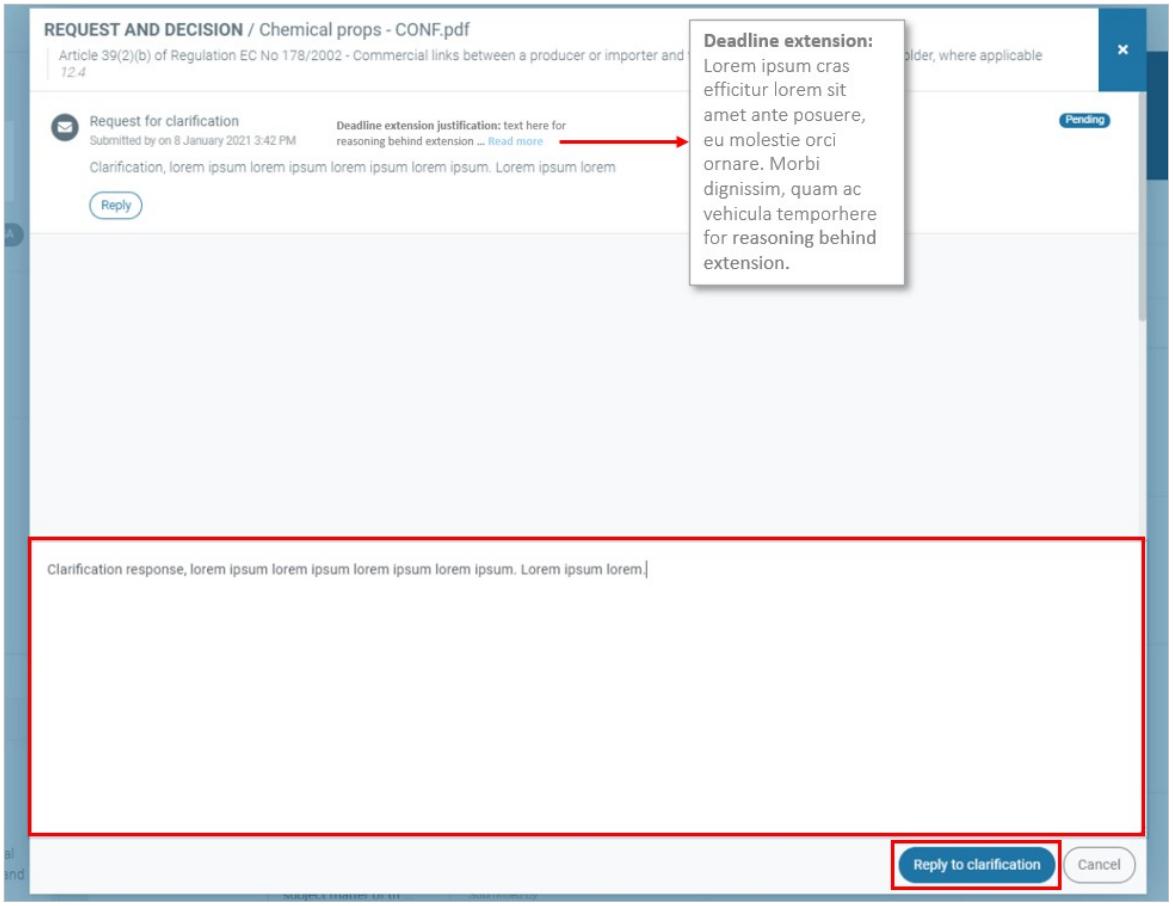
2. Click the '**Confidentiality Assessment**' tab. This shows the section and number of clarification requests in 'pending' state. Click the '**+**' to open the relevant section.



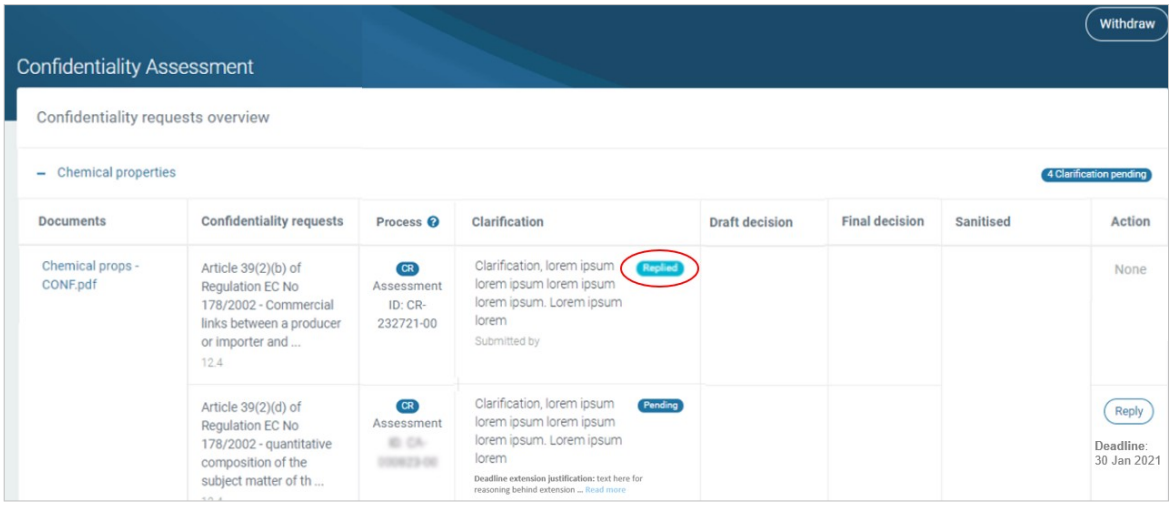
3. You will see the file, the confidentiality request ground, and the assessor question. Click '**Reply**' to read it in full and respond. EFSA may reduce or extend the reply deadline and provide a justification.
   Note that after the deadline has been reached, the **Reply** button disappears.



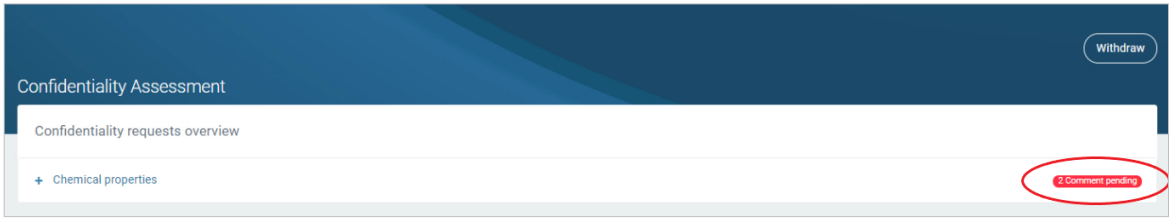
4. Read the clarification and respond with free-text in the box below. No files can be uploaded. Click '**Reply to clarification**'. The screen will display your reply – it has now been sent.



5. The '**Pending**' badge is replaced by '**Replied**'.



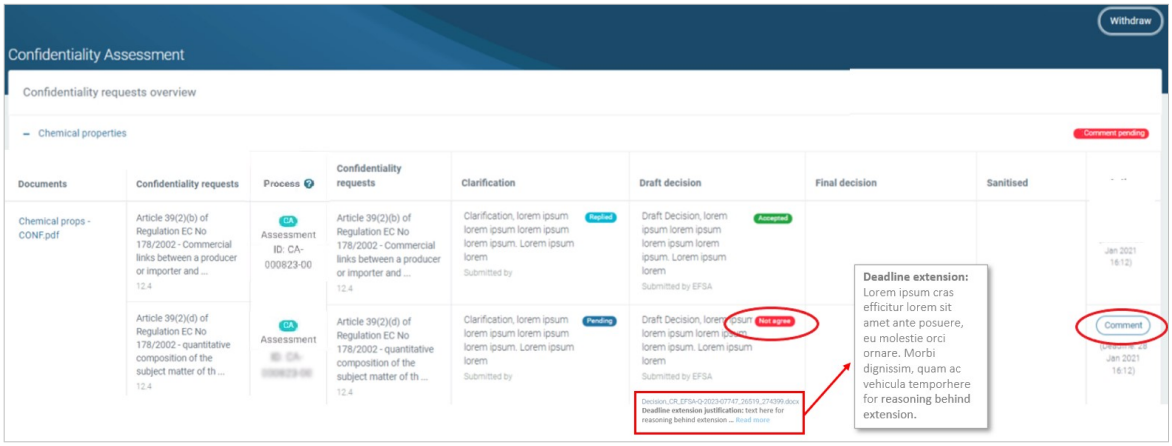
6. After further consideration, a draft decision for each confidentiality request arrives.



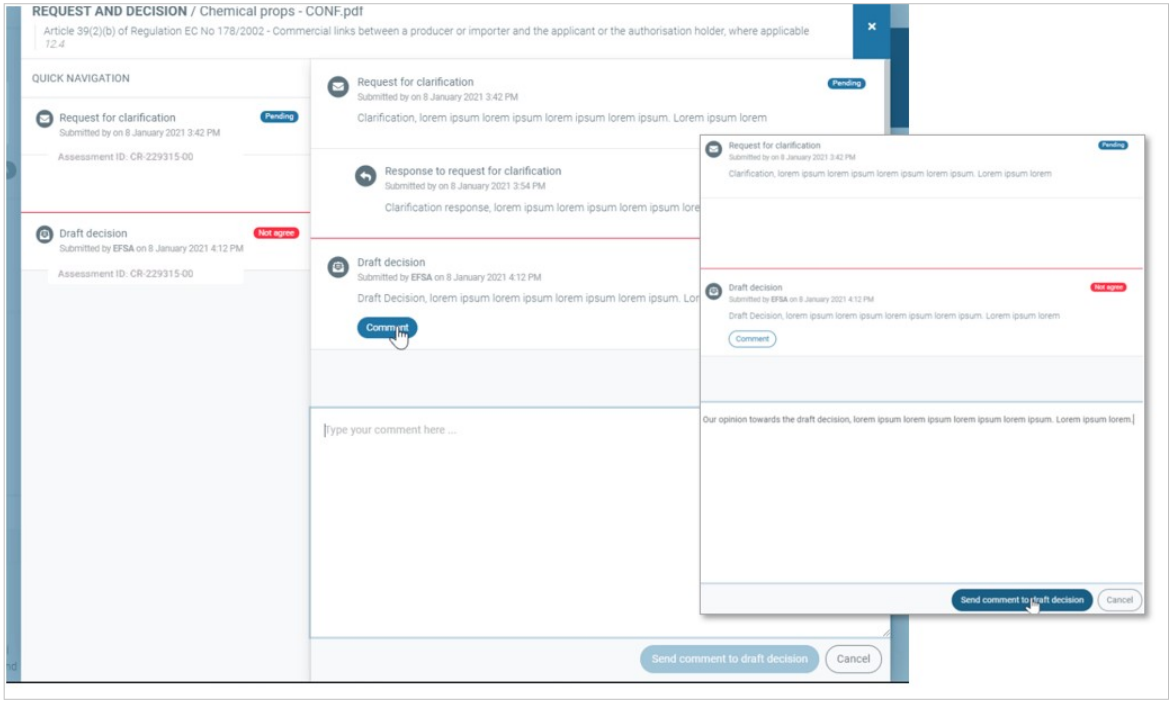
10.4 Draft and final CR decisions

The applicant receives a notification that a draft decision has been notified.

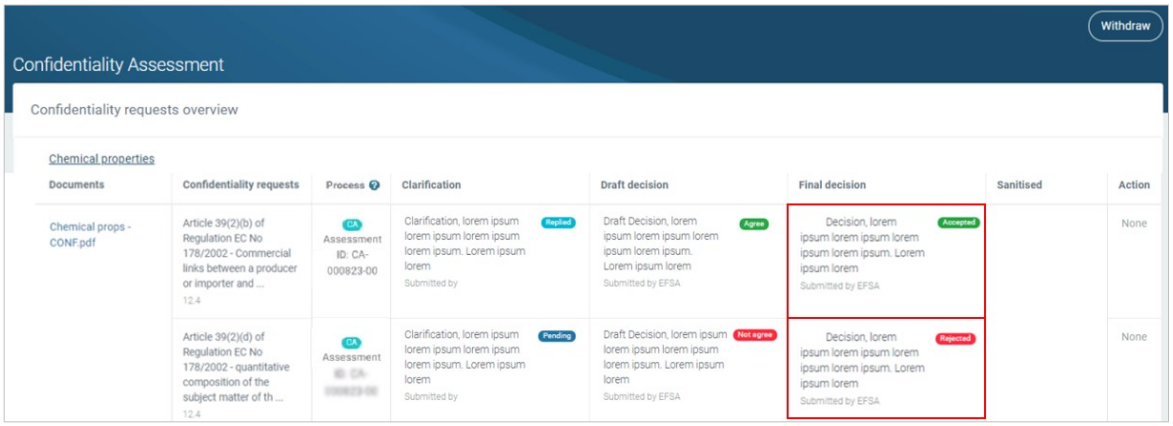
1. In the dashboard, the badges indicate the CR status. If the assessor does '**Not agree**' with the confidentiality request, a decision document is provided. The **Comment** button allows the applicant to react to the decision up until the comment deadline. When notifying the draft, EFSA may extend that deadline to comment on the draft decision, in which case they provide a justification. Click 'Read more' to view the full text. However, once the draft is notified, the deadline cannot be further extended.



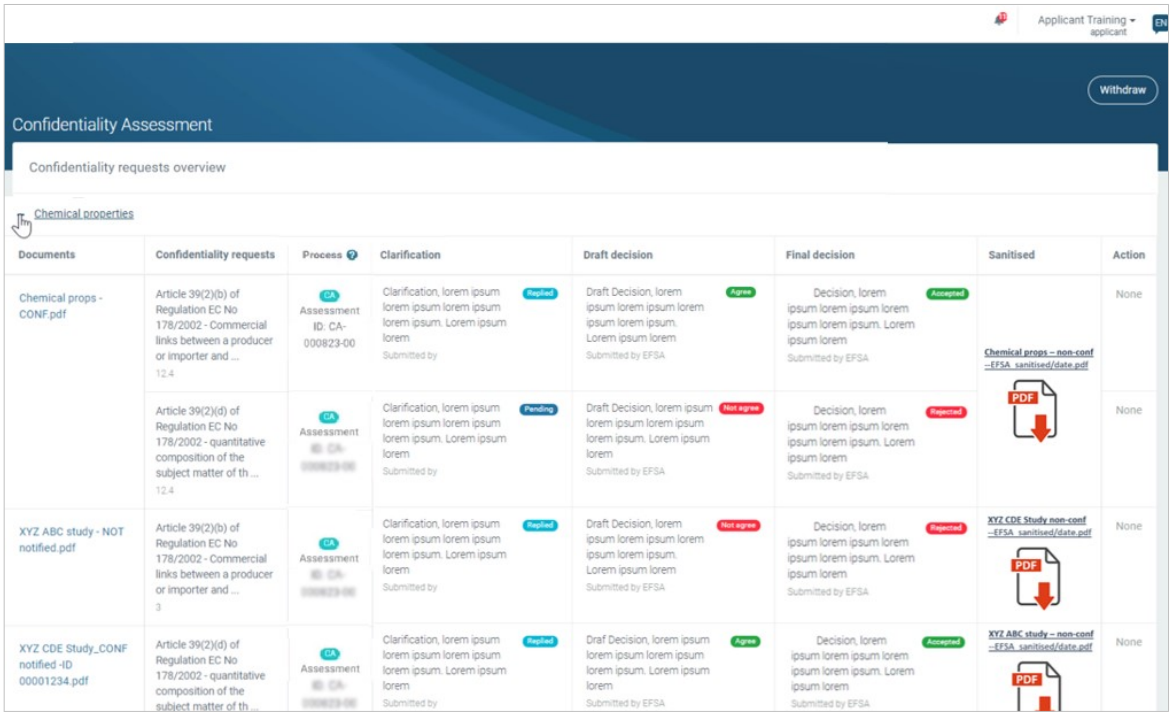
2. Input your comment, then click '**Send comment to draft decision**'.



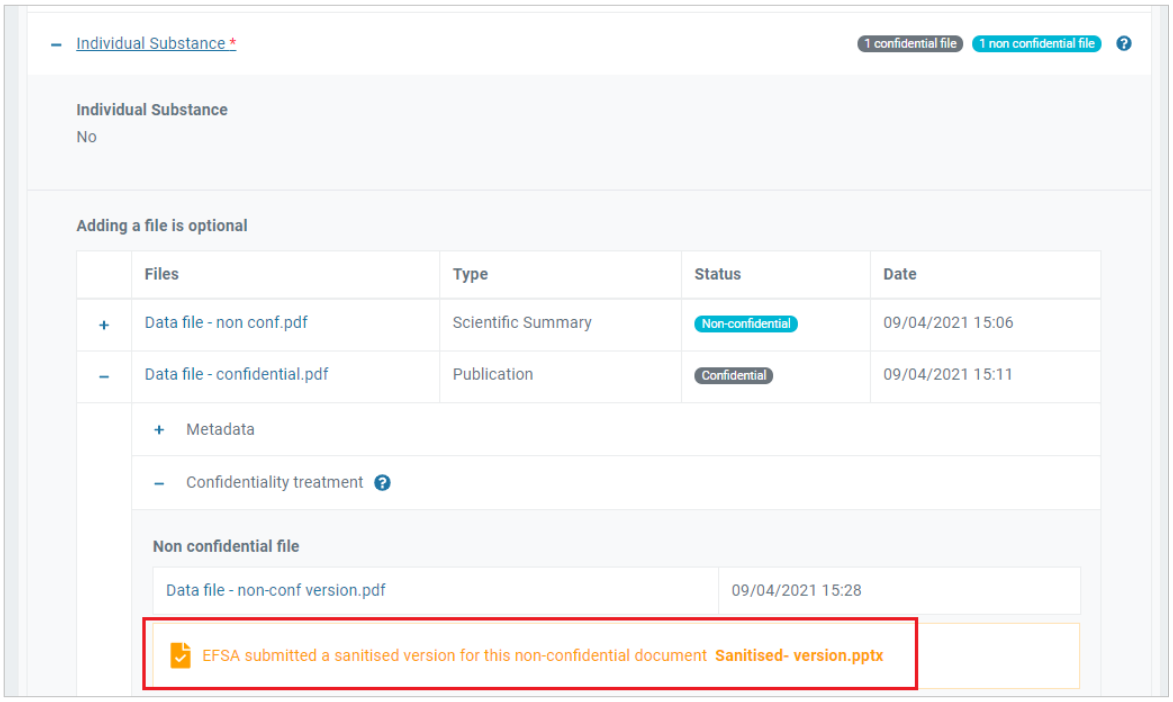
3. The final decision is signed, either 'Rejected' or 'Approved' as shown in the dashboard. Click on the field for details.



4. You receive the **notification**. Through the dashboard you can now access each non-confidential document version, now 'sanitised' by EFSA. The document(s) reflect the assessment decisions and are unredacted accordingly.



5. Each 'sanitised' document also appears in the relevant section, positioned directly under the non-confidential version it is replacing.



IMPORTANT
If an Applicant disagrees with a decision, within a dossier for which EFSA conducts the assessment, pursuant to Article 39b of Regulation (EC) 178/2002 they may submit a Confirmatory Application to EFSA. A button will appear to launch the reassessment of a negative decision, which will be handled through the platform.

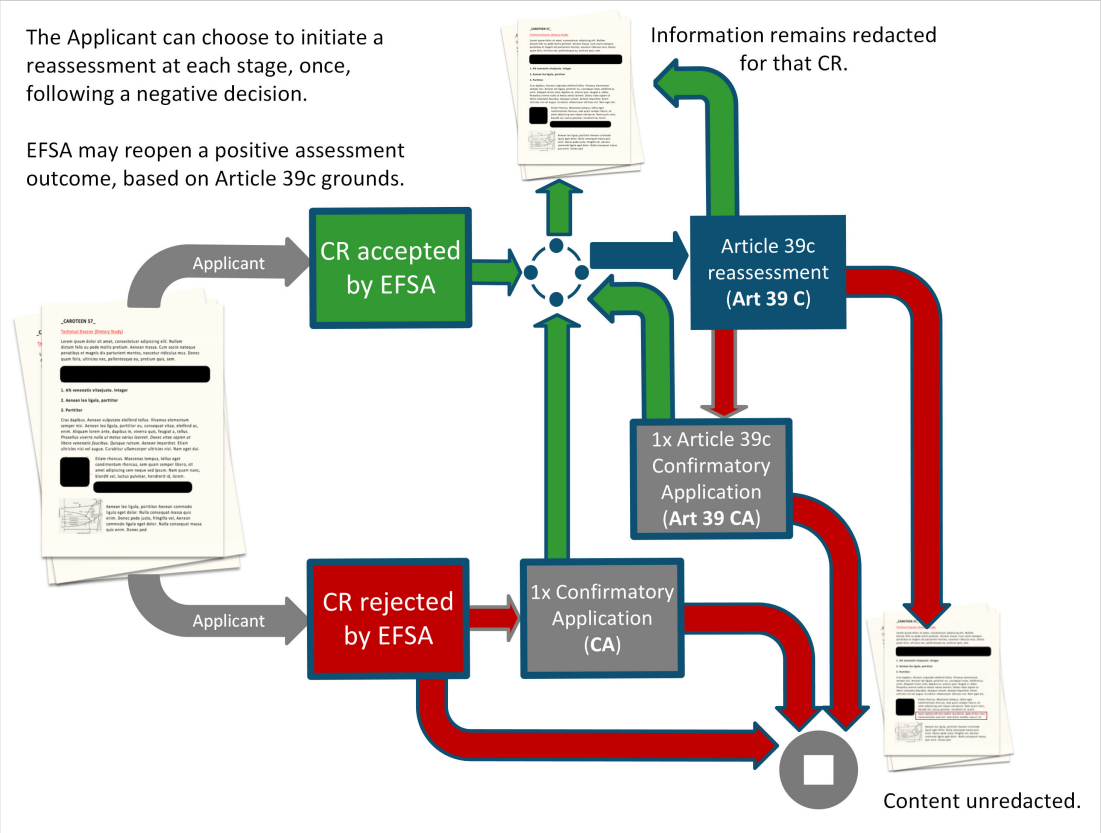
WARNING
If an Applicant disagrees with a single opinion to disclose the content subjected to a confidentiality request, they can also withdraw the dossier from the process. The top-of-page **'Withdraw'** button applies to the entire dossier, not just that particular document or request. Following a withdrawal, all non-confidential content submitted will be removed immediately from the dissemination portal (see Withdrawal [117]).

10.5 Decision reassessments

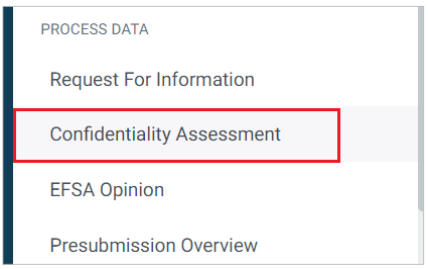
Two processes can trigger a reassessment of a final decision taken by EFSA on a confidentiality request (CR): a Confirmatory Application (CA), and a reassessment under **Article 39c Regulation (EU) 2019/1381**.

- The Applicant can only submit **one** CA on each CR decision level (Final Decision, Article 39c reassessment and decision on the confidentiality requests submitted in the framework of the additional data requests).

- EFSA can initiate **unlimited** reassessments under Article 39c.



The reassessment track is displayed on the ESFC **confidentiality assessment dashboard**. This is accessed by the Applicant via the left-pane tab, providing the same functionality as during the initial clarification and decision-making process for each CR.



IMPORTANT
Dossiers that do not enter Risk Assessment are not impacted by the Transparency Regulation provisions on transparency and confidentiality, in which case the following reassessment options **do not apply**. The confidentiality dashboard, displaying interactions and decisions, is **only viewable by the Applicant and the assessor**.

10.5.1 Article 39c re-evaluation

REGULATION (EU) 2019/1381 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003

Article 39c

Review of confidentiality

Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with point (b) of Article 39(4). Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply *mutatis mutandis*.

Pursuant to **Article 39c**, where EFSA identify information that forms part of the conclusions of its scientific outputs relating to foreseeable effects on animal health, human health or the environment, and confidentiality decisions awarding confidential status to that information were already issued, EFSA must review **these previous confidentiality decisions** (i.e. not limited to the accepted requests) to verify whether information that has been previously accepted as confidential must nevertheless be made public.

The re-evaluation may result in a sanitised file after the opinion is adopted.

A negative (i.e. rejected) CR outcome of an Article 39c re-evaluation **may also be challenged** by the Applicant through a Confirmatory Application. If the outcome is positive (i.e. the CR is upheld), the result may again be reassessed under Article 39c by EFSA. All actors are informed when a new sanitised file is created.

NOTE
See Article 14 in EFSA's Practical arrangements concerning transparency and confidentiality

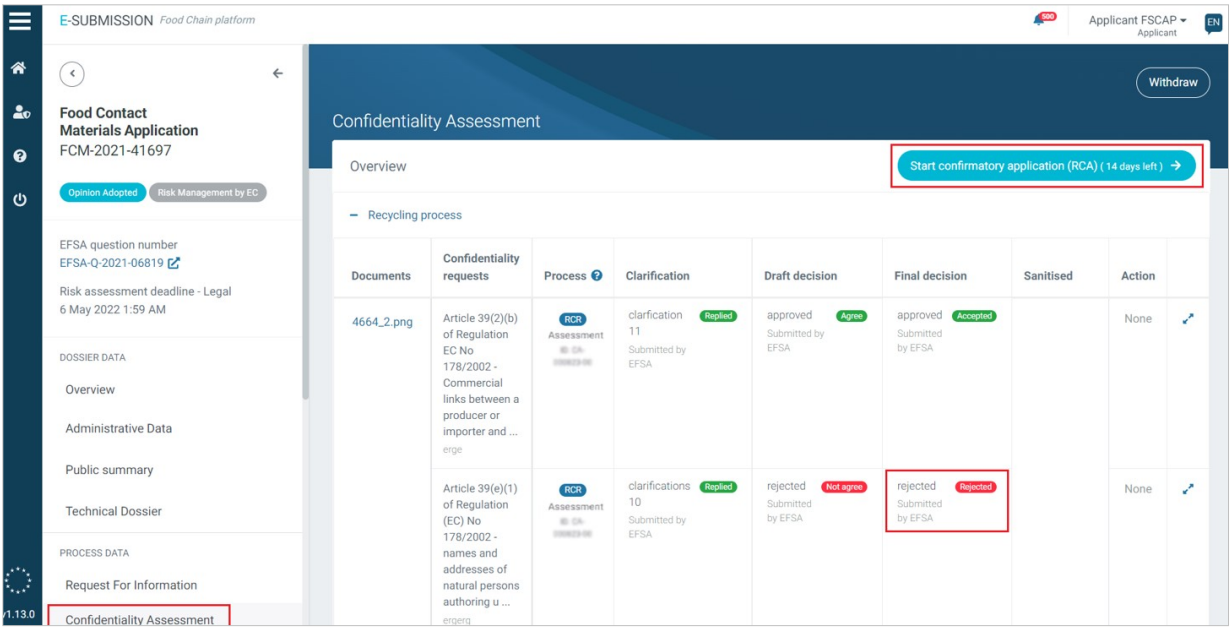
10.5.2 Confirmatory Application

An applicant may challenge a negative (i.e. rejected) adopted CR decision through a **Confirmatory Application** (CA) during a two-week window after notification of the reasoned decision, pursuant to **Article 39b (2)**. The Authority has three weeks to reach a reasoned decision on that confirmatory application. Decisions taken by the Authority, only with regard to decisions on confirmatory application, may be subject to an action before the **General Court of the EU** under the conditions laid down in Articles 263 and 278 of the Treaty on the Functioning of the European Union (TFEU) respectively.

NOTE
See Article 12 in EFSA's Practical arrangements concerning transparency and confidentiality.

The confidentiality assessment dashboard shows the progress of each CR. The CA has a suspensive effect for the effected CRs. File sanitisation will proceed after the 14 days, omitting those under review.

To initiate a CA, the Applicant clicks the '**Start confirmatory application**' button within the deadline. A countdown of days appears, after which this action is no longer available.



See Hands-on reassessments [145] for the CA process.

*The CA process allows for Assessor clarifications, but the draft decision is **not shared** with the Applicant. The final decision **cannot be challenged** with a follow-up CA.*

NOTE
During a Confirmatory Application, there is **no Draft Decision or commenting period** for the Applicant.

10.6 Hands-on reassessments

A **Confirmatory Application** (CA) is started by Applicant request, under **Article 39b (2)** of the Transparency Regulation, to reassess a 'negative' reasoned decision that has been adopted for a confidentiality treatment request (CR). The re-evaluation of a 'positive' final decision, **under Article 39c**, can be started on EFSA's initiative.

Both processes can produce a sanitised file as an outcome, provided by EFSA, i.e. the revised non-confidential version of the file to which the reassessed CR belongs. Article 39c re-runs the assessments of the **entire set of CRs**, including those CRs which have been rejected **and for which a CA may have already been started (or visa versa)**.

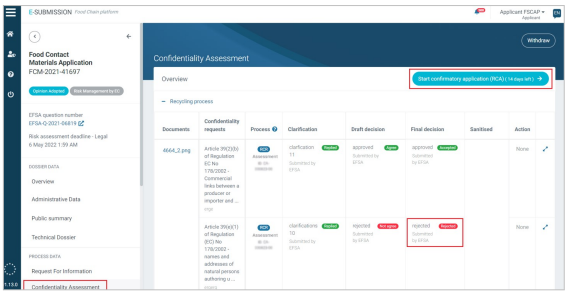
These parallel assessments would consider different criteria, using different assessors. The sanitised file resulting from the Article 39c process will prevail.

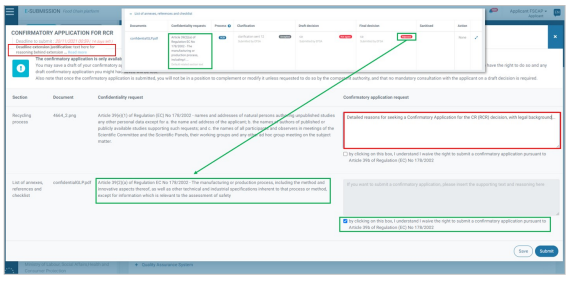
A file can be sanitised multiple times, resulting in multiple versions uploaded. The Applicant can track the assessment process and outcomes on the dashboard.

Example Confirmatory Application process

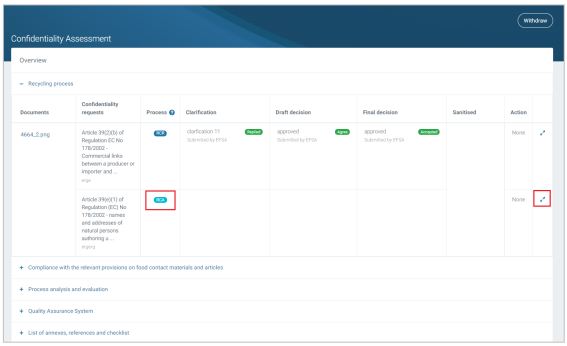
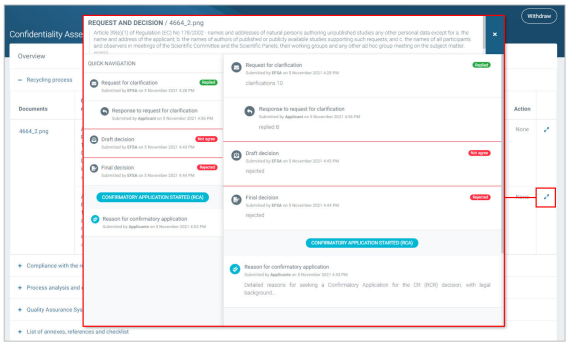
1. The confidentiality assessment dashboard shows the progress of each CR, and in this case this RCR (i.e. a CR added during Risk Assessment). Here one request has been rejected.
   - Click the left '**Confidentiality assessment**' tab to open the dashboard to view decisions, clarification status.
   - If you wish to launch a CA, click the '**Start confirmatory application**' button within the deadline period. When notifying the final decision, EFSA may extend the deadline to submit a confirmatory application. Note the remaining day tally shows, after which time the option is no longer available. 

   - The Applicant can prepare one or more CAs, but they can only be submitted together.
   - The CA window (right) only displays **Rejected requests** for confidentiality. Provide detailed reasoning for initiating each CA reassessment. Note the waiver tick-box below each rejection, which states that you **do not** wish to pursue the CA for that rejection.
   - Click '**Submit**' to inform EFSA. This has a suspensive effect for that CR/RCR. File sanitisation will proceed after the 14 days, omitting this CR/RCR under review.

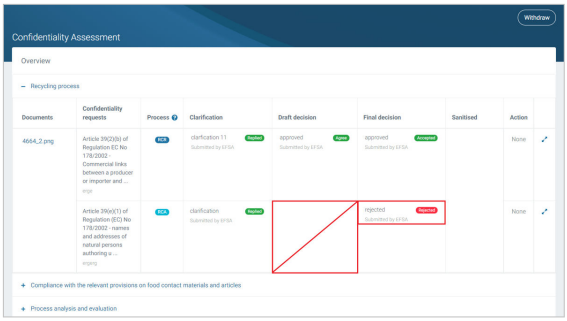




2. The CA is initiated. The '**RCR**' badge changes to '**RCA**'.
   - Click the '⤢' symbol to see an overview of the regular CR/RCR steps and decisions, and the initiated CA.

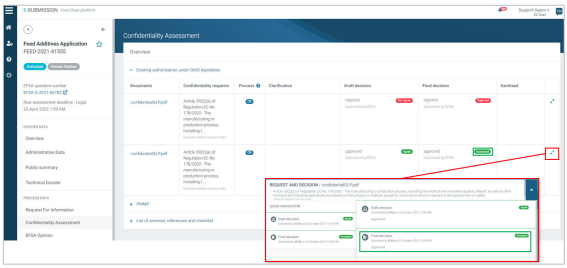
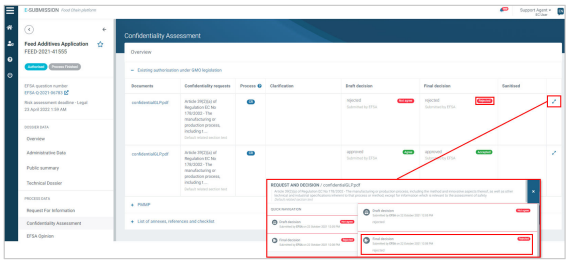
3. CA process follows the same pattern as CR. However, there is **no Draft Decision**. Clarifications may be requested by EFSA and answered as before, within at least three working days (and until the Final Decision is sent). In this case, the 'Rejected' decision remains.



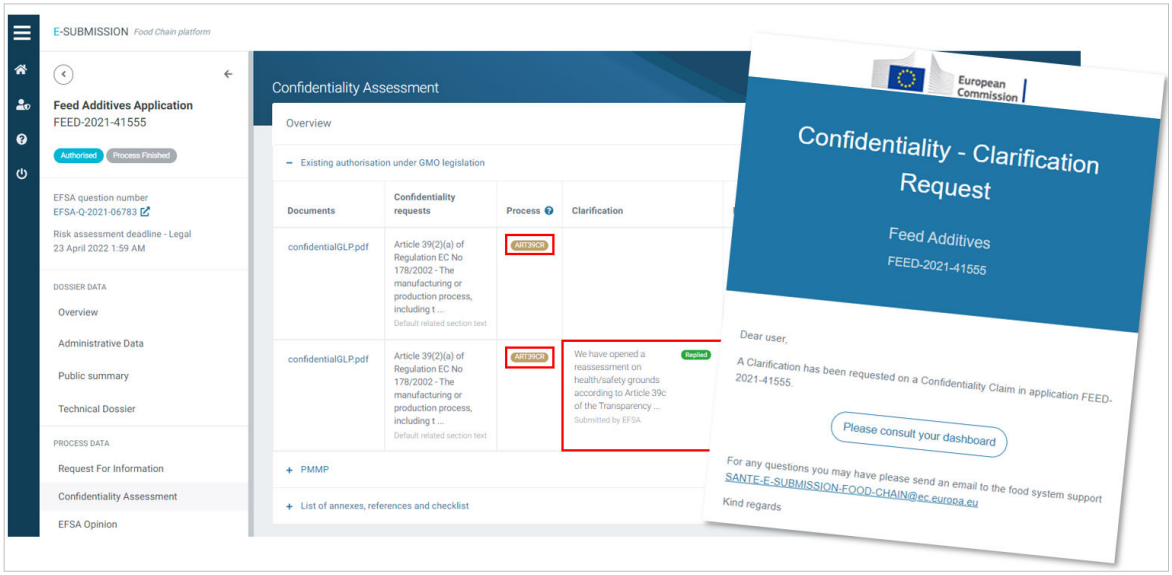
Article 39c re-evaluation

In this example, a positive (accepted) CR has been re-evaluated under **Article 39c**, and a Draft Decision is shared with the Applicant. The Applicant is not informed of the re-evaluation until a Draft Decision is taken, or a clarification request is sent. The Authority has three weeks in which to come to a final decision. Note that the Applicant **may open** a CA on a 'rejected' Article 39c decision within a two-week window.

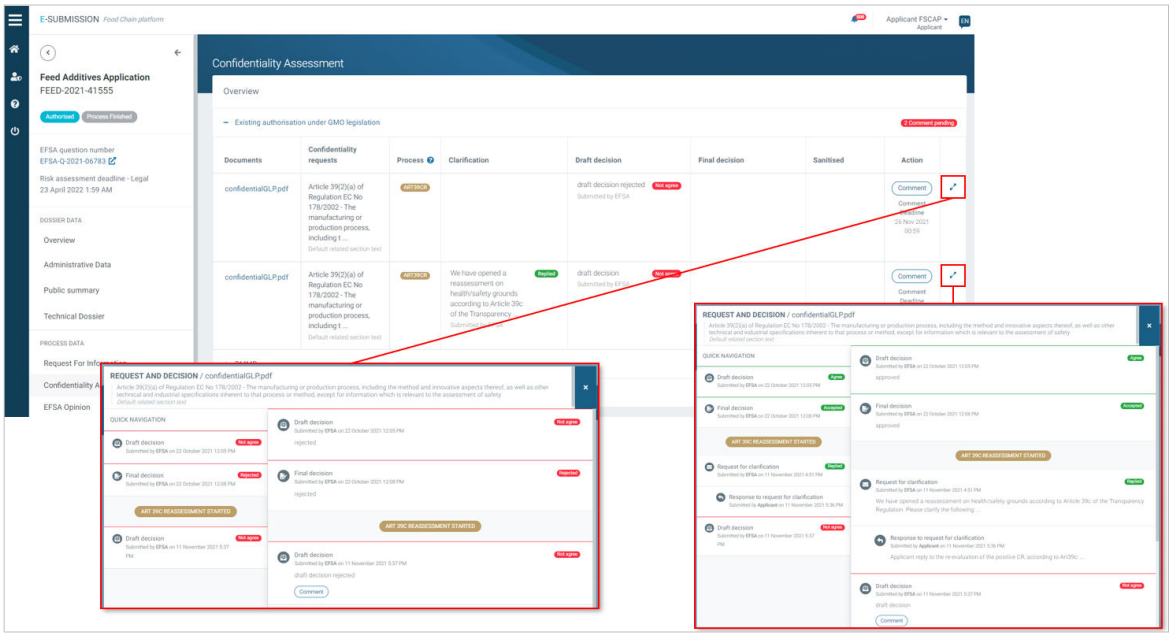
1. There are two CRs in the document. 1 accepted, 1 rejected.
   - Click the '⤢' symbol to see the CR status and stages.

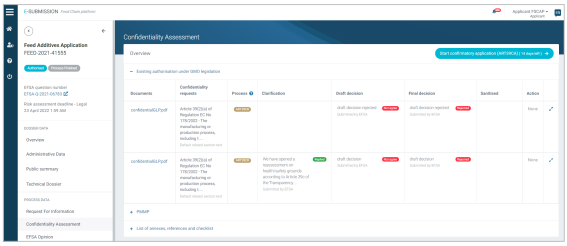
2. The positive CR is reopened under Article 39c. A clarification is sent and the Applicant is notified by email, who responds in the standard way. The label changes to ' ART39CR ' for both CRs.
   - The clarification status appears in the dashboard Clarification column.

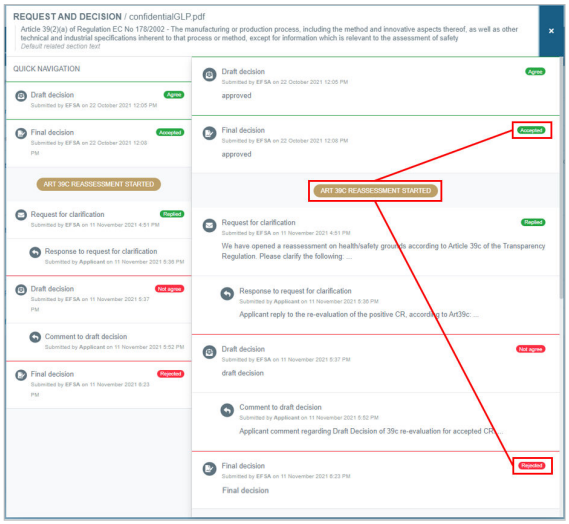


3. The Draft Decision is made for each ART39CR. The ' ⤢ ' shows the clarification steps, and also present the comment button. Note that **you may need to scroll down**.



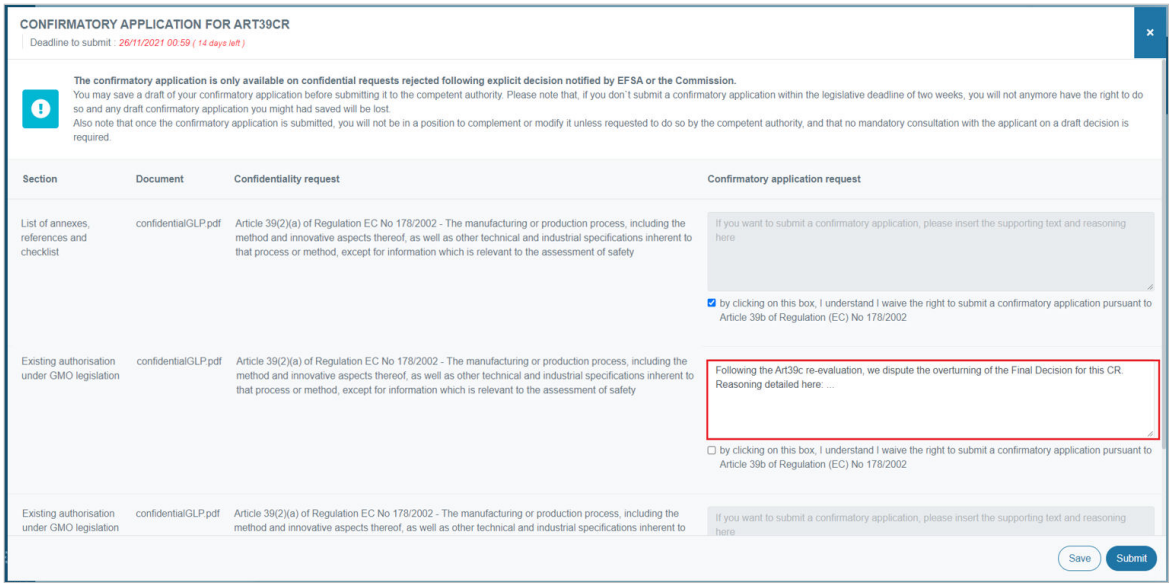
4. The Applicant is notified of the Final Decision – in this case, the previously accepted CR has been rejected. The file has not yet been sanitised because the Applicant may initiate a CA.



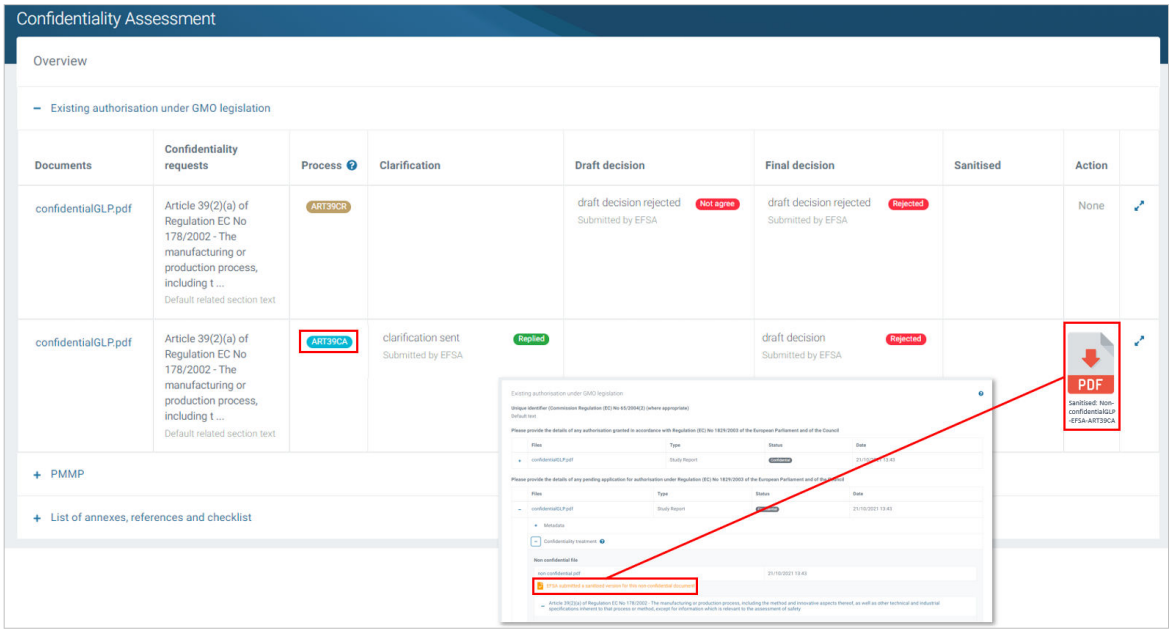


5. As above, if you wish to launch a CA, the Applicant clicks the '**Start confirmatory application**' button within the deadline shown 

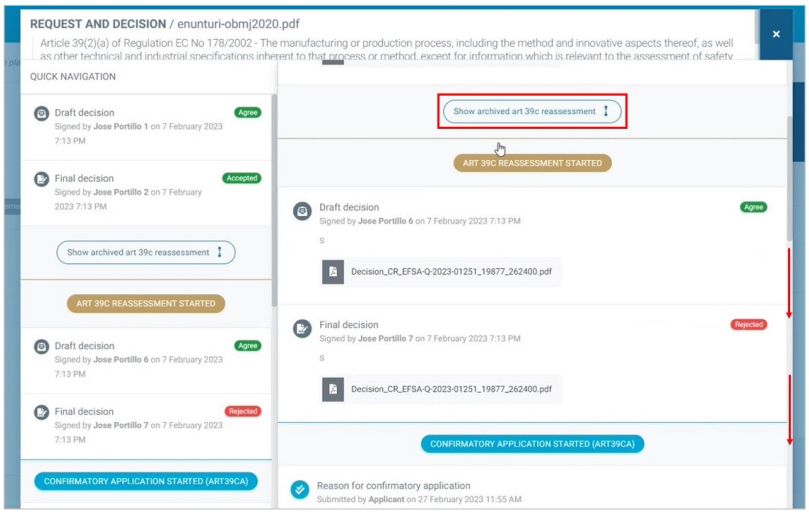
. The CRs in question are not impacted by document sanitisation until the CA process is concluded. Then the decisions are incorporated into a new sanitised file, if necessary.
   - Provide the reason for the CA.
   - Click to confirm you do not wish to initiate a CA on the other negative final decisions displayed.
   - Click '**Save**' to return later, or click '**Submit**' to proceed immediately. The ART39CR label is replaced with a ART39CA.



6. The ART39CA process continues to a final decision (with no draft decision). It is identical to the CA process.
   In this case the decision remains negative, and the non-confidential file version is sanitised and uploaded to the dashboard, the ESFC dossier section and to OpenEFSA.



7. In the case of a **positive ART39CA outcome** (i.e. the confirmatory application overturns the ART39CR reassessment outcome), EFSA may re-open that assessment by initiating another ART39CR.
   The '⤢' button provides the process in detail, with an Archive accordion containing the full assessment history.



10.7 Dashboard badges

Process badges in the Confidentiality Assessment dashboard

CR – **Confidentiality Requests**: these are reviewed during Suitability Check phase. If found to be eligible, they are primed to appear in the Confidentiality Assessment

platform at dossier validation. This enables the confidentiality assessment process to start immediately. If ineligible, the Applicant may be contacted by RFI.

RCR – **Risk Assessment Confidentiality Requests**: confidentiality treatment requests attached to information within new documents provided during Risk Assessment (i.e. responses to EFSA Additional Data Requests). The RCRs become visible in EFSA's assessment platform **after Risk Assessment has been completed** (i.e. output Adopted/ approved), and only then will assessment on the RCR set begin.

CA – **Confirmatory Application for CR**: triggered by the Applicant within two weeks of a final negative decision, with no Draft Decision step.

RCA – **Confirmatory Application for RCR**: triggered by the Applicant within two weeks of a final adopted reasoned decision, with no Draft Decision step.

ART39CR – **Re-evaluation under Article 39c**: initiated after Risk Assessment, opening all CR decisions within the same document to reassessment.

ART39CA – **Confirmatory Application on Art39CR**: standard CA process for a negative decision, including a draft decision.

11 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 entered into application on 27 March 2021.

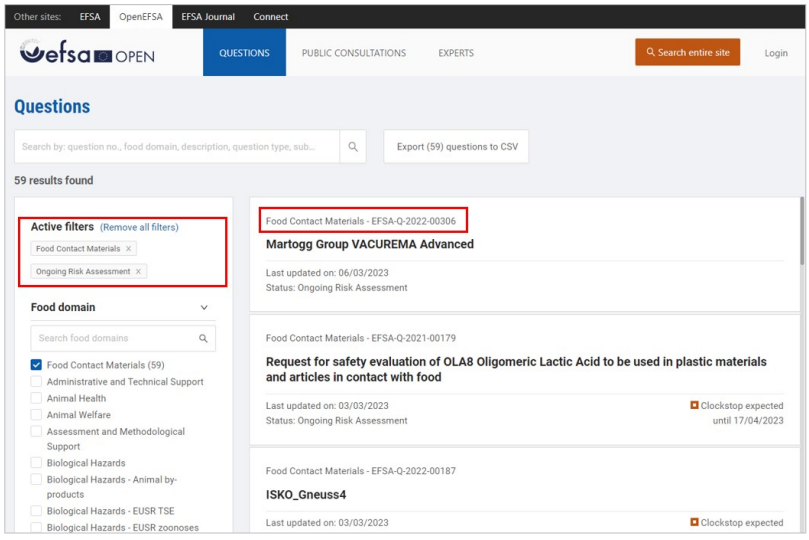
Upon validity of an application or notification, the non-confidential version of the dossier as submitted by the applicant or notifier is disseminated on the OpenEFSA portal. After confidentiality assessment, the revised ('sanitised') versions of these files are disseminated as well. Data accepted as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

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

11.1 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

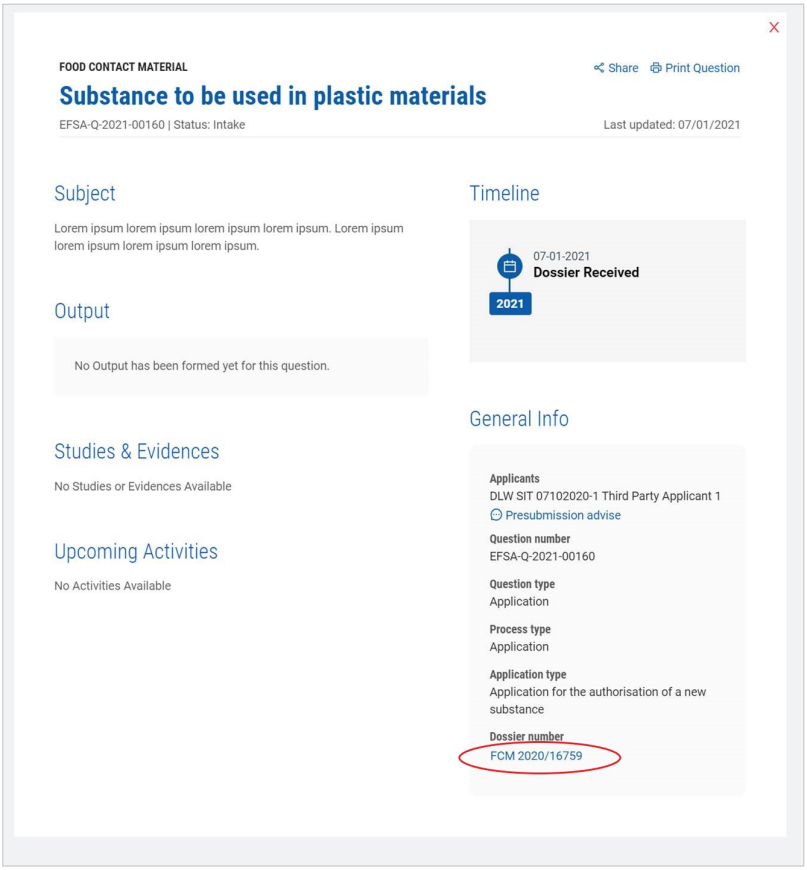


The OpenEFSA dissemination portal lists ongoing and previous submissions. Click on the Question Number to access the overview page.

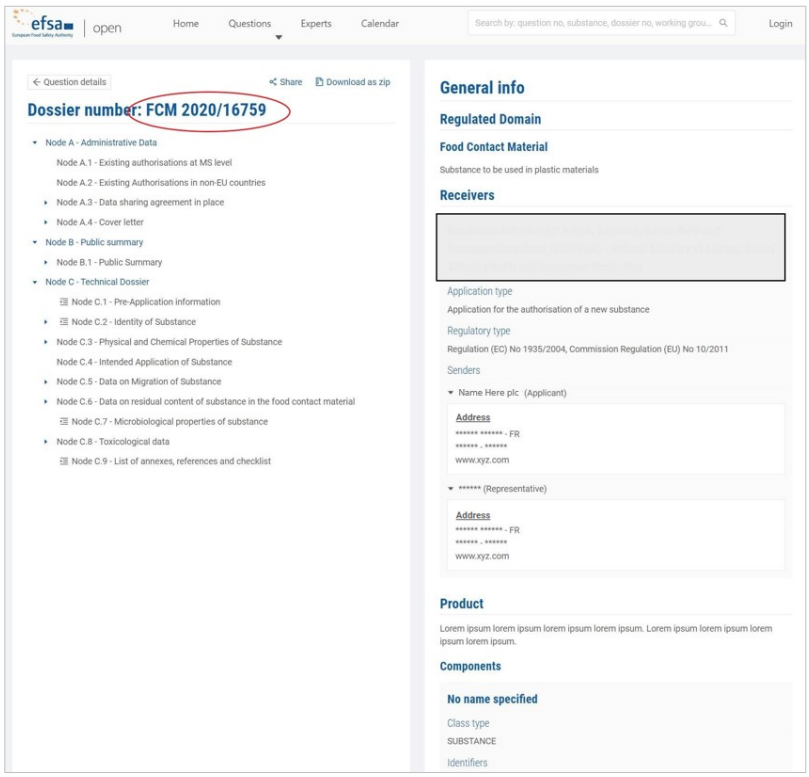
The EFSA Question overview page contains the follow features:

- 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 [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 dossier, 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.

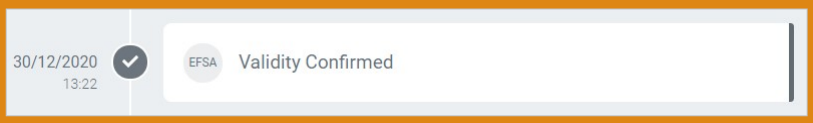


Click the dossier number to display the dossier's structure, data, and access non-confidential supporting information.



IMPORTANT

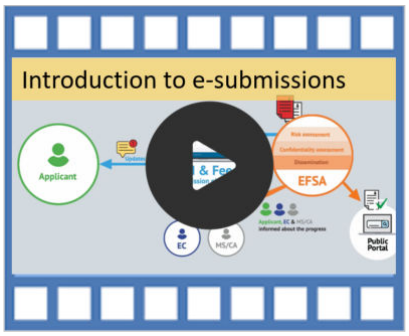
The dossier is publicly disseminated only when it is considered 'valid'. You will be informed through email notification, and this significant point in the process will display in the dossier timeline.



12 Video tutorials and support

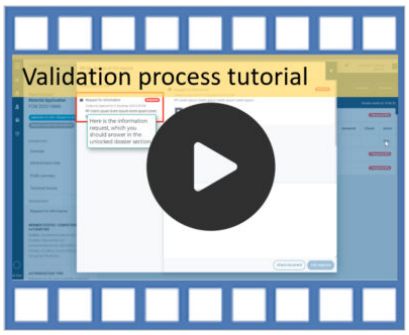
Are you a new user and looking for a better understanding of how the ESFC platform works? Watch our hands-on tutorial videos by clicking the link above each icon or visit EFSA's 'Applicant Toolkit' webpage for more details on their support and activities. This EC support page outlines the Implementation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

Introduction to the process

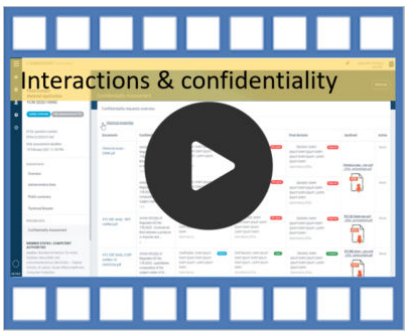


Preparing your dossier

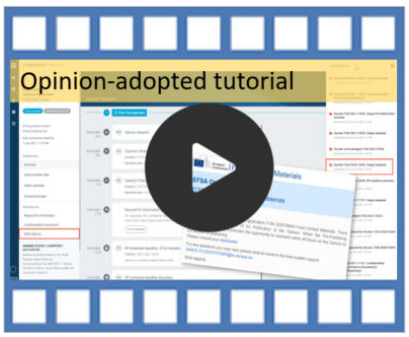
The validation process



Interactions and confidentiality



Opinion adopted and publication



Managing confidentiality requests

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 a laboratory, 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 publish 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.

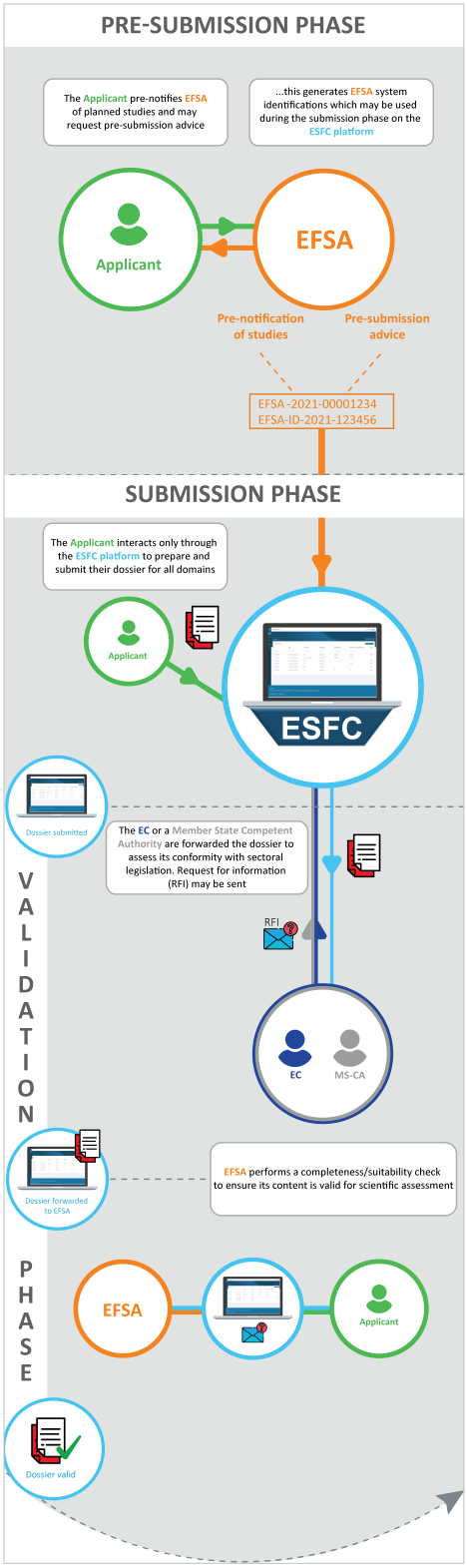
Study report

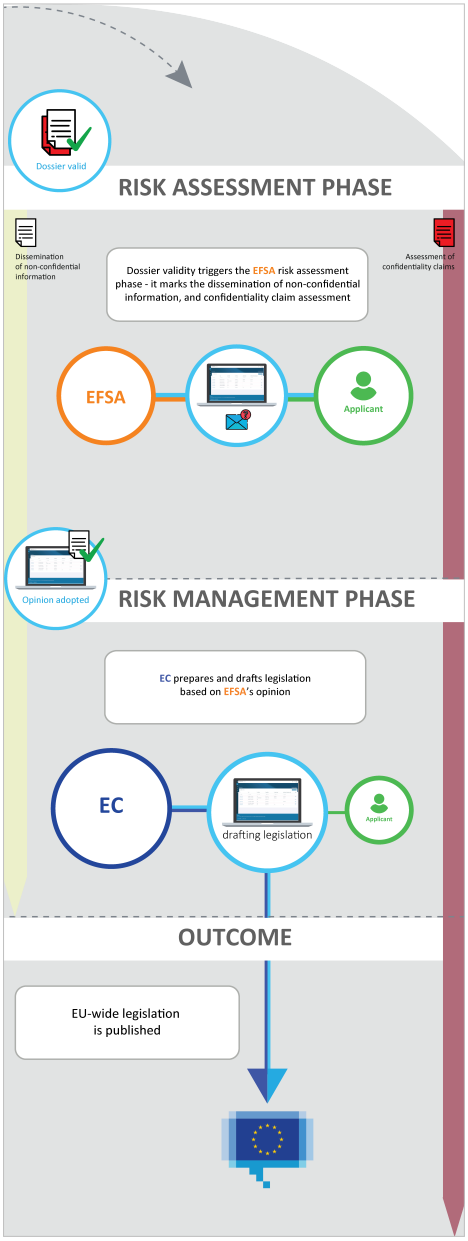
This refers to the unpublished study reports used to support the application. This document type will trigger some additional data requirements (e.g. notification IDs, Study type, Guideline, Authors etc.) and will support the applicant in complying with the Practical Arrangements on the Notification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