



European
Commission

e-submission system for Novel Foods

Updated User Guide

December 2019



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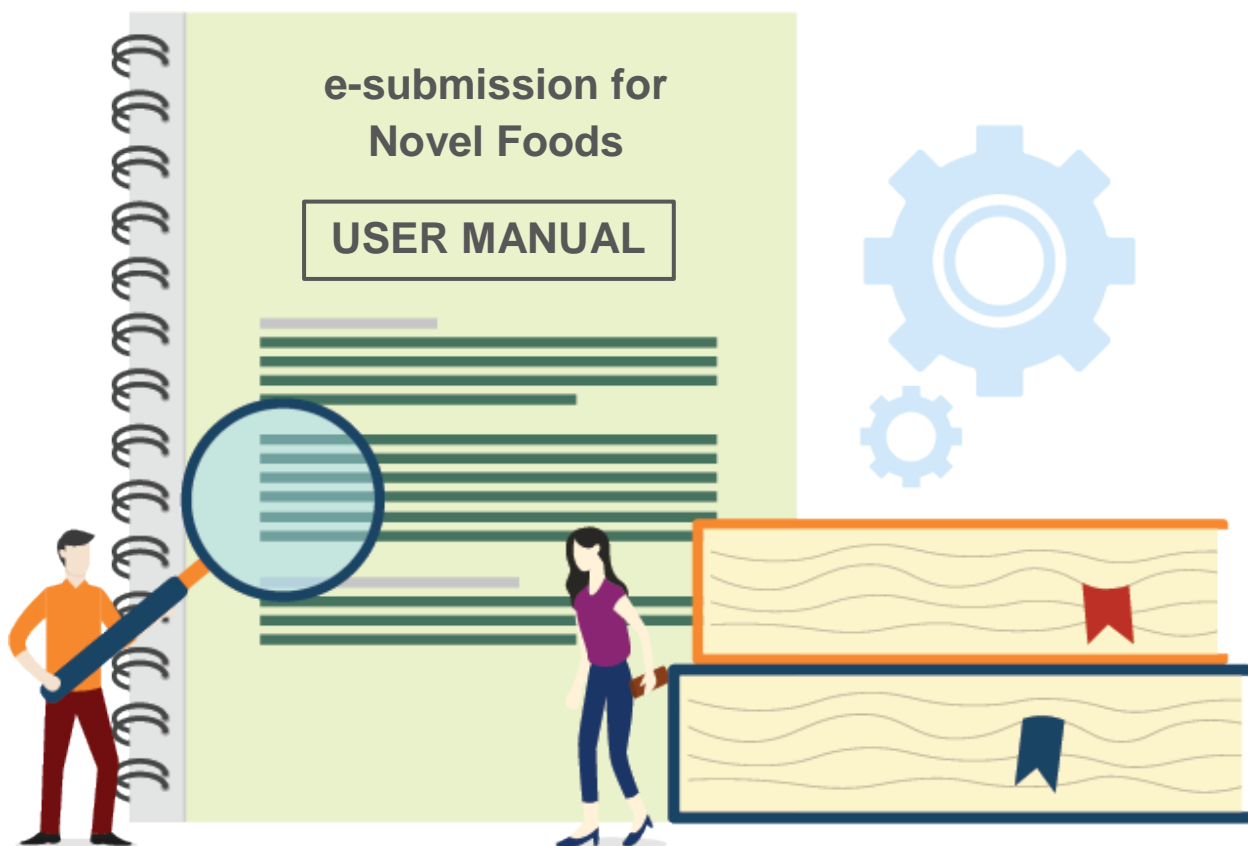
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Welcome to the e-submission system for Novel Foods!

The objective of the **e-submission system** is to automate the authorisation process through an online submission system in the context of the current legislation for novel foods. It will be shortly extended to other relevant Food Sectors such as food additives, food enzymes and food flavourings,.

The system allows you to submit and follow-up on your applications through an online web interface from the start to the end of the authorisation process.

Tip: The system notifies you of any change in the status of the application. In order to access the system you need an [EU Login account](#).

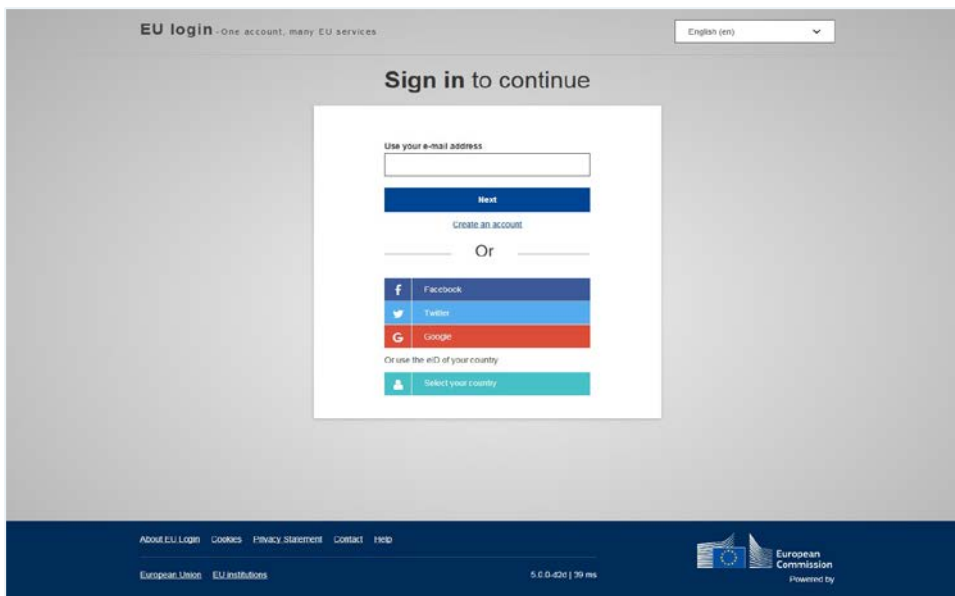


Create an EU Login account

Note: To create an account in EU Login, you need a valid e-mail address. After following the steps below, you will receive an Email to confirm your access and ensuring that you will be able to upload documents in the application. Check your spam folder settings in order to make sure that you receive the confirmation email.

Please follow these steps:

- ➔ Go to the EU Login by entering the following address in the browser:
<https://webgate.ec.europa.eu/cas/login>

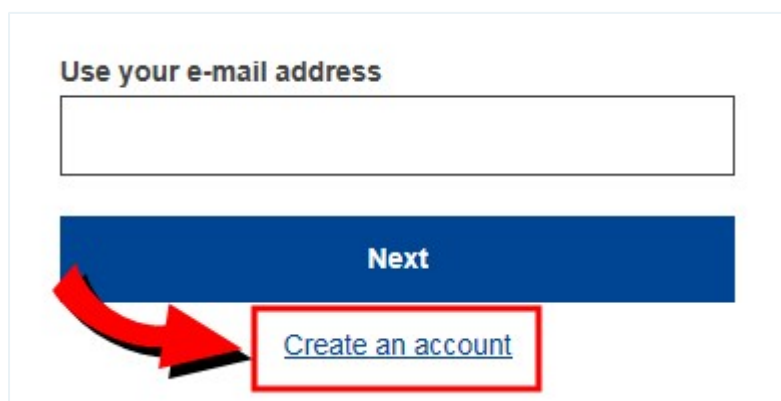


The screenshot shows the EU Login sign-in interface. At the top left, it says "EU login - One account, many EU services" and at the top right, there is a language dropdown menu set to "English (en)". The main heading is "Sign in to continue". Below this, there is a form with the following elements:

- A text input field labeled "Use your e-mail address".
- A blue "Next" button.
- A link "Create an account".
- A separator "Or" with horizontal lines on either side.
- Three social media login buttons: Facebook (blue), Twitter (light blue), and Google (red).
- A section "Or use the eID of your country" with a "Select your country" button.

The footer contains navigation links: "About EU Login", "Cookies", "Privacy Statement", "Contact", and "Help". It also includes the European Union flag, the text "European Commission", and "Powered by".

- ➔ Click on the "**Create an account**" link so the system displays a sign up form:



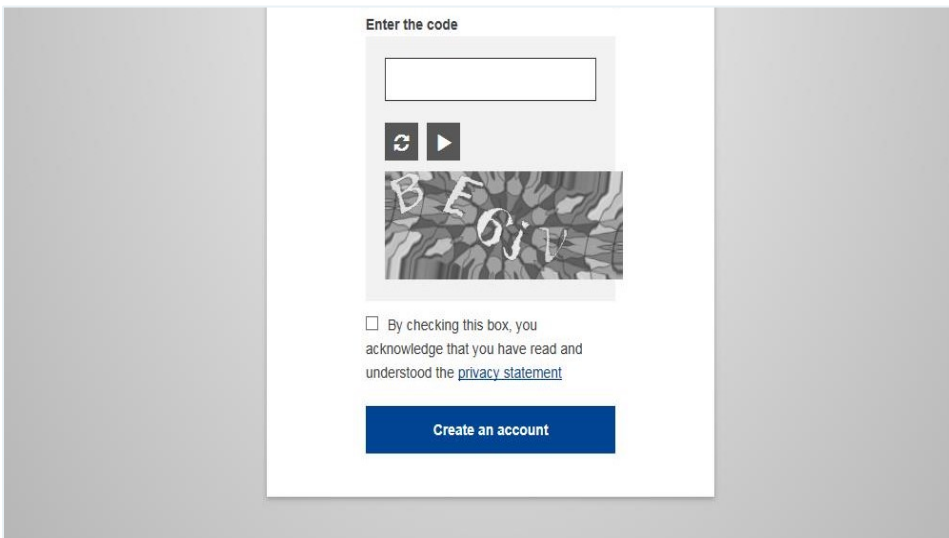
The image shows a sign-up form with the following elements:

- A text input field with the label "Use your e-mail address" above it.
- A blue button labeled "Next" below the input field.
- A red arrow pointing from the "Next" button to a red-bordered box containing the text "[Create an account](#)".



Complete the form:


- ➔ **First name** – Your first name cannot be empty and can contain letters in any alphabet;
- ➔ **Last name** – Your last name cannot be empty and can contain letters in any alphabet;
- ➔ **E-mail** – An e-mail address that you have access to;
- ➔ **Confirm e-mail** – Type your e-mail address again to make sure it is correct; • **E-mail language** – The language used when EU Login sends you e-mails regardless of the language used in the interface. It guarantees that you are able to understand these e-mails even if they were triggered mistakenly. EU Login only sends you e-mails for validating your identity or for notifying you about security events affecting your account;
- ➔ **Enter the code** – By entering the letter and numbers in the picture, you demonstrate that you are a human being who is legitimately creating an account. If the code is too difficult to read, click on the button with two arrows to generate a new one;
- ➔ **Check the privacy statement** by clicking on the link and tick the box to accept the conditions

Do not forget to tick the box regarding the fact that you have read privacy statement!



Enter the code

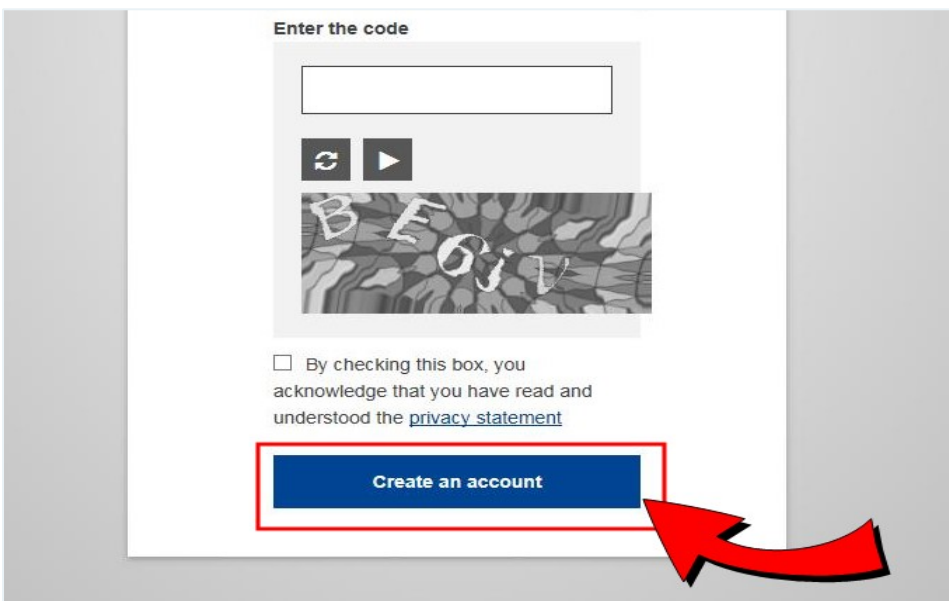
 





By checking this box, you acknowledge that you have read and understood the [privacy statement](#)


Create an account

➔ After you have provided all the requested information, click on '**Create an account**':



Enter the code



By checking this box, you acknowledge that you have read and understood the [privacy statement](#)

Create an account

The system displays a confirmation message explaining that an email was sent to you.

Create an account

Thank you for registering, you will receive an e-mail allowing you to complete the registration process.

- ➔ In order to confirm your account and create your password, simply click on the link in the email body or copy and paste it into an internet browser:

Dear ...,

You have been registered in EU Login.

Your email address is [...@...](#).

To create your password, follow the link below:

[this link](#)



You have a maximum of 5 min, starting from the time that this message was sent, to create your password, but you are encouraged to do so immediately if possible. After this time, you can make another request by following the same link: you will then need to re-enter your username and confirm your request.

If the above link does not work, you can copy the following address (make sure the complete address is copied!) and paste it into your browser's address bar:

<https://ecas.ec.europa.eu/cas/init/initialisePasswordLogin.cgi?xxx...>



Instead of replying to this message, if you have a problem, please follow the help or contact information on the site where you were trying to register.

Note that it may take up to 5 minutes after reception of this mail before the above-mentioned site will recognize your registration.

Sent to you by EU Login

If you cannot find the e-mail, check your spam or junk folder.

- ➔ To create your new EU Login password, enter your new password and click on **'Submit'**:

EU Login
One account, many EU services

English (en)

New password **Login**

New password

Please choose your new password.

E-mail

New password

Confirm new password

Submit

Passwords cannot include your username and must contain at least 10 characters chosen from at least three of the following four character groups (white space permitted):

- Upper Case: A to Z
- Lower Case: a to z
- Numeric: 0 to 9
- Special Characters: !"#%&'()*+,-./:;<=>?@[\\^_`{|}~

Examples: TEeiNoLwk} xLxk65{TPq YNKtIK14nf

[\[Generate other sample passwords\]](#)

It must contain at least 10 characters and a combination of:

- ➔ upper case letters
- ➔ lower case letters
- ➔ numbers
- ➔ special characters
- ➔ Select a password as long and as complex as you can in order to make your account more secure but keep in mind that you will have to remember it.

The system displays a message indicating that your EU LOGIN password has been changed.

- ➔ Click on '**Submit**' in order to proceed to the service you want to use:

Submit

Passwords cannot include your username and must be at least 10 characters chosen from at least three of the following four character groups (white space permitted):

- Upper Case: A to Z
- Lower Case: a to z
- Numeric: 0 to 9
- Special Characters: !"#\$%&'()*+,-./:;<=>?@[\\]^_`{|}~

Examples: TEeINoLwk} xLxk65{TPq YNKtIKt4nf

Note: In order to know more about EU Login, go to the [EU Login help page](#)

Log into the e-submission system

Please note: If your access rights have not yet been fully granted, you will not be able to upload documents and the following error message will be displayed on the screen:



This is because you require **specific permissions** in the e-submission system in order to upload documents (e.g. the cover letter and for the scientific fields files).

A notification is automatically sent to the support mailbox to set up your access rights **the first time you connect to the system**.

This task is currently done manually by the FSCAP support team. The support team work from:

Monday to Friday during working hours (from 08:00 to 18:00 CET).

If a new user accesses the system for the first time **during the weekend**, they will have to wait until **Monday at 08:00 CET** for the setup of their access rights.

If a new user accesses the system for the first time **outside of working hours**, they will have to wait until **the following work day** for the setup of their access rights.

- ➔ Once you have logged into the e-submission you must click on “Confirm you have read the Privacy Notice to continue”:

Specific Privacy Statement

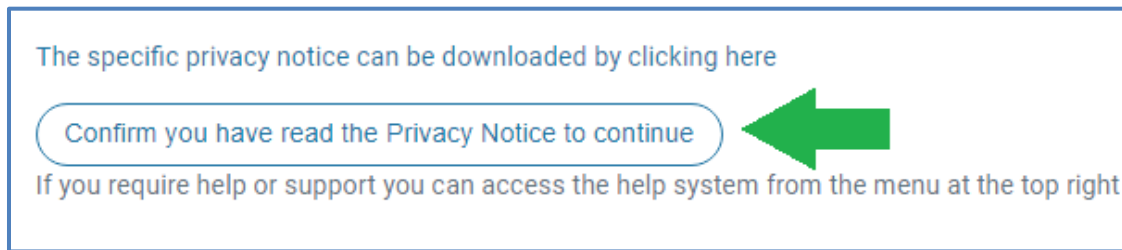
Welcome to the food system e-submission platform.

Before using the application you must confirm that you have read the specific privacy notice for this application.

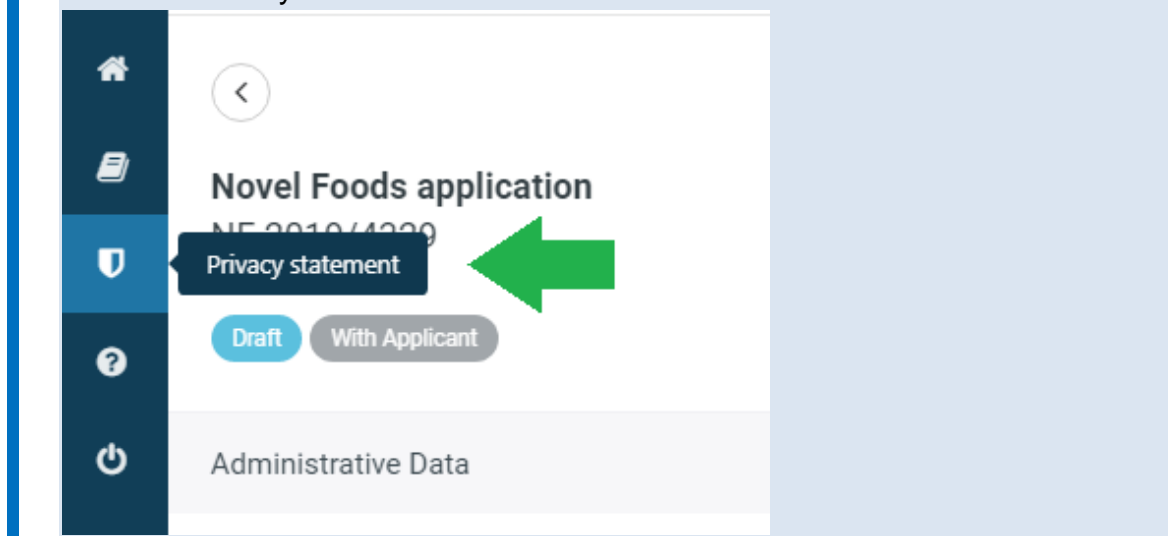
The specific privacy notice can be downloaded by [clicking here](#)

If you require help or support you can access the help system from the menu at the top right of the screen. You can also contact the support team by using the link in the top right of the screen

- ➔ Once you have read the notice, continue by clicking on the “Confirm that you have read the privacy notice in order to continue” button inside the dialogue box:

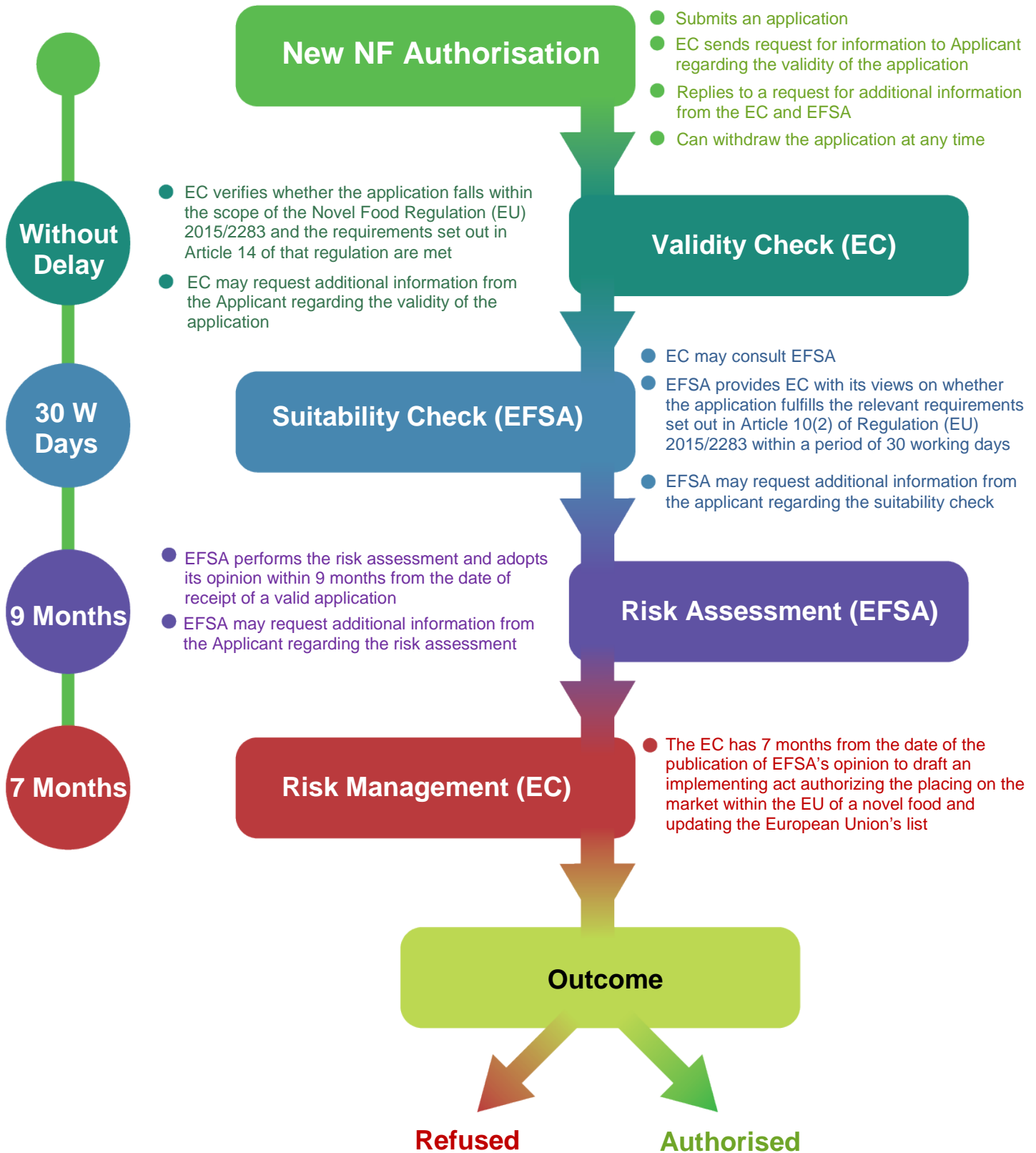


Note: You can access the Privacy Statement at any time by simply clicking on the “Privacy Statement” icon on the left-hand side of the dashboard:



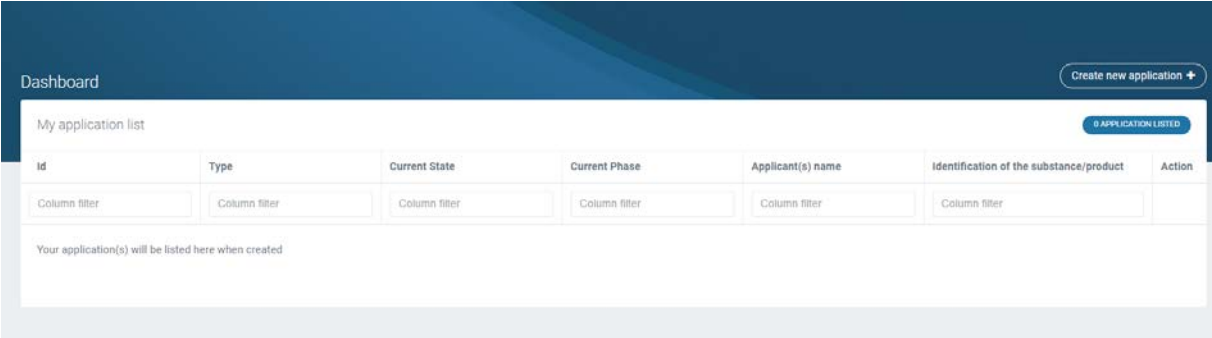
You have now successfully logged into the e-submissions system.

Novel Food Authorisation Workflow



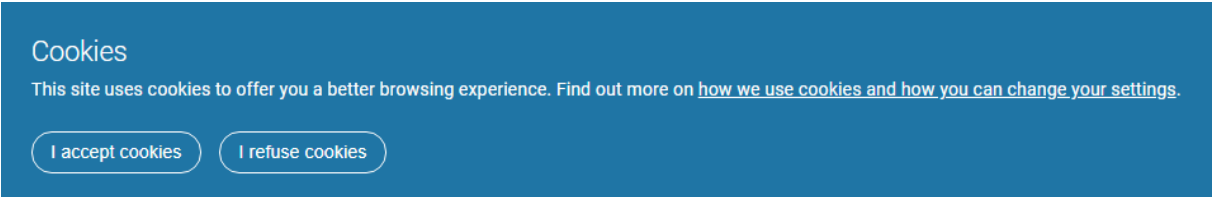
How to create and submit a Novel Food Authorisation

Once you have signed in to the food e-submission system, you will be taken straight to the dashboard:



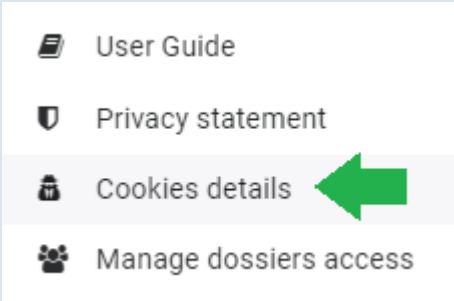
Cookies

- The first step is to accept Cookies on the website – do this by clicking on “I accept cookies” inside the Cookies pop-up window at the bottom of your screen:

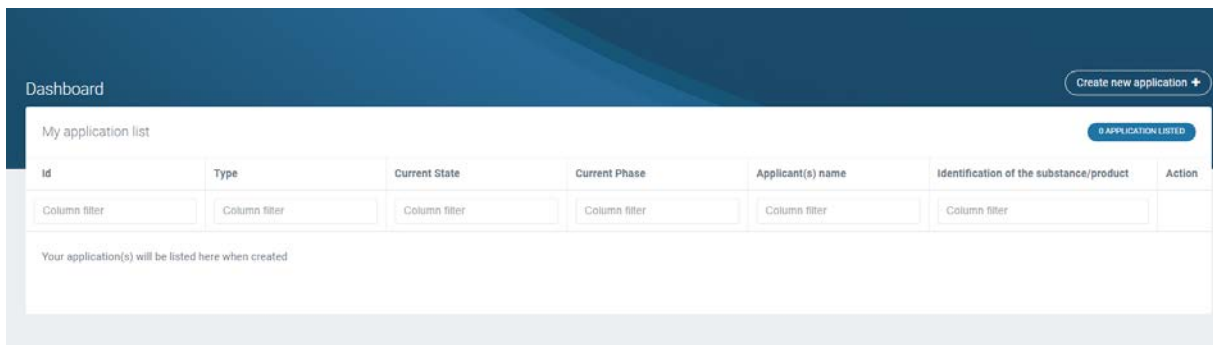


Note: For more information regarding how we use cookies and how you can change your settings, simply follow this link: “How we use cookies”.

Note: You can still access the cookies content description at any time, by simply clicking on “Cookies details” in the drop down menu under your name on the top-right hand corner of the screen located on the dashboard:



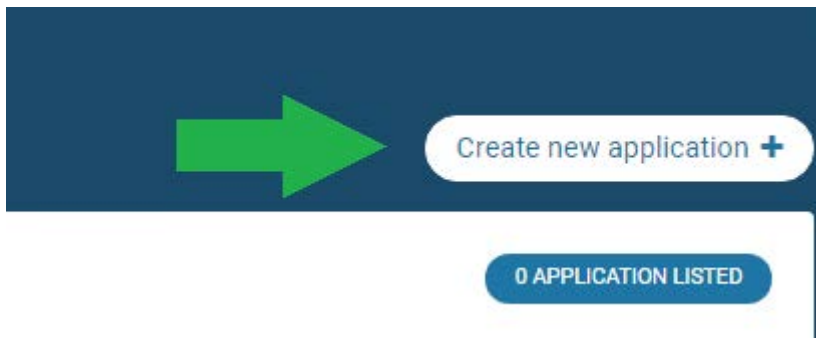
You will then be taken to the dashboard which displays your application list:



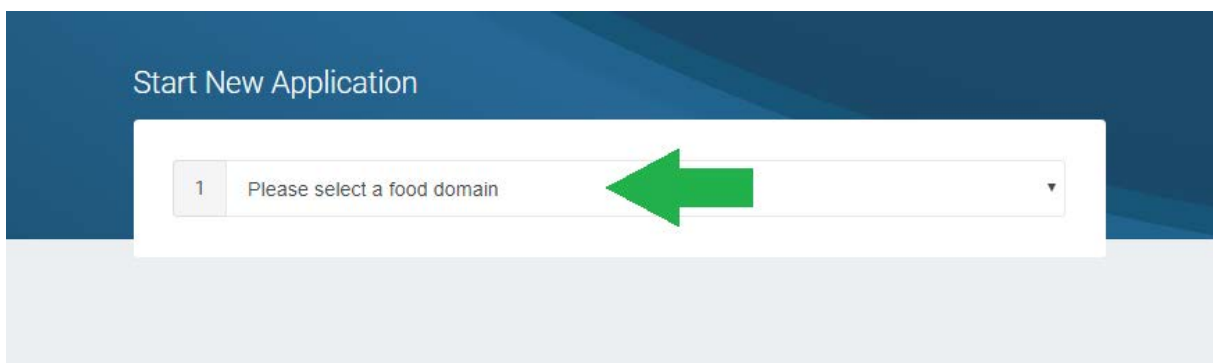
Creating a New Application

Detailed steps and more information

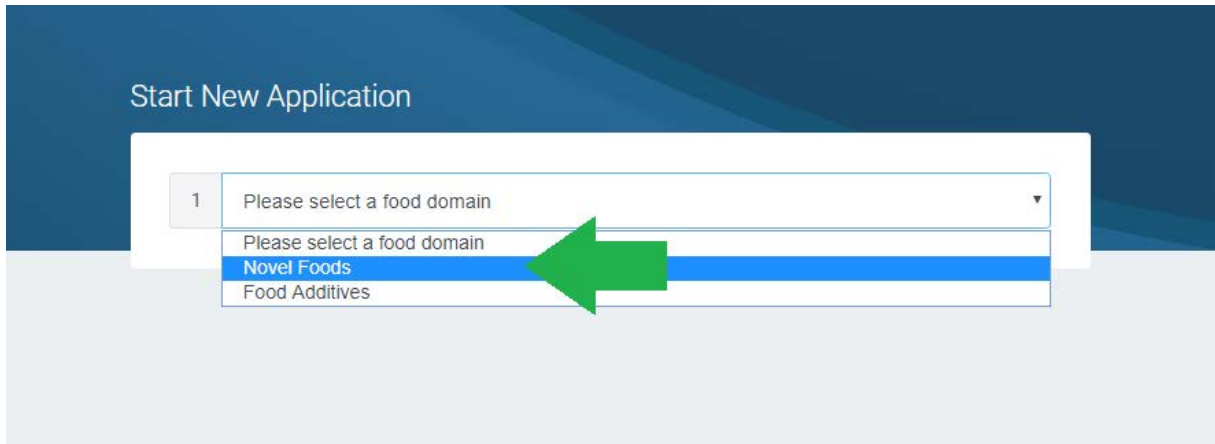
- ➔ On the dashboard, click on **Create a new application** (located on the top right hand side of the dashboard):



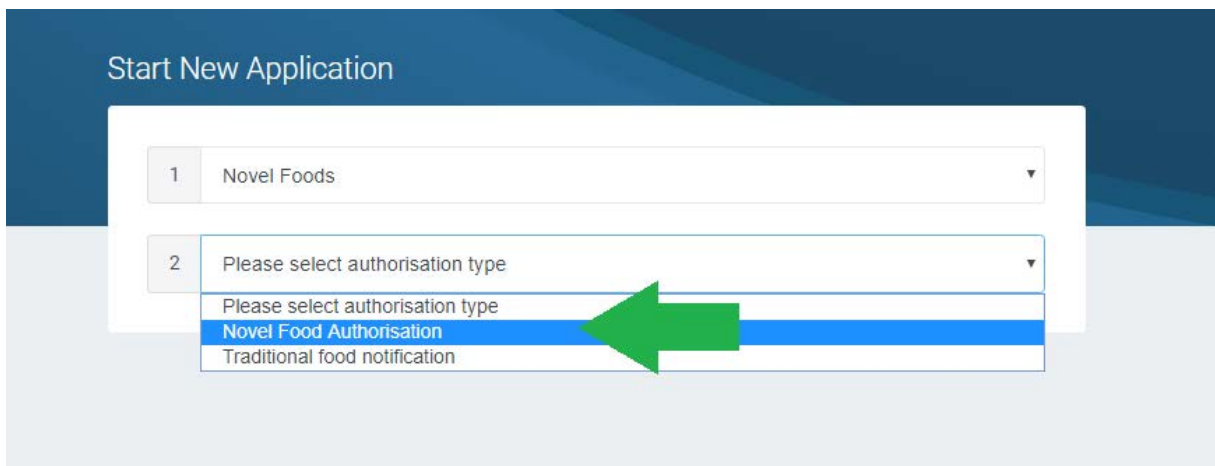
- ➔ You will now be prompted to select a food-domain from the drop-down list:



➔ Select “Novel Foods”:

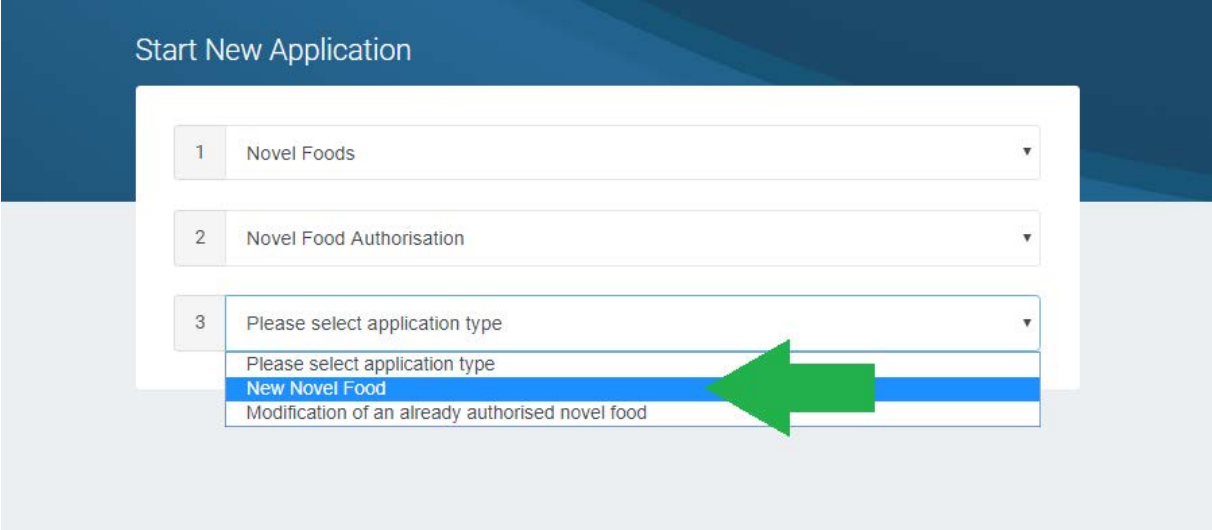


➔ You will then be prompted to select an authorisation type. Select “Novel Food Authorisation”:



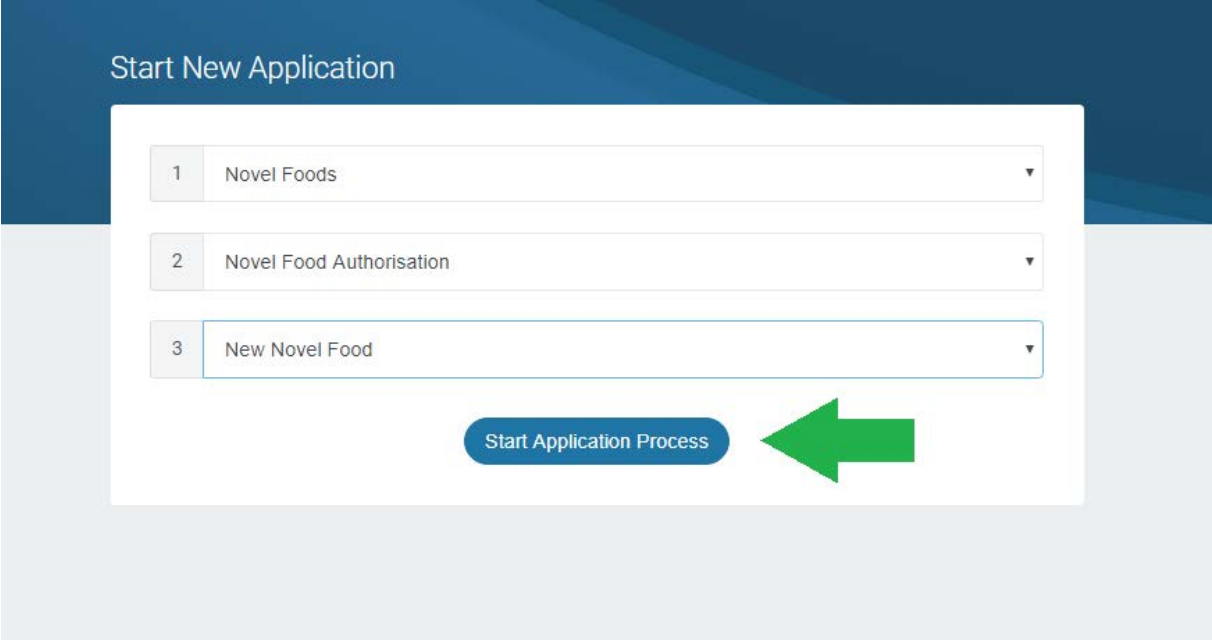
You will now be prompted to select the application type. Here you can select between starting a new Novel Food application or modifying a pre-existing application which has already been authorised.

➔ Select “New Novel Food”:



Once these three fields have been selected, a button entitled “Start Application Process” will appear.

➔ Click on “Start Application Process”:



After a few seconds of loading, you will be taken to the application screen which includes the web form for the novel food that needs to be completed.

- ➔ On the left-hand side of the screen you will notice a side menu, which includes the ID number of the Novel Foods application:



Novel Foods application

NF 2019/4329



Draft

With Applicant

Note: You will notice that the system indicates that the application is in draft mode (in blue), as it has not yet been submitted for review.

- ➔ Underneath, you will notice that you are currently viewing the “Administrative Data” tab, which is the first section of the application that needs to be completed

Novel Foods application

NF 2019/4329

Draft

With Applicant

Administrative Data



Summary

Scientific Data

Cover Letter

Dossier History

Administrative Data tab

- ➔ Start by filling in the first “identity” section of the Administrative Data tab, including the name of the novel food and an identity description:

Administrative Data Dossier saved at 10:45:43

1. Identity of the novel food to be authorised

Name

B I

Nova cibum

Description *

Enter identity description here

Novel Food category *

Please select Food Category type

Note: The **Autosave** function ensures that the encoded content is saved automatically. Therefore, there is no **Save** button in the system. You will notice it on the top-right hand side of the web form.

Be aware that while the autosave information message is displayed, any insertions/modifications are not taken into account. Please make sure that all information is correctly updated.

- ➔ Next, select the food category type (Article 3(2)(a) of [Regulation \(EU\) 2015/2283](#)) from the drop-down menu:

Novel Food category *

Please select Food Category type

food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where: – a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or – they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;

food consisting of engineered nanomaterials as defined in point (f) of this paragraph;

food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: – traditional propagating practices which have been used for food production within the Union before 15 May 1997; or – non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

food consisting of, isolated from or produced from material of mineral origin;

food consisting of, isolated from or produced from microorganisms, fungi or algae

food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances

- ➔ In the section underneath, fill in the applicant name, email address and other details:

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name	Joe Bloggs		
Email	joe@bloggs.com	Address *	
Phone *		Post code *	
Website		Country *	Please Select

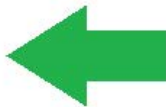
Add Applicant

- ➔ You have the option of adding another applicant, if more than one applicants are associated with the application:

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name	Joe Bloggs		
Email	joe@bloggs.com	Address	1 Main Street Anytown
Phone	0123456	Post code	5555
Website	www.bloggs.com	Country	Belgium

Add Applicant




Note: Fields marked with a red asterisk * are mandatory. You should see a blue check mark appear briefly on your screen once you have correctly filled in a field.

- ➔ Continuing down to section 3, fill in the details concerning the person responsible for the dossier:

3. Person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission Copy applicant contact details ▾

Applicant Name *	<input type="text"/>		
Contact Name *	<input type="text"/>	Address *	<input type="text"/>
Email *	<input type="text"/>		
Phone *	<input type="text"/>	Post code *	<input type="text"/>
Website	<input type="text"/>	Country *	Please Select ▾

Note: If this is the same person as the applicant, you have the option of copying the applicant contact details (button on the top-right hand side of the section):

on behalf of the applicant with the Commission  Copy applicant contact details ▾

Address *	<input type="text"/>
-----------	----------------------

➔ Continuing down to section 4, fill in the contact details for the Producer:

4. Producer

Producer Name *	<input type="text"/>	Copy applicant contact details ▾	
Email *	<input type="text"/>	Address *	<input type="text"/>
Phone *	<input type="text"/>	Post code *	<input type="text"/>
Website	<input type="text"/>	Country *	Please Select ▾

[Add Producer](#)

➔ Once the details have been filled in, you have the option of adding another producer, if more than one producers are associated with the application:

4. Producer

Producer Name	<input type="text" value="John Doe"/>	Copy applicant contact details ▾	
Email	<input type="text" value="john@doe.com"/>	Address	<input type="text" value="1 Main St
Anytown"/>
Phone	<input type="text" value="0123456"/>	Post code	<input type="text" value="5555"/>
Website	<input type="text" value="www.doe.com"/>	Country	<input type="text" value="Belgium"/>

[Add Producer](#) 

➔ Next, indicate “Yes”, if the application includes any confidential data in accordance with Article 23 of Regulation (EU) 2015/2283. If it doesn’t, simply select “No”:

5. Confidentiality

Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

Yes No

- ➔ The same applies regarding Data Protection. If the application includes a request regarding the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283, select “Yes”. You are then requested to provide more information in the box below. You also have the option of attaching any relevant documents using the “attach document” button:

5. Confidentiality

Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

Yes No

6. Data Protection

Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283

Yes No

Please provide information [Attach document](#)

[Lorem ipsum](#)

No document uploaded

- ➔ You will then be prompted to identify the food category to which your application belongs, by selecting one or more category(ies) in the corresponding drop-down list:

7. Proposed entry in the union list

Conditions of uses

Food Category *

Please select Food Category type

- 0 All categories of foods excluding foods for infants and young children, except where specifically provided for
- 1 Dairy products and analogues**
 - 1.1 Unflavoured pasteurised and sterilised (including UHT) milk
 - 1.2 Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation
 - 1.3 Unflavoured fermented milk products, heat-treated after fermentation
 - 1.4 Flavoured fermented milk products including heat-treated products
 - 1.5 Dehydrated milk as defined by Directive 2001/114/EC
 - 1.6 Cream and cream powder

Should the food category is not included in the drop-down list, the applicant is requested to type the food or food category under which the novel food may be used.


➔ You are then requested to indicate the maximum level:

7. Proposed entry in the union list

Conditions of uses

Food Category

Ripened cheese

Maximum Level * 

Save to list ✓ Cancel ✕

➔ If there are any specific labelling requirements or any other requirements unique to your application, type them in the corresponding boxes with the relevant titles:

Specific labelling requirement

← → **B** *I*

Other requirements

← → **B** *I*

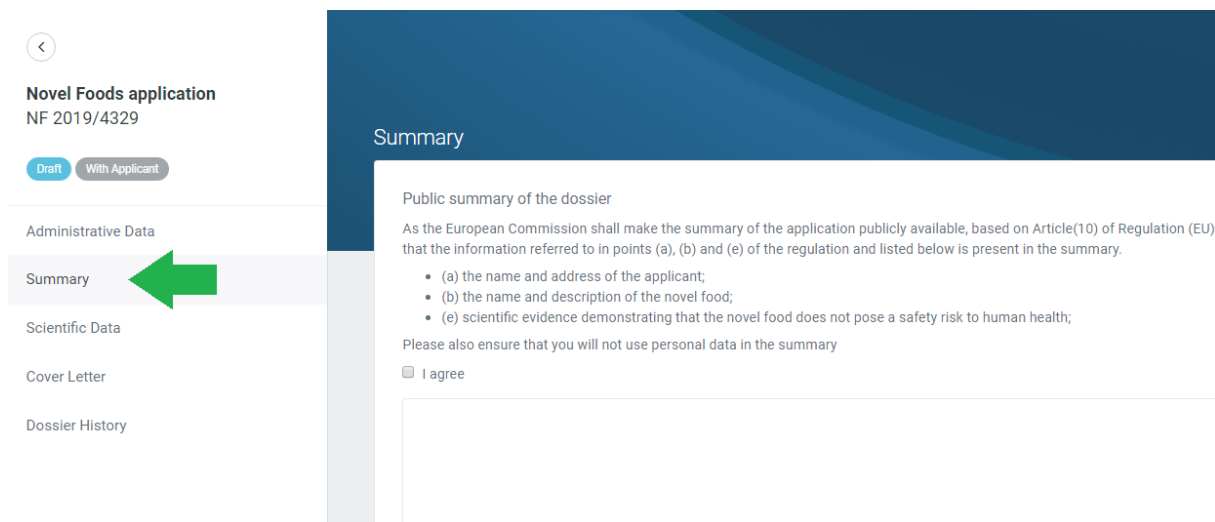
- ➔ Lastly, indicate whether or not the novel food has regulatory status outside of the EU:

8. Regulatory status outside EU

Yes No

Summary

- ➔ Underneath the “Administrative Data” tab in the menu on the left-hand side of the screen is the “Summary Tab”. You’ll also need to complete this section of web-form in order to submit your application successfully:



The screenshot shows a web interface for a 'Novel Foods application' (NF 2019/4329). On the left, a navigation menu includes 'Administrative Data', 'Summary', 'Scientific Data', 'Cover Letter', and 'Dossier History'. A green arrow points to the 'Summary' tab. The main content area is titled 'Summary' and contains the following text:

Public summary of the dossier

As the European Commission shall make the summary of the application publicly available, based on Article(10) of Regulation (EU) that the information referred to in points (a), (b) and (e) of the regulation and listed below is present in the summary.

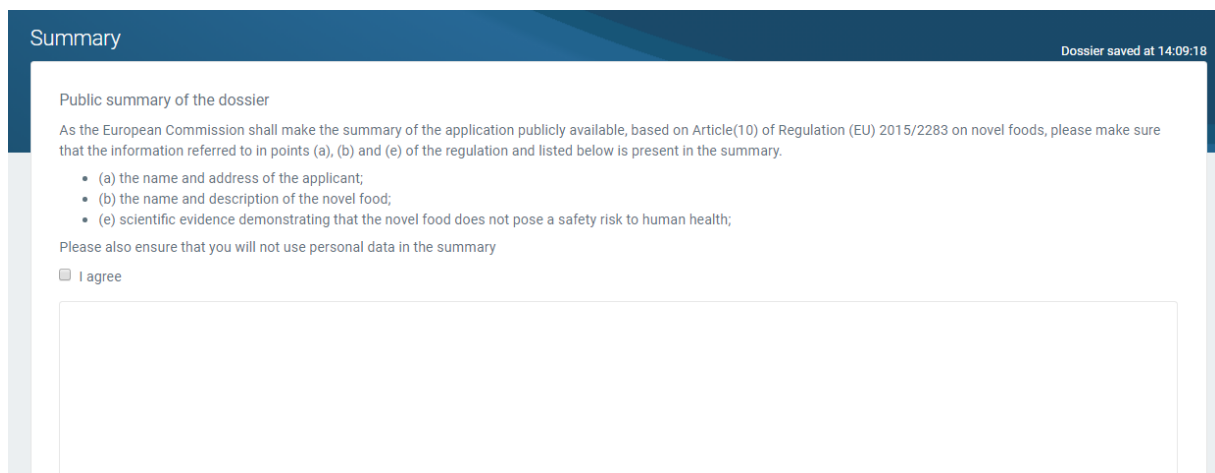
- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

Please also ensure that you will not use personal data in the summary

I agree

Below the text is a large empty text box for the user to input the summary.

- ➔ Complete the summary tab as requested, and click on “I agree” in order to make sure that you will not use any personal data in the summary:



This screenshot provides a closer view of the 'Summary' tab. The header 'Summary' is on the left, and 'Dossier saved at 14:09:18' is on the right. The main content area contains the same text as the previous screenshot:

Public summary of the dossier

As the European Commission shall make the summary of the application publicly available, based on Article(10) of Regulation (EU) 2015/2283 on novel foods, please make sure that the information referred to in points (a), (b) and (e) of the regulation and listed below is present in the summary.

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

Please also ensure that you will not use personal data in the summary

I agree

A large empty text box is provided for the user to enter the summary.

Scientific Data tab

➔ Now you can move on to the Scientific Data tab:

Novel Foods application

NF 2019/4329

Draft

With Applicant

Administrative Data

Summary

Scientific Data




Cover Letter

Dossier History

Note: This is the most time-consuming section of the application process, as you will notice, as a number of documents need to be uploaded.

➔ Start by clicking on the “**Add New File**” button located at the top of the web form:

Scientific Data Dossier saved at 14:09:18

 [Add new file +](#)

Identity of the novel food	No Documents
The production Process	No Documents
Compositional data	No Documents
Specifications	No Documents
The history of use of novel food and/or its source	No Documents
The proposed use(s) and use levels and anticipated intake	No Documents
Absorption, Distribution, Metabolism and Excretion (ADME)	No Documents

- ➔ Select the field in the drop-down menu to which the uploaded document will belong:

The screenshot shows a web form titled "Scientific Data". Under the heading "Scientific field *", there is a dropdown menu. The menu is open, showing a list of options. The first option, "Identity of the novel food", is highlighted in blue. Other options include "The production Process", "Compositional data", "Specifications", "The history of use of novel food and/or its source", "The proposed use(s) and use levels and anticipated intake", "Absorption, Distribution, Metabolism and Excretion (ADME)", "Nutritional information", "Toxicological information", "Genotoxicity", "Subchronic toxicity", "Chronic toxicity and carcinogenicity", "Reproductive and developmental toxicity", "Human data", "Allergenicity", "Concluding remarks", "References", "Annexes to the dossier", and "Other relevant information".

- ➔ Next, upload the relevant file by clicking on the "Browse" button. This will open up a navigation window in which you will be able to search for the corresponding document on your PC/device:

The screenshot shows the same "Scientific Data" form. The "Scientific field" dropdown menu now displays "Identity of the novel food". Below it, the "Upload file(s) *" section contains a text input field with the placeholder "Choose file(s) ...". To the right of this field is a grey "Browse" button, which is highlighted by a large green arrow. Below the input field are two buttons: "Upload" with a checkmark icon and "Cancel" with an 'x' icon.

A green marker flashes once the document has been successfully uploaded:



- ➔ Once the document has been uploaded, you have the option of indicating whether or not the document contains any confidential information. If it does, you'll need to write a justification in the corresponding text box:

Confidential	Justification
<input checked="" type="checkbox"/>	<p>Provide detailed justification on confidentiality per section and/or annex ...</p>

- ➔ Repeat this process for every scientific field. You also have the ability to upload several documents to one field.

Note: The analysis of data shall be presented in a clear format, using standardised scientific units. The raw data and the format of the file used for the statistical analysis should be submitted in an editable form.

All the scientific fields need to be filled in order to proceed with the submission of your application.

Cover Letter tab

Select the “Cover Letter” tab in the left-hand menu:

Novel Foods application
NF 2019/4329

Draft With Applicant

Administrative Data

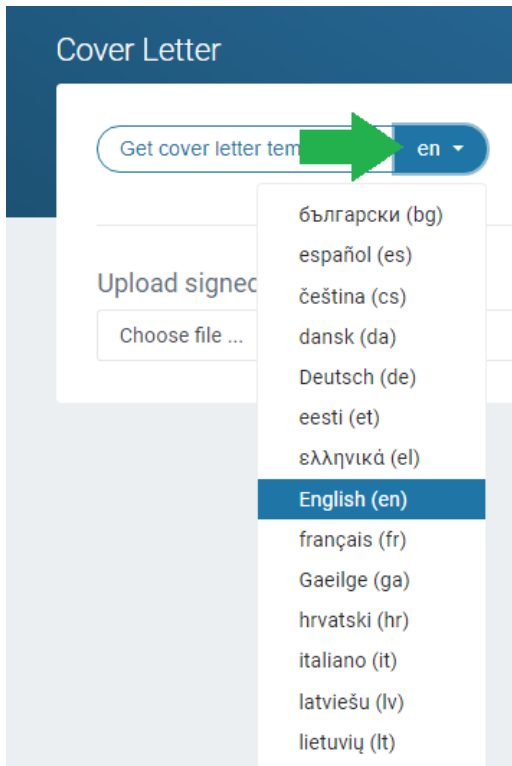
Summary

Scientific Data

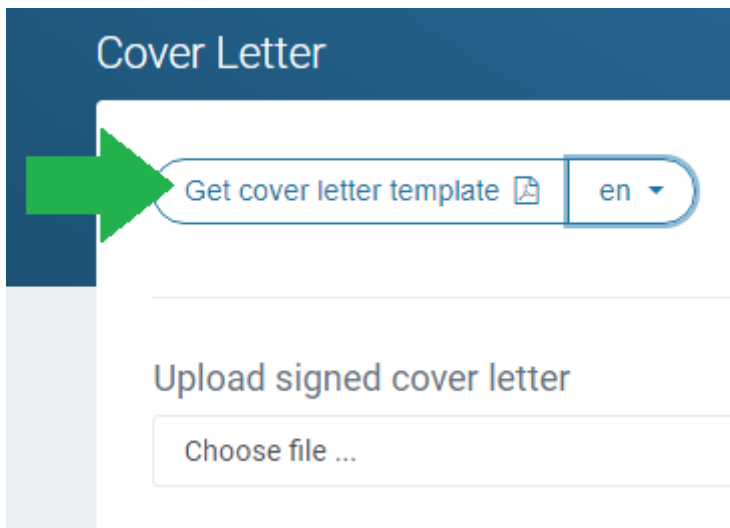
Cover Letter ←

Dossier History

- ➔ Here you can download the Cover Letter template. Select which language you would like the Cover Letter to be in by selecting the relevant language in the drop-down list:



- ➔ Then, click on "Get cover letter template". This will download a template of the cover letter in your chosen language in PDF format:



➔ Save the Cover Letter on your desktop.

EN
ANNEX
ANNEX I

TEMPLATE COVER LETTER ACCOMPANYING AN APPLICATION FOR NOVEL FOOD
EUROPEAN COMMISSION
Directorate General
Directorate
Unit
Date: _____

Subject: Application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283.

(Please indicate clearly by ticking one of the boxes)

- Application for an authorisation of a new novel food.
- Application for adding, removing or changing the conditions of use of an already authorised novel food. Please provide a reference to that authorisation.
- Application for adding, removing or changing the specifications of an already authorised novel food. Please provide a reference to that authorisation.
- Application for adding, removing or changing additional specific labelling requirements of an already authorised novel food. Please provide a reference to that authorisation.
- Application for adding, removing or changing post market monitoring requirements of an already authorised novel food. Please provide a reference to that authorisation.

The Applicant(s) or their Representative(s) in the Union
(name(s), address(es),...)

submit(s) this application in order to update the Union list on novel foods.

Identity of the novel food (information on the identity of the novel food should be provided, depending on the category(ies) under which the novel food falls):

1

Confidentiality¹. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

- Yes
- No

Data Protection². Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283:

- Yes
- No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature _____

Enclosures:

- Complete dossier
- Summary of the dossier
- List of the parts of the dossier requested to be treated as confidential and verifiable justification for such claims
- Information supporting the protection of proprietary data relating to the novel food application
- Copy of administrative data of applicant(s)

¹ Applicants should use the format established in Annex II to indicate which information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

² Applicant should specify the part(s) of the application which include(s) proprietary data for which protection is requested, clearly stating section(s) and page number(s). Applicant should provide verifiable justification /declaration for the proprietary claim.

2

➔ Fill in the template, print it out, **sign it manually**, scan it and save it on your desktop **as a PDF**. Click on "**Browse**" and locate the signed cover letter on your desktop. **Double click on the document** and it will be uploaded onto the application.

Upload signed cover letter

Choose file ...

Browse

➔ If you want to remove and replace the document that you've just uploaded, simply click on the "Remove" button:



Dossier History tab

You can check out the status of your application by clicking on the “Dossier History” tab:

Novel Foods application
NF 2019/4329


Draft **With Applicant**

Administrative Data

Summary

Scientific Data

Cover Letter

Dossier History 

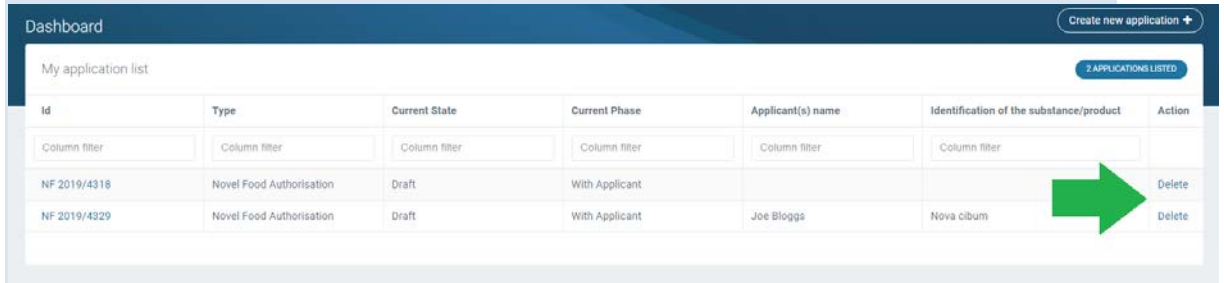
Here you will find a summary of the status of your application(s), including the date that it was created, the dossier state, substate, etc:

Dossier History Dossier saved at 15:32:12

Event/Action	Date	Dossier State	Dossier SubState	Comments	Document
Dossier Created	20/11/2019 10:21AM	Draft	With Applicant		

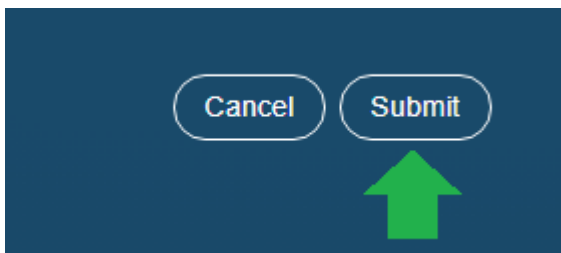
Showing 1 to 1 of 1 records.

Please note: Whilst the application is still in “draft” phase, you have the possibility of deleting it completely from your application list. Simply head to your application list on your dashboard, and click on the corresponding “Delete” button underneath the “Action” tab:



Submitting your application

- ➔ Once all the information marked with a red star (mandatory fields) has been filled in and the cover letter uploaded, submit the application by clicking on the "**Submit**" button:

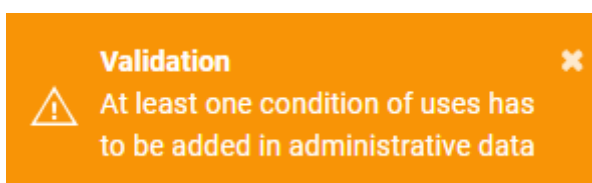


You also have the option of cancelling the application.

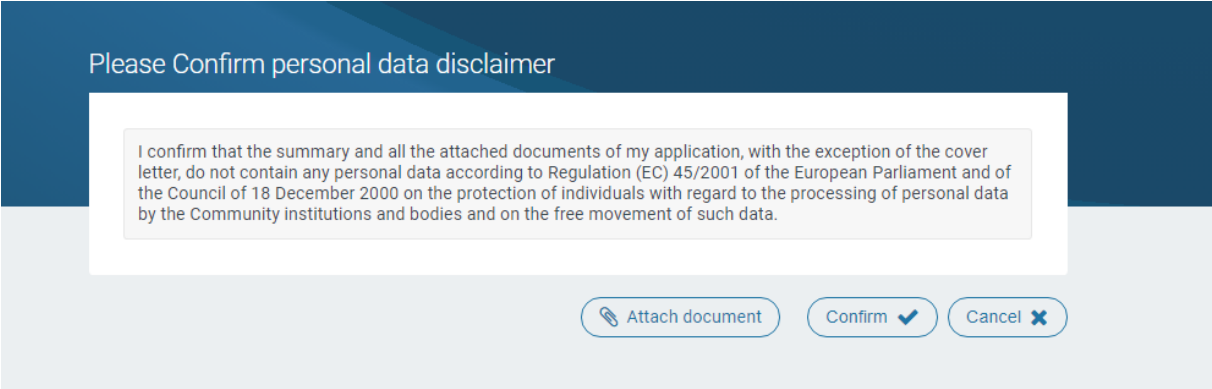
Warning: Only a draft (Not submitted) dossier can be cancelled/deleted

Please make sure that all mandatory fields (with a red asterisk) in all relevant tabs (Administrative Data, Summary, Scientific Data, Cover Letter) are filled in correctly.

If you click on “Submit Application” and a mandatory field is missing, an orange “error message” will appear indicating which tab needs to be filled in:



Before your application is confirmed, you must confirm your personal data. Simply click on the “Confirm” button do to so. You also have the option of attaching any supporting documents – simply click on the “Attach document” button and add any relevant files from your computer/device:



A pop-up will now appear asking you to confirm your application and informing you that your dossier will now be moved to “Application Acknowledged” phase. An email will then be sent to you and the European Commission (EC). Click on “Confirm” to proceed:

By confirming :

- the dossier will be moved to this state/phase : Application Acknowledged / Perform Validity Check
- An email will be sent to : EC, MS



The system will now direct you back to your dashboard. Here you will note that the state of the application has moved from “Draft” to the “Application Acknowledged” phase and the current phase of the application now reads “Perform Validity Check”:

Dashboard

My application list

id	Type	Current State	Current Phase	Applicant(s) name
Column filter	Column filter	Column filter	Column filter	Column filter
NF 2019/4318	Novel Food Authorisation	Draft	With Applicant	
NF 2019/4329	Novel Food Authorisation	Application Acknowledged	Perform Validity Check	Joe Bloggs

When the status of the notification changes, you will receive an automatic email update.

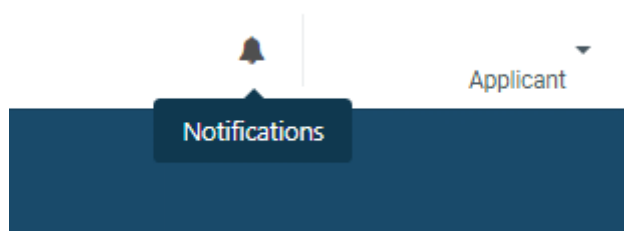
Note: To edit information after having submitted your notification, please send an authorisation request to the Support Team, and specify the number of your notification and which section(s) need(s) to be edited. This is very important for the support team to be able to identify your application quickly and respond to you in a timely manner. The support team email address is: Sante-FOODSYSTEMS@ec.europa.eu The section(s) in question will be editable, whilst the rest of the notification remains in read-only mode.

Request for Information

You will receive an email once your application has been submitted.

The EC will verify the validity of the application. Subsequently, if your dossier is any way incomplete, the EC or EFSA will require more information concerning any part of an application and you will receive a “Request for Information” detailing which section of the application needs to be completed/include more details.

Once you have logged into the system, you will notice a bell shaped notifications icon on the top right hand corner of the window, next to your user name:



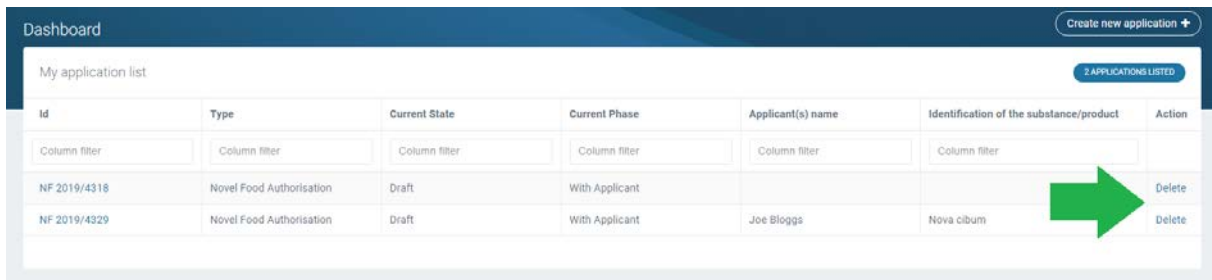
Here the system will send you updates concerning the status of your application(s). This can be a request for information, detailing which section of the application needs updating, a notification informing you that your application has moved on to the next

stage, amongst others. The notification icon will not disappear until you have dealt with it.

Please Note: If you have received a notification/email request for information, remember to re-submit your request, once all of the information has been entered. Do this by clicking on the re-submit button on the top right of your screen.

Withdrawing your Application

At any moment, you have the option of withdrawing/deleting your application. Simply click on the “Delete” button on the right hand side of the application details on the dashboard. You will receive a message asking you to confirm the deleting of the dossier:

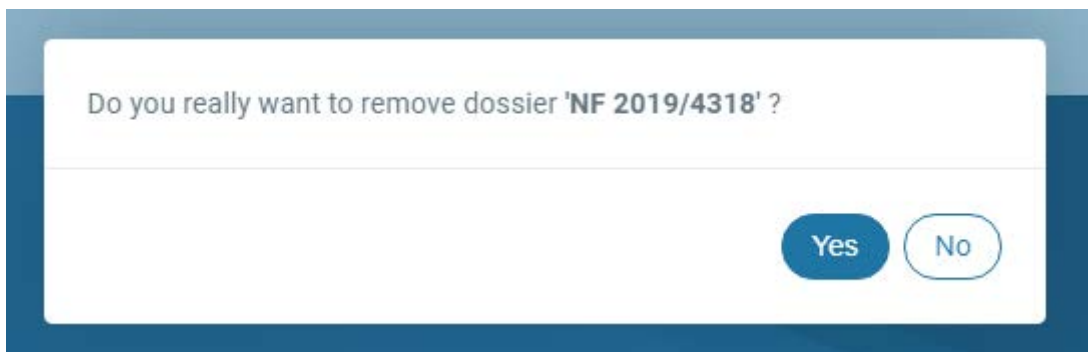


Dashboard

My application list

2 APPLICATIONS LISTED

Id	Type	Current State	Current Phase	Applicant(s) name	Identification of the substance/product	Action
Column filter	Column filter	Column filter	Column filter	Column filter	Column filter	
NF 2019/4318	Novel Food Authorisation	Draft	With Applicant			Delete
NF 2019/4329	Novel Food Authorisation	Draft	With Applicant	Joe Bloggs	Nova cibum	Delete



Do you really want to remove dossier 'NF 2019/4318' ?

Yes No

Editing your contact details

You have the possibility of editing your contact details linked to an application (in any phase).

➡ Simply click on the application ID number on your Dashboard:

Dashboard		
My application list		
Id	Type	Current State
Column filter	Column filter	Column filter
NF 2019/4318	Novel Food Authorisation	Draft
NF 2019/4329	Novel Food Authorisation	Application Acknowledged

The system will load the application.

You will be taken straight to the administrative data section of the application in question.

➔ Here, simply click on the **“Edit”** icon to the right of the screen:

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name	Joe Bloggs		
Email	joe@bloggs.com	Address	1 Main Street Anytown
Phone	0123456	Post code	1040
Website	www.bloggs.com	Country	Belgium

➔ Once you have done editing the details, click on the **“Save”** button to the right of your screen:

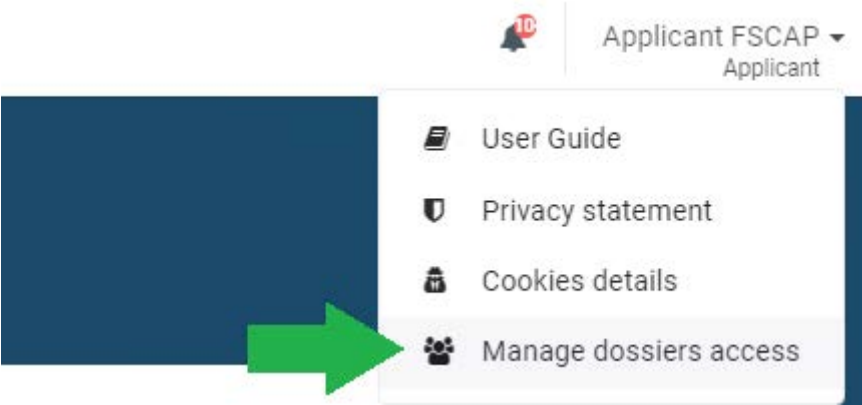
2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name	Joe Bloggs			Save ✓	Cancel ✕
Email	joe@bloggs.com	Address	1 Main Street Anytown		
Phone	0123456	Post code	1040		
Website	www.bloggs.com	Country	Belgium		

Managing Dossier Access

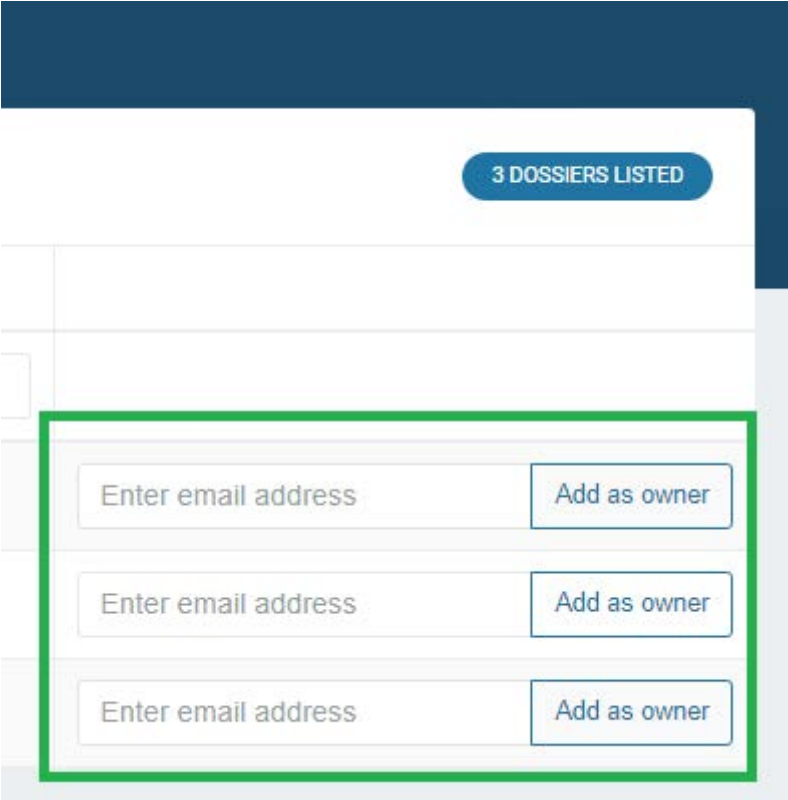
You have the ability to manage user access to any dossier at any time.

- ➔ When you are logged into the system, simply click on the drop-down menu where you see your name on the top-right hand side of the window, then click on the **“Manage dossiers access”** tab:



You will be taken to the **“Manage applicant user access to dossier”** page.

- ➔ Here you can add another user as “owner” of an application by entering their email address in the corresponding box:



Note: Bear in mind, the user that you are adding should have a valid EU login account and should already have logged into the FSCAP system *at least once*.

Once you have clicked on “**Add as owner**”, a green box should briefly appear indicating that the user has been added successfully. Now you will notice that the email address of the individual has been added to the application owners:

Draft	With Applicant	applicantfscap@gmail.com ✕	Enter email address	Add as owner
		Fscapefsa1@gmail.com ✕		

Note: You can remove owners at any time by clicking on the blue X to the right of their email address. Please bear in mind that at least 1(one) owner needs to be associated to an application.

Checking for Version Updates

At any time you have the option of checking for any updates/improvements that have been made to the platform.

- ➔ From your dashboard, simply click on the version number on the very bottom left of the window:



Now you will be able to view details concerning the latest release of the application, including any updates and fixes that have been released and are operational:

FSCAP 2.0.7

22 October 2019

What's new :

- New possibility for EFSA risk assessors to request clarification when a response from the applicant to a request for information is not complete.
- The display of the list of request for information (RFI) and request for clarification has been improved
- At the complete action page a visible timeline of the next steps in the flow is now displayed to all the users, including the list of emails sent by the system.
- European Commission users are now able to inform the applicant about the safety objection(s) through the system (for traditional food notifications)
- Union list module for European Commission users has been improved
- Application list is now printable

Bug fixes :

- Performance improved
- Bug fixes
- Several issues related to accessibility (access to the system for people with disabilities, or special needs) have been fixed

FSCAP 1.2.1

2 October 2018

Corrective version

FSCAP 1.2.0

30 August 2018

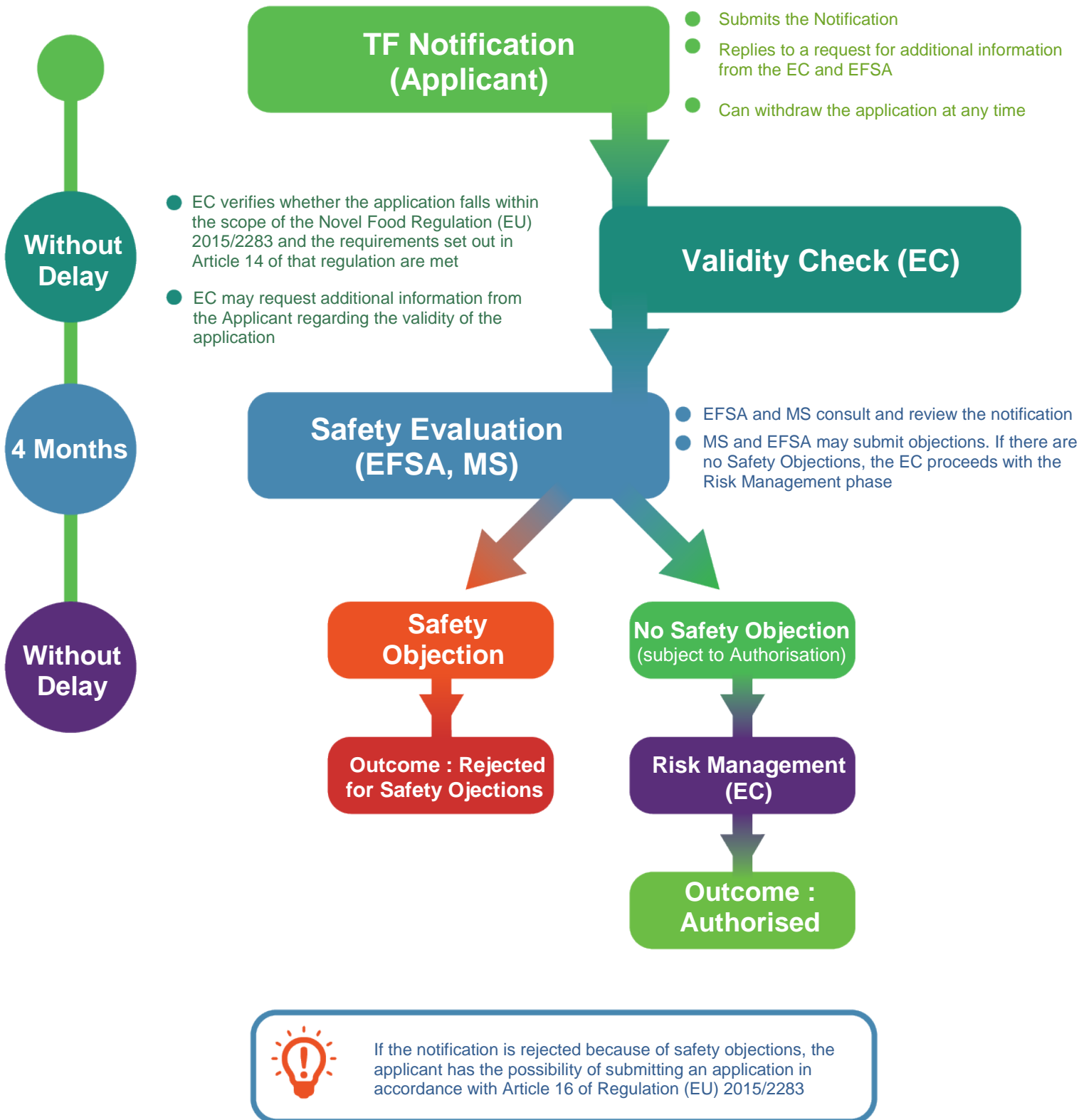
A lot of new features

Close release notes

Contact Details

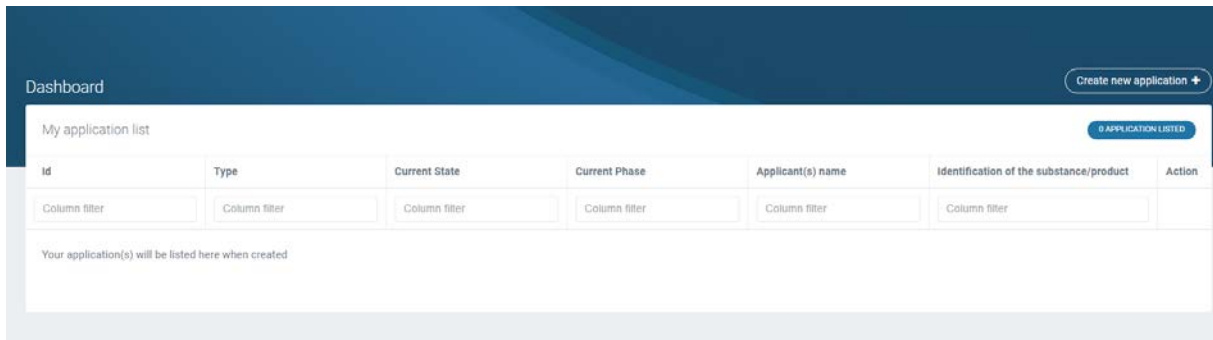
If you have any questions regarding your application, do not hesitate to contact the dedicated support team at: SANTE-FOODSYSTEMS@ec.europa.eu

Traditional Food Autorisation Workflow



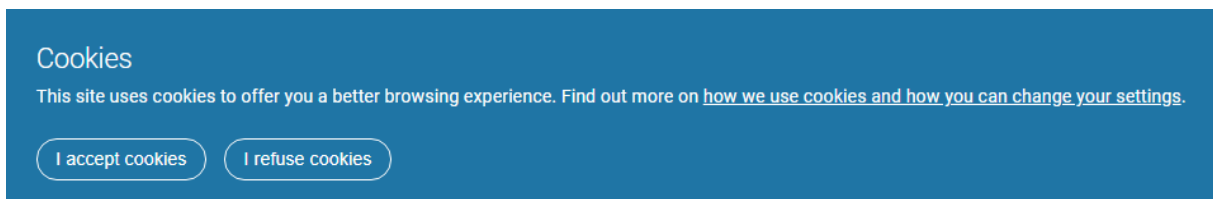
Traditional Food Notification

Once you have signed in to the food e-submission system, you will be taken straight to the dashboard:



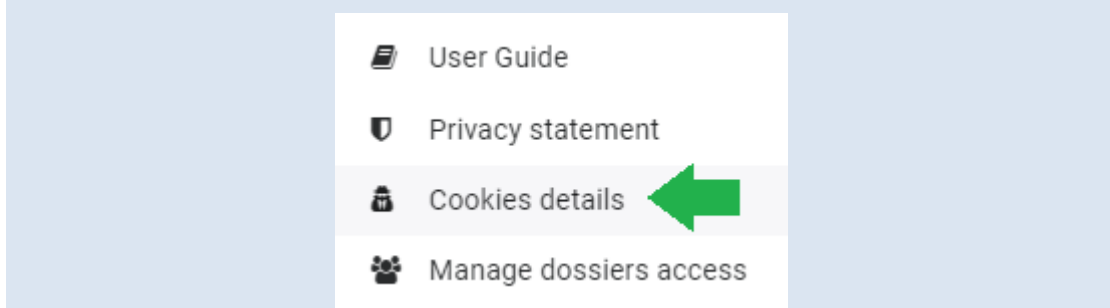
Cookies

- The first step is to accept Cookies on the website – do this by clicking on “I accept cookies” inside the Cookies pop-up window at the bottom of your screen:

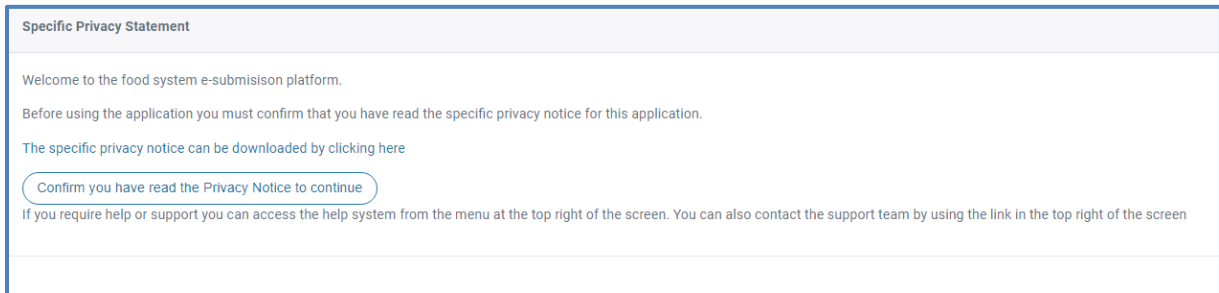


Note: For more information regarding how we use cookies and how you can change your settings, simply follow this link: “How we use cookies”.

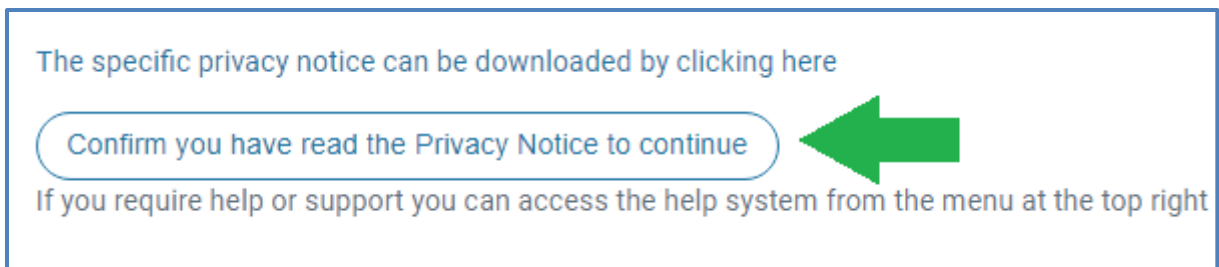
Note: You can still access the cookies content description at any time, by simply clicking on “Cookies details” in the drop down menu under your name on the top-right hand corner of the screen located on the dashboard:



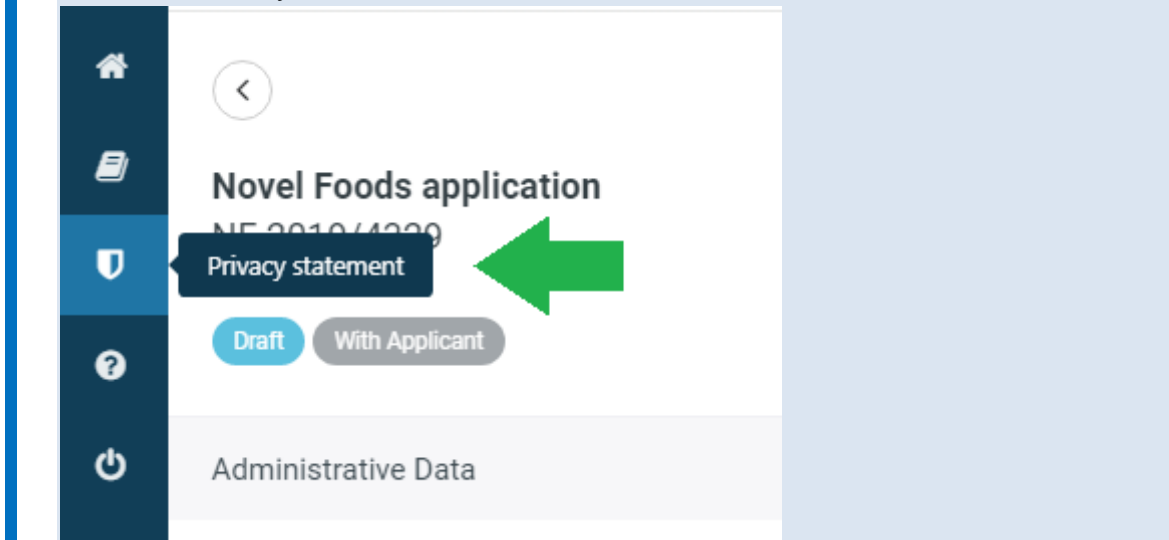
- The second step is to read and confirm that you have read the Privacy Notice. In order to download and read the Privacy Notice, simply click on the relevant text inside the dialogue box:



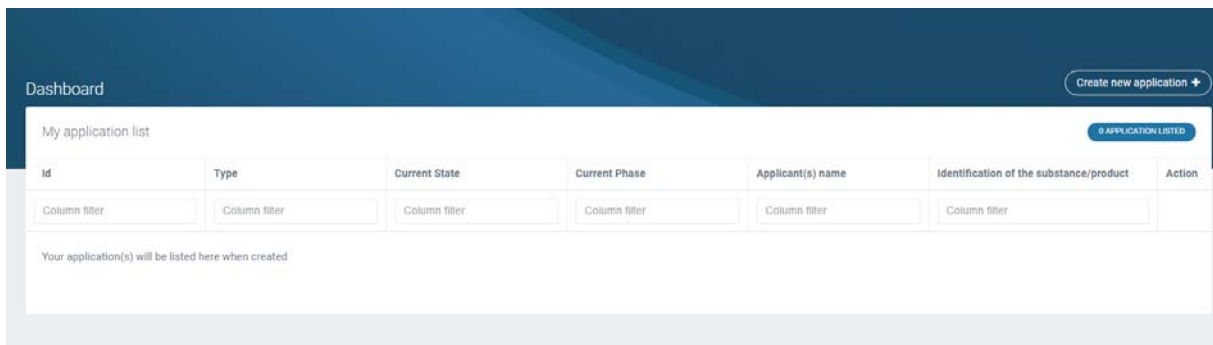
- Once you have read the notice, continue by clicking on the "Confirm that you have read the privacy notice in order to continue" button inside the dialogue box:



Note: You can access the Privacy Statement at any time by simply clicking on the "Privacy Statement" icon on the left-hand side of the dashboard:



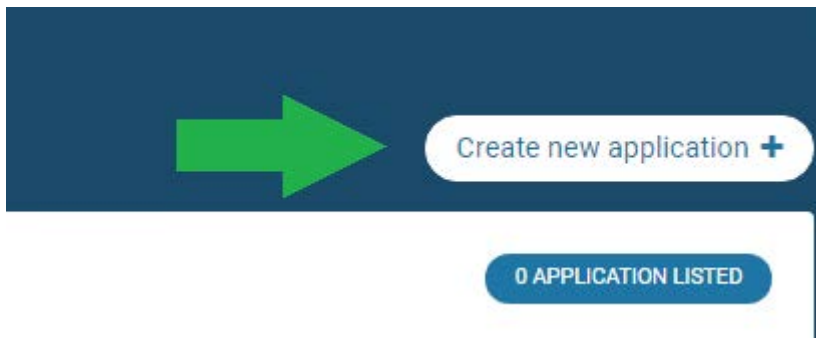
You will then be taken to the dashboard which displays your application list:



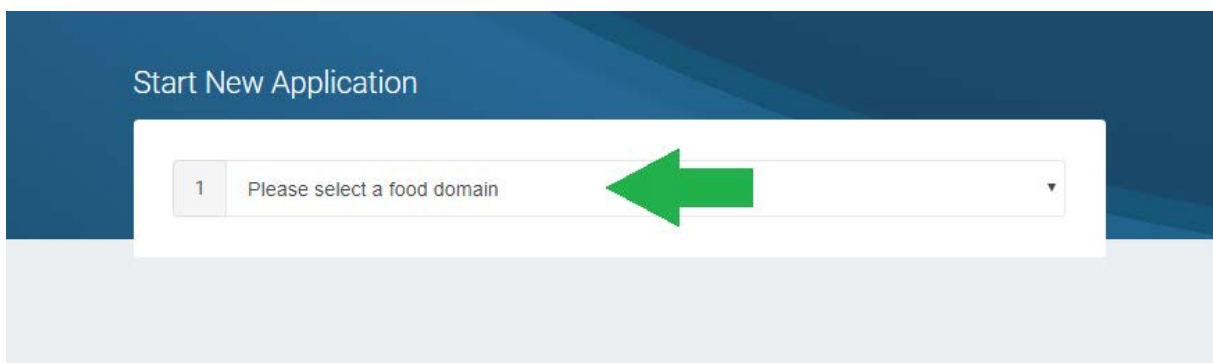
Creating a New Application

Detailed steps and more information

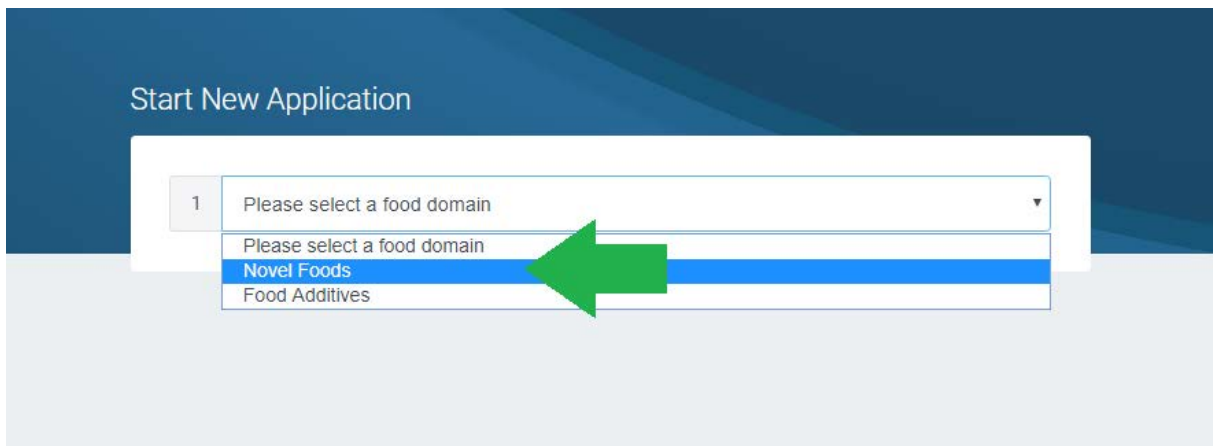
- ➔ On the dashboard, click on **Create a new application** (located on the top right hand side of the dashboard):



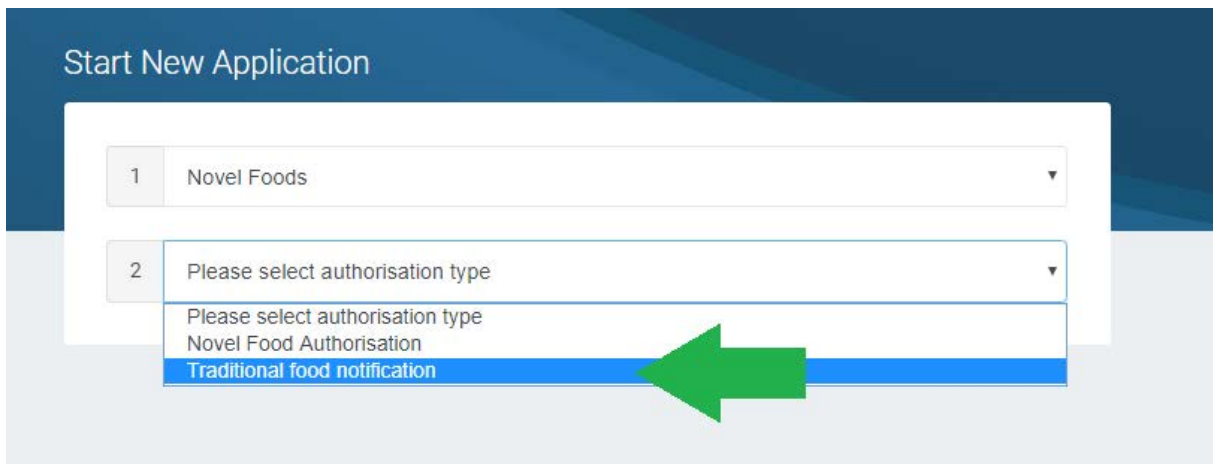
- ➔ You will now be prompted to select a food-domain from the drop-down list:



➔ Select “Novel Foods”:

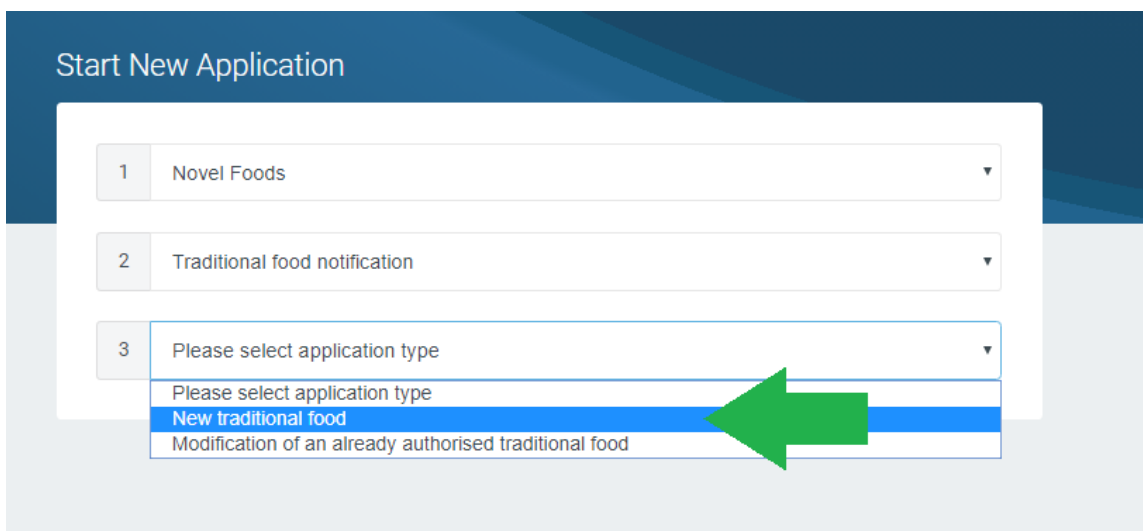


In the second drop down menu, select “**Traditional food notification**”:



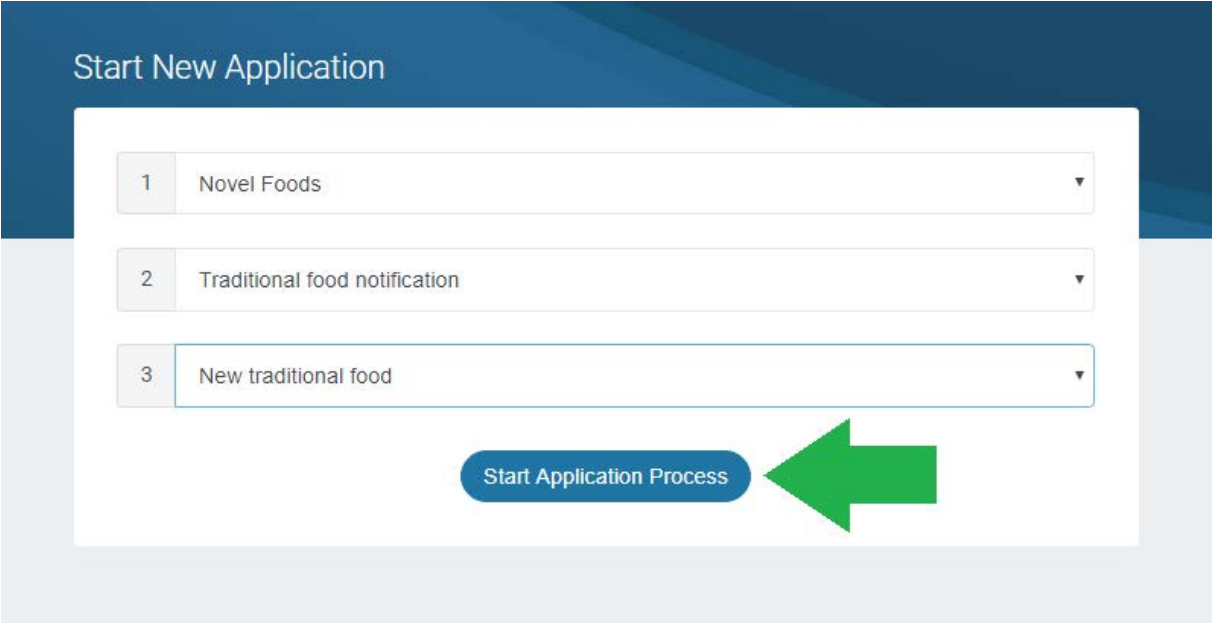
You will now be prompted to select the application type. Here you can select between starting a new Novel Traditional application or modifying a pre-existing application which has already been authorised.

➔ Select “New Traditional Food”:



Once these three fields have been selected, a button entitled “Start Application Process” will appear.

➔ Click on “Start Application Process”:



After a few seconds of loading, you will be taken to the application screen which includes the web form for the traditional food that needs to be completed.

➔ On the left-hand side of the screen you will notice a side menu, which includes the ID number of the Traditional Foods application:



Novel Foods application

NF 2019/4349

Draft With Applicant

Note: You will notice that the system indicates that the application is in draft mode (in blue), as it has not yet been submitted for review.

- ➔ Underneath, you will notice that you are currently viewing the “Administrative Data” tab, which is the first section of the application that needs to be completed

Novel Foods application

NF 2019/4329

Draft

With Applicant

Administrative Data

Summary

Scientific Data

Cover Letter

Dossier History

Administrative Data tab

- ➔ Start by filling in the first “identity” section of the Administrative Data tab, including the name of the traditional food and an identity description:

Administrative Data Dossier saved at 10:45:43

1. Identity of the novel food to be authorised

Name

B I
Nova cibum

Description *

Enter identity description here

Novel Food category *

Please select Food Category type

Note: The **Autosave** function ensures that the encoded content is saved automatically. Therefore, there is no **Save** button in the system. You will notice it on the top-right hand side of the web form.

Be aware that while the autosave information message is displayed, any insertions/modifications are not taken into account. Please make sure that all information is correctly updated.

- ➔ Next, select the food category type (Article 3(2)(a) of [Regulation \(EU\) 2015/2283](#)) from the drop-down menu:

Novel Food category *

Please select Food Category type

food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by: – traditional propagating practices which have been used for food production within the Union before 15 May 1997; or – non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

food consisting of, isolated from or produced from microorganisms, fungi or algae

- ➔ In the section underneath, fill in the applicant name, email address and other details:

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name

Email

Phone *

Website

Address *

Post code *

Country *

Add Applicant

- ➔ You have the option of adding another applicant, if more than one applicants are associated with the application

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name

Email

Phone

Website

Address

Post code

Country

Add Applicant 

Note: Fields marked with a red asterisk * are mandatory. You should see a blue check mark appear briefly on your screen once you have correctly filled in a field.


- ➔ Continuing down to section 3, fill in the details concerning the person responsible for the dossier:

3. Person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission Copy applicant contact details ▾

Applicant Name *	<input type="text"/>
Contact Name *	<input type="text"/>
Email *	<input type="text"/>
Phone *	<input type="text"/>
Website	<input type="text"/>
Address *	<input type="text"/>
Post code *	<input type="text"/>
Country *	Please Select ▾

Note: If this is the same person as the applicant, you have the option of copying the applicant contact details (button on the top-right hand side of the section):

Person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission Copy applicant contact details ▾



Address *

- ➔ Next, indicate “Yes”, if the application includes any confidential data in accordance with Article 23 of Regulation (EU) 2015/2283. If it doesn’t, simply select “No”:

4. Confidentiality

Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

Yes No

- ➔ You will then be prompted to identify the food category to which your application belongs, by selecting a category in the corresponding drop-down list:

5. Proposed entry in the union list

The screenshot shows a web form titled "Conditions of uses". Under the heading "Food Category *", there is a dropdown menu. The menu is open, showing a list of categories. The top option is "All categories of foods excluding foods for infants and young children, except where specifically provided for", which is highlighted in blue. Below it are several numbered options: "1 Dairy products and...", "1.1 Unflavoured pasteurised and sterilised (including UHT) milk", "1.2 Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation", "1.3 Unflavoured fermented milk products, heat-treated after fermentation", "1.4 Flavoured fermented milk products including heat-treated products", "1.5 Dehydrated milk as defined by Directive 2001/114/EC", and "1.6 Cream and cream powder".

Should the food category is not included in the drop-down list, the applicant is requested to type the food or food category under which the novel food may be used.

- ➔ You are then requested to indicate the maximum level:

7. Proposed entry in the union list

The screenshot shows a web form titled "Conditions of uses". Under the heading "Food Category", the text "Ripened cheese" is entered. Below this, there is a field labeled "Maximum Level *". A large green arrow points to this field. At the bottom of the form, there are two buttons: "Save to list ✓" and "Cancel ✕".

- ➔ If there are any specific labelling requirements or any other requirements unique to your application, type them in the corresponding boxes with the relevant titles:

Specific labelling requirement

← → **B** *I*

Other requirements

← → **B** *I*

- ➔ Lastly, indicate whether or not the novel food has regulatory status outside of the EU:

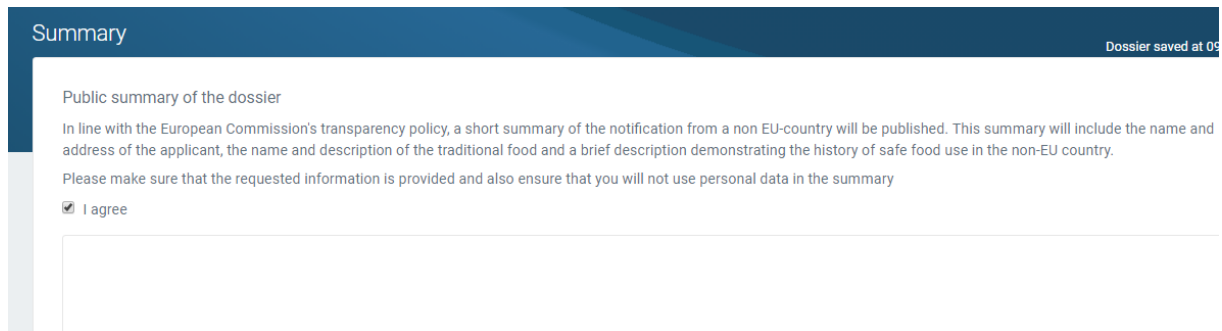
6. Regulatory status outside EU

Yes No

Summary

Underneath the “Administrative Data” tab in the menu on the left-hand side of the screen is the “Summary Tab”.

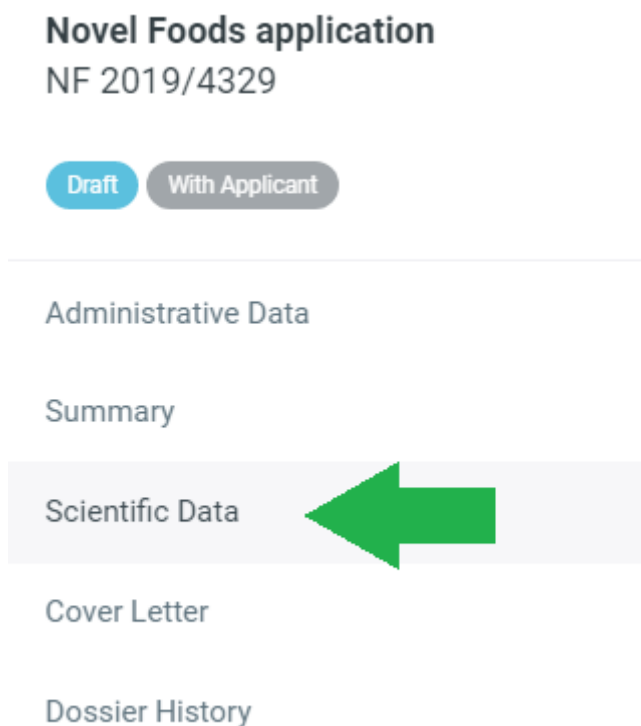
- ➔ You’ll also need to complete this section of web-form in order to submit your application successfully:



The screenshot shows the 'Summary' tab of a web application. At the top, there is a dark blue header with the word 'Summary' on the left and 'Dossier saved at 09' on the right. Below the header, the text reads: 'Public summary of the dossier'. A paragraph follows: 'In line with the European Commission's transparency policy, a short summary of the notification from a non EU-country will be published. This summary will include the name and address of the applicant, the name and description of the traditional food and a brief description demonstrating the history of safe food use in the non-EU country. Please make sure that the requested information is provided and also ensure that you will not use personal data in the summary'. Below this text is a checkbox labeled 'I agree' which is checked. At the bottom of the form area, there is a large empty rectangular box for text input.

Scientific Data tab

- ➔ Now you can move on to the Scientific Data tab:



The screenshot shows a vertical menu of application stages. At the top, it says 'Novel Foods application' followed by 'NF 2019/4329'. Below this are two buttons: 'Draft' (highlighted in blue) and 'With Applicant' (grey). A horizontal line separates this from the menu items: 'Administrative Data', 'Summary', 'Scientific Data', 'Cover Letter', and 'Dossier History'. The 'Scientific Data' item is highlighted with a grey background and has a large green arrow pointing to it from the right.

Note: This is the most time-consuming section of the application process, as you will notice, as a number of documents need to be uploaded.

- ➔ Start by clicking on the “Add New File” button located at the top of the web form:

Scientific Data

Add new file +

Identity of the traditional food	No Documents
The production Process	No Documents
Compositional data	No Documents
Specifications	No Documents
Data from experience of continued use	No Documents
Proposed conditions of use for the EU market	No Documents
Concluding remarks	No Documents

- ➔ Select the field in the drop-down menu to which the uploaded document will belong:

Scientific Data

Scientific field *

Select a field

- Select a field
- Identity of the traditional food
- The production Process
- Compositional data
- Specifications
- Data from experience of continued use
- Proposed conditions of use for the EU market
- Concluding remarks
- References
- Annexes to the dossier
- Other relevant information

Please read before uploading any document

- ! The information provided should be structured following the different scientific fields. Please upload the relevant information only on the corresponding sections.
- ! Analysis of data shall be presented in a clear format, using standardised scientific units. The raw data and the format of the file used for the statistical analysis shall be given in an editable form. In case the applicant requests confidential treatment of certain sections of the dossier, we kindly request to attach separately the section without confidential information

- ➔ Next, upload the relevant file by clicking on the “Browse” button. This will open up a navigation window in which you will be able to search for the corresponding document on your PC/device:

Scientific Data

Scientific field *

The production Process

Upload file(s) *

Choose file(s) ...

Browse

Upload ✓

Cancel ✕

A green marker flashes once the document has been successfully uploaded:



- ➔ Once the document has been uploaded, you have the option of indicating whether or not the document contains any confidential information. If it does, you'll need to write a justification in the corresponding text box:

Confidential	Justification
<input checked="" type="checkbox"/>	<p>Provide detailed justification on confidentiality per section and/or annex ...</p>

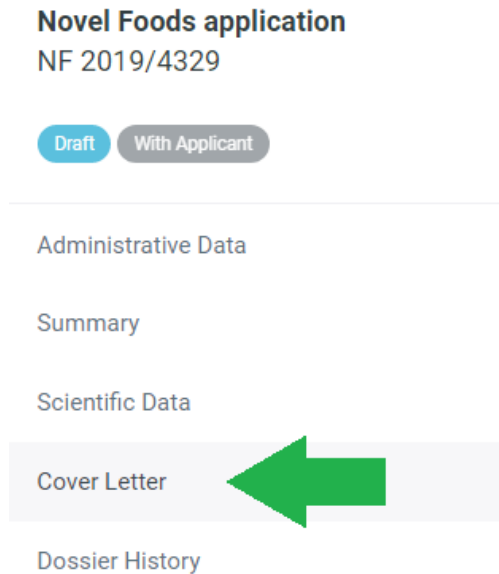
- ➔ Repeat this process for every scientific field. You also have the ability to upload several documents to one field.

Note: The analysis of data shall be presented in a clear format, using standardised scientific units. The raw data and the format of the file used for the statistical analysis should be submitted in an editable form.

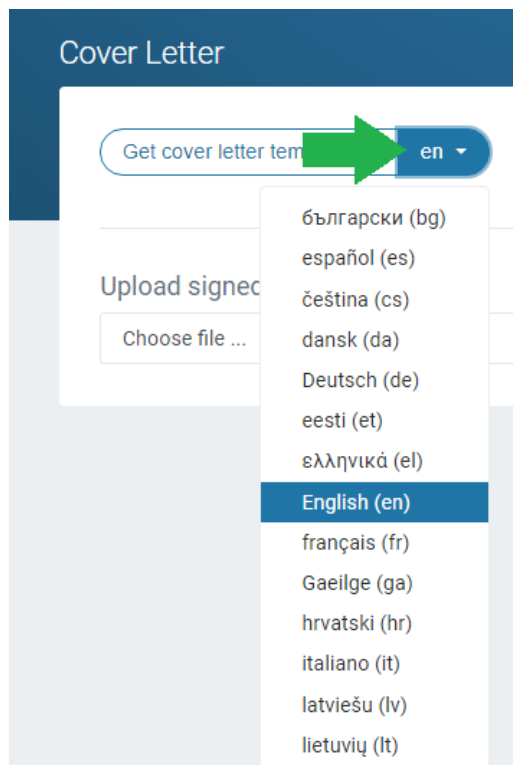
All the scientific fields need to be filled in order to proceed with the submission of your application.

Cover Letter tab

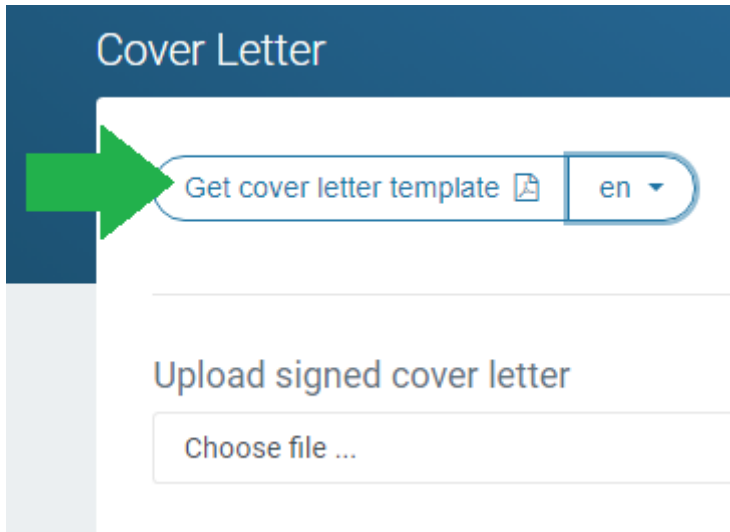
Select the “Cover Letter” tab in the left-hand menu:



- ➔ Here you can download the Cover Letter template. Select which language you would like the Cover Letter to be in by selecting the relevant language in the drop-down list:



- ➔ Then, click on “Get cover letter template”. This will download a template of the cover letter in your chosen language in PDF format:



- ➔ Save the Cover Letter on your desktop.

EN
ANNEX
ANNEX

TEMPLATE COVER LETTER ACCOMPANYING A NOTIFICATION FOR TRADITIONAL FOOD FROM A THIRD COUNTRY FOLLOWING THE REQUIREMENTS OF ARTICLE 14 OF REGULATION (EU) 2015/2283

EUROPEAN COMMISSION
Directorate General
Directorate
Unit
Date: _____

Subject: Notification for authorisation of a traditional food from a third country in accordance with Regulation (EU) 2015/2283

(Please indicate clearly by ticking one of the boxes)

- Notification for an authorisation of a new traditional food
- Notification for adding, removing or changing the conditions of use of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing the specifications of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing additional specific labelling requirements of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing the post-market monitoring requirements of an already authorised traditional food. Please provide a reference to that notification.

The Applicant(s) or their Representative(s) in the Union
(name(s), address(es)...) _____

submit(s) this notification in order to update the Union list on novel foods.

Identity of the traditional food

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

→ Yes

→ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement
-	=	=
=	=	=

Yours sincerely,

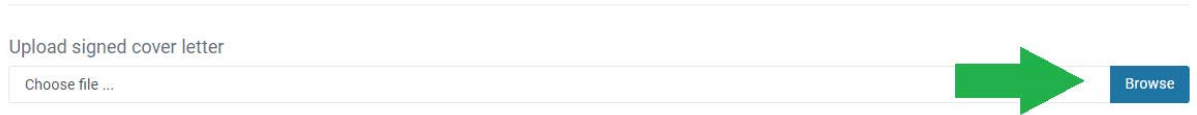
Signature: _____

Enclosures

- Complete technical dossier
- Summary of the dossier
- List of the parts of the dossier requested to be treated as confidential and verifiable justification for such claims
- Copy of administrative data of applicant(s) _____ Section Break (Next Page) _____

Applicants should use the format established in Annex III to indicate which information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

- ➔ Fill in the template, print it out, **sign it manually**, scan it and save it on your desktop **as a PDF**. Click on "**Browse**" and locate the signed cover letter on your desktop. **Double click on the document** and it will be uploaded onto the application.



- ➔ If you want to remove and replace the document that you've just uploaded, simply click on the "Remove" button:



Dossier History tab

You can check out the status of your application by clicking on the "Dossier History" tab:

Novel Foods application

NF 2019/4329

Draft

With Applicant

Administrative Data

Summary

Scientific Data

Cover Letter

Dossier History



Here you will find a summary of the status of your application(s), including the date that it was created, the dossier state, substate, etc:

Dossier History Dossier saved at 15:32:12

Filter history ...

Event/Action	Date	Dossier State	Dossier SubState	Comments	Document
Dossier Created	20/11/2019 10:21AM	Draft	With Applicant		


Showing 1 to 1 of 1 records.

Please note: Whilst the application is still in “draft” phase, you have the possibility of deleting it completely from your application list. Simply head to your application list on your dashboard, and click on the corresponding “Delete” button underneath the “Action” tab:

Dashboard Create new application +

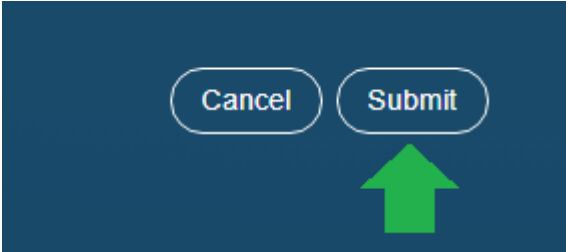
My application list 2 APPLICATIONS LISTED

Id	Type	Current State	Current Phase	Applicant(s) name	Identification of the substance/product	Action
<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	<input type="text" value="Column filter"/>	
NF 2019/4318	Novel Food Authorisation	Draft	With Applicant			Delete
NF 2019/4329	Novel Food Authorisation	Draft	With Applicant	Joe Bloggs	Nova cibum	Delete



Submitting your application

- ➔ Once all the information marked with a red star (mandatory fields) has been filled in and the cover letter uploaded, submit the application by clicking on the "Submit" button:

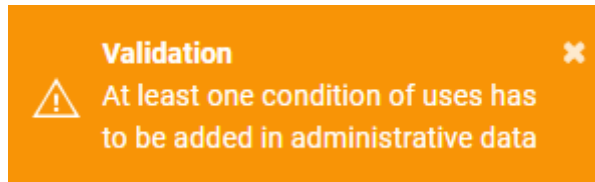


You also have the option of cancelling the application.

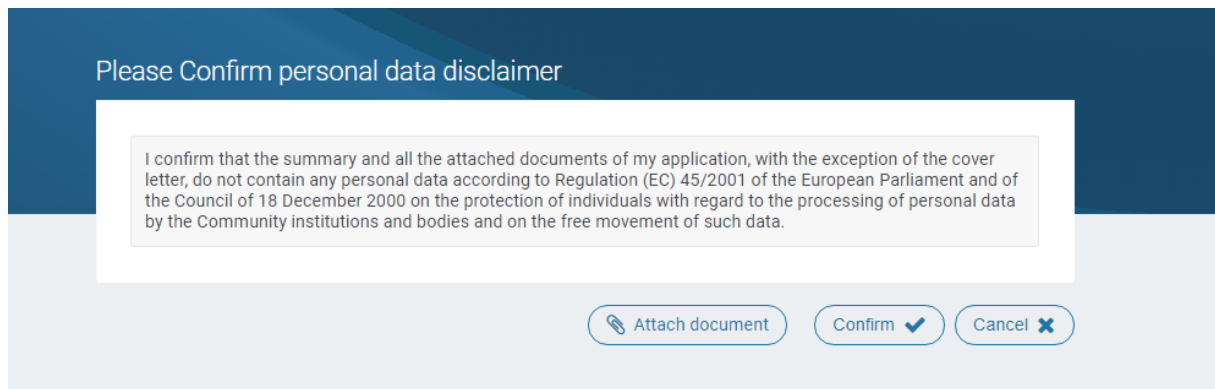
Warning: Only a draft (Not submitted) dossier can be cancelled/deleted

Please make sure that all mandatory fields (with a red asterisk) in all relevant tabs (Administrative Data, Summary, Scientific Data, Cover Letter) are filled in correctly.

If you click on “Submit Application” and a mandatory field is missing, an orange “error message” will appear indicating which tab needs to be filled in:



Before your application is confirmed, you must confirm your personal data. Simply click on the “Confirm” button to do so. You also have the option of attaching any supporting documents – simply click on the “Attach document” button and add any relevant files from your computer/device:



A pop-up will now appear asking you to confirm your application and informing you that your dossier will now be moved to “Application Acknowledged” phase. An email will then be sent to you and the EC. Click on “Confirm” to proceed:

By confirming :

- the dossier will be moved to this state/phase : Application Acknowledged / Perform Validity Check
- An email will be sent to : EC, MS



The system will now direct you back to your dashboard. Here you will note that the state of the application has moved from “**Draft**” to the “**Application Acknowledged**” phase and the current phase of the application now reads “**Perform Validity Check**”:

The system will now direct you back to your dashboard. Here you will note that the state of the application has moved from “**Draft**” to the “**Application Acknowledged**” phase and the current phase of the application now reads “**Perform Validity Check**”:

Dashboard

My application list

Id	Type	Current State	Current Phase	Applicant(s) name
Column filter	Column filter	Column filter	Column filter	Column filter
NF 2019/4318	Novel Food Authorisation	Draft	With Applicant	
NF 2019/4329	Novel Food Authorisation	Application Acknowledged	Perform Validity Check	Joe Bloggs

When the status of the notification changes, you will receive an automatic email update.

Note: To edit information after having submitted your notification, please send an authorisation request to the Support Team, and specify the number of your notification and which section(s) need(s) to be edited. This is very important for the support team to be able to identify your application quickly and respond to you in a timely manner. The support team email address is: Sante-FOODSYSTEMS@ec.europa.eu The section(s) in question will be editable, whilst the rest of the notification remains in read-only mode.

Request for Information

You will receive an email once your application has been submitted.

Subsequently, if your dossier is any way incomplete, the EC will require more information concerning any part of an application and you will receive a “Request for Information” detailing which section of the application needs to be completed/include more details.

Once you have logged into the system, you will notice a bell shaped notifications icon on the top right hand corner of the window, next to your user name:

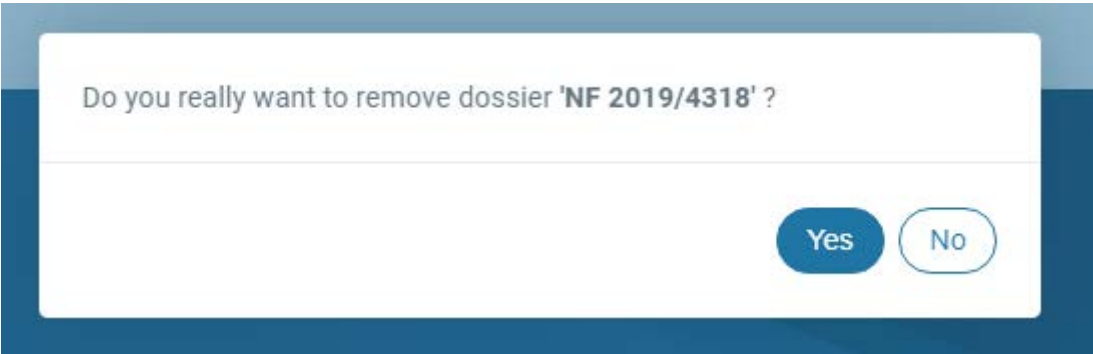
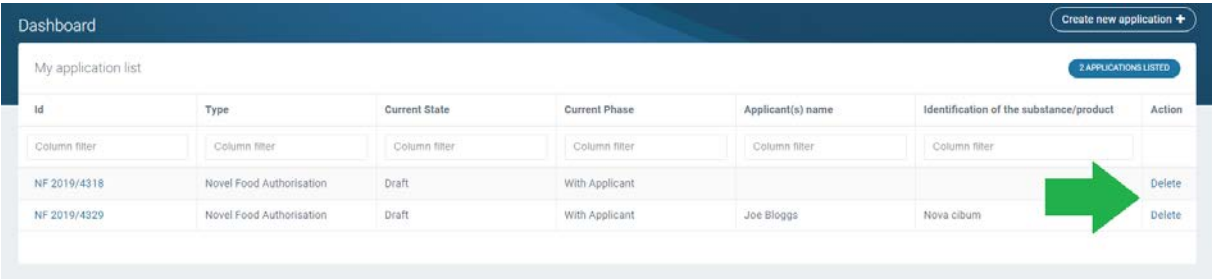


Here the system will send you updates concerning the status of your application(s). This can be a request for information, detailing which section of the application needs updating, a notification informing you that your application has moved on to the next stage, amongst others. The notification icon will not disappear until you have dealt with it.

Please Note: If you have received a notification/email request for information, remember to re-submit your request, once all of the information has been entered. Do this by clicking on the re-submit button on the top right of your screen.

Withdrawing your Application

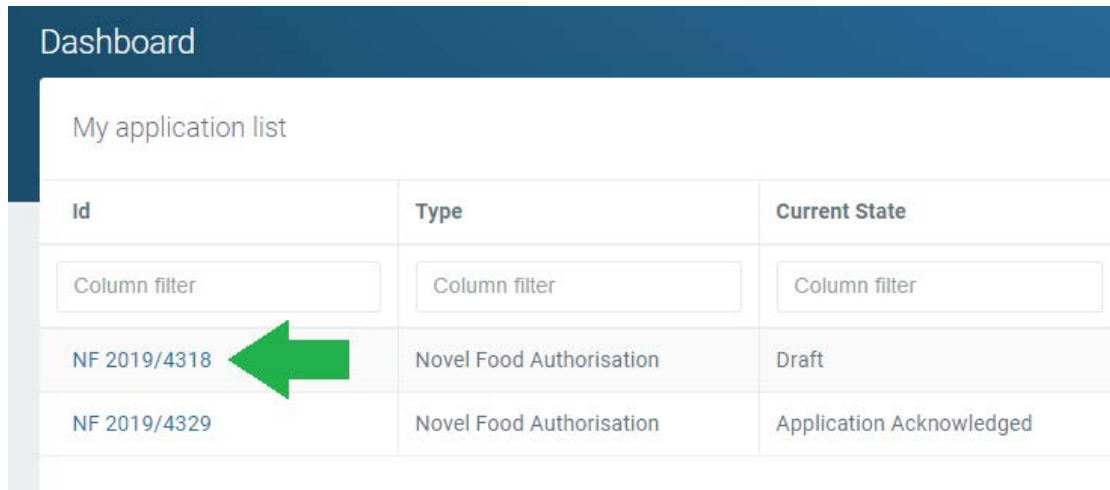
At any moment, you have the option of withdrawing/deleting your application. Simply click on the “Delete” button on the right hand side of the application details on the dashboard. You will receive a message asking you to confirm the deleting of the dossier:



Editing your contact details

You have the possibility of editing your contact details linked to an application (in any phase).

➔ Simply click on the application ID number on your Dashboard:



Dashboard

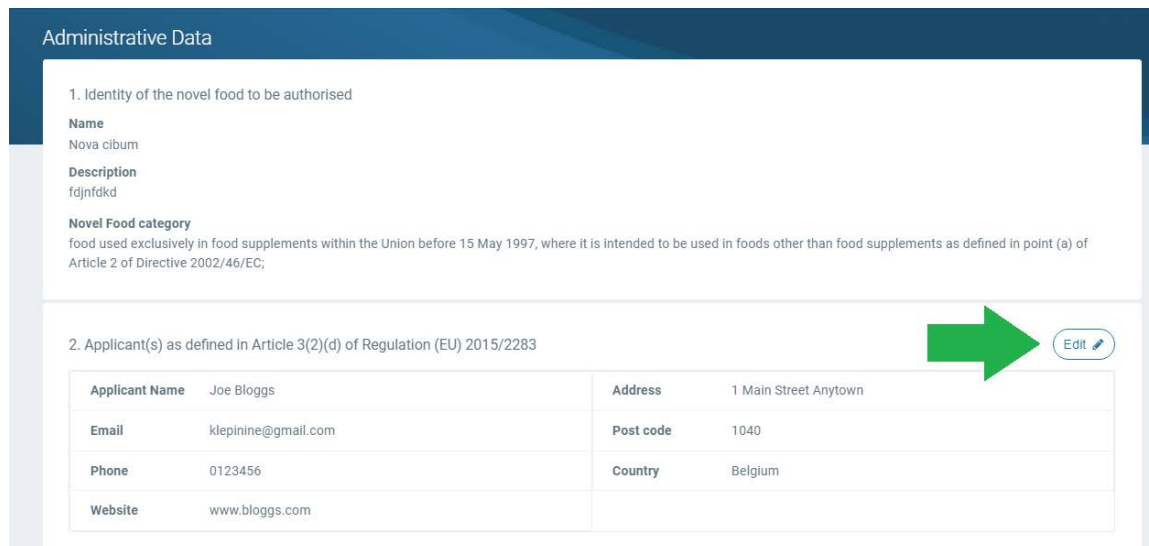
My application list

Id	Type	Current State
Column filter	Column filter	Column filter
NF 2019/4318	Novel Food Authorisation	Draft
NF 2019/4329	Novel Food Authorisation	Application Acknowledged

The system will load the application.

You will be taken straight to the administrative data section of the application in question.

➔ Here, simply click on the “**Edit**” icon to the right of the screen:



Administrative Data

1. Identity of the novel food to be authorised


Name
Nova cibum

Description
fdjnfkd

Novel Food category
food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

Applicant Name	Joe Bloggs	Address	1 Main Street Anytown
Email	klepinine@gmail.com	Post code	1040
Phone	0123456	Country	Belgium
Website	www.bloggs.com		

Edit 

➔ Once you have done editing the details, click on the “**Save**” button to the right of your screen:

2. Applicant(s) as defined in Article 3(2)(d) of Regulation (EU) 2015/2283

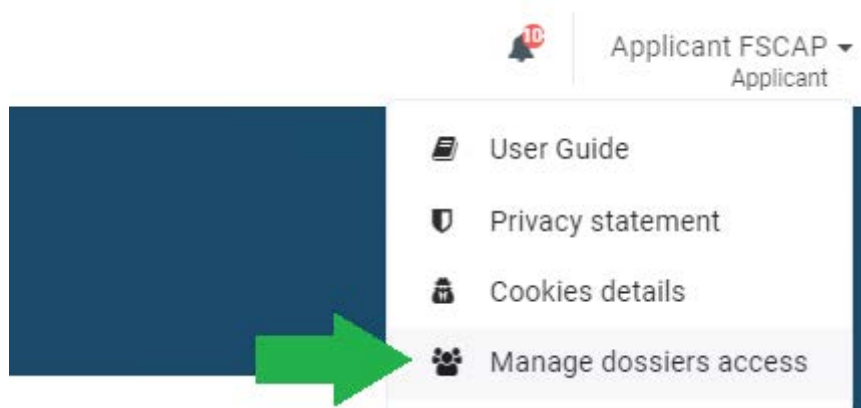


Applicant Name	Joe Bloggs			
Email	joe@bloggs.com	Address	1 Main Street Anytown	
Phone	0123456	Post code	1040	
Website	www.bloggs.com	Country	Belgium	

Managing Dossier Access

You have the ability to manage user access to any dossier at any time.

- ➔ When you are logged into the system, simply click on the drop-down menu where you see your name on the top-right hand side of the window, then click on the **“Manage dossiers access”** tab:



You will be taken to the **“Manage applicant user access to dossier”** page.

- ➔ Here you can add another user as “owner” of an application by entering their email address in the corresponding box:

Manage applicant user access to dossier

My application list 3 DOSSIERS LISTED

id	Type	Current State	Current Phase	Owner(s)	
Column filter	Column filter	Column filter	Column filter	Column filter	
NF 2019/4318	Novel Food Authorisation	Draft	With Applicant	Andre.KLEPININE@ext.ec.europa.eu	<input type="text" value="Enter email address"/> <input type="button" value="Add as owner"/>
NF 2019/4329	Novel Food Authorisation	Application Acknowledged	Perform Validity Check	Andre.KLEPININE@ext.ec.europa.eu	<input type="text" value="Enter email address"/> <input type="button" value="Add as owner"/>
NF 2019/4347	Novel Food Authorisation	Draft	With Applicant	Andre.KLEPININE@ext.ec.europa.eu	<input type="text" value="Enter email address"/> <input type="button" value="Add as owner"/>

Note: Bear in mind, the user that you are adding should have a valid EU login account and should already have logged into the FSCAP system *at least once*.

Once you have clicked on “**Add as owner**”, a green box should briefly appear indicating that the user has been added successfully. Now you will notice that the email address of the individual has been added to the application owners:

Draft	With Applicant	applicantfscap@gmail.com ✕	Enter email address	Add as owner
		Fscapefsa1@gmail.com ✕		

Note: You can remove owners at any time by clicking on the blue X to the right of their email address. Please bear in mind that at least 1(one) owner needs to be associated to an application.

Checking for Version Updates

At any time you have the option of checking for any updates/improvements that have been made to the platform.

- ➔ From your dashboard, simply click on the version number on the very bottom left of the window:



Now you will be able to view details concerning the latest release of the application, including any updates and fixes that have been released and are operational:

FSCAP 2.0.7

22 October 2019

What's new :

- New possibility for EFSA risk assessors to request clarification when a response from the applicant to a request for information is not complete.
- The display of the list of request for information (RFI) and request for clarification has been improved
- At the complete action page a visible timeline of the next steps in the flow is now displayed to all the users, including the list of emails sent by the system.
- European Commission users are now able to inform the applicant about the safety objection(s) through the system (for traditional food notifications)
- Union list module for European Commission users has been improved
- Application list is now printable

Bug fixes :

- Performance improved
- Bug fixes
- Several issues related to accessibility (access to the system for people with disabilities, or special needs) have been fixed

FSCAP 1.2.1

2 October 2018

Corrective version

FSCAP 1.2.0

30 August 2018

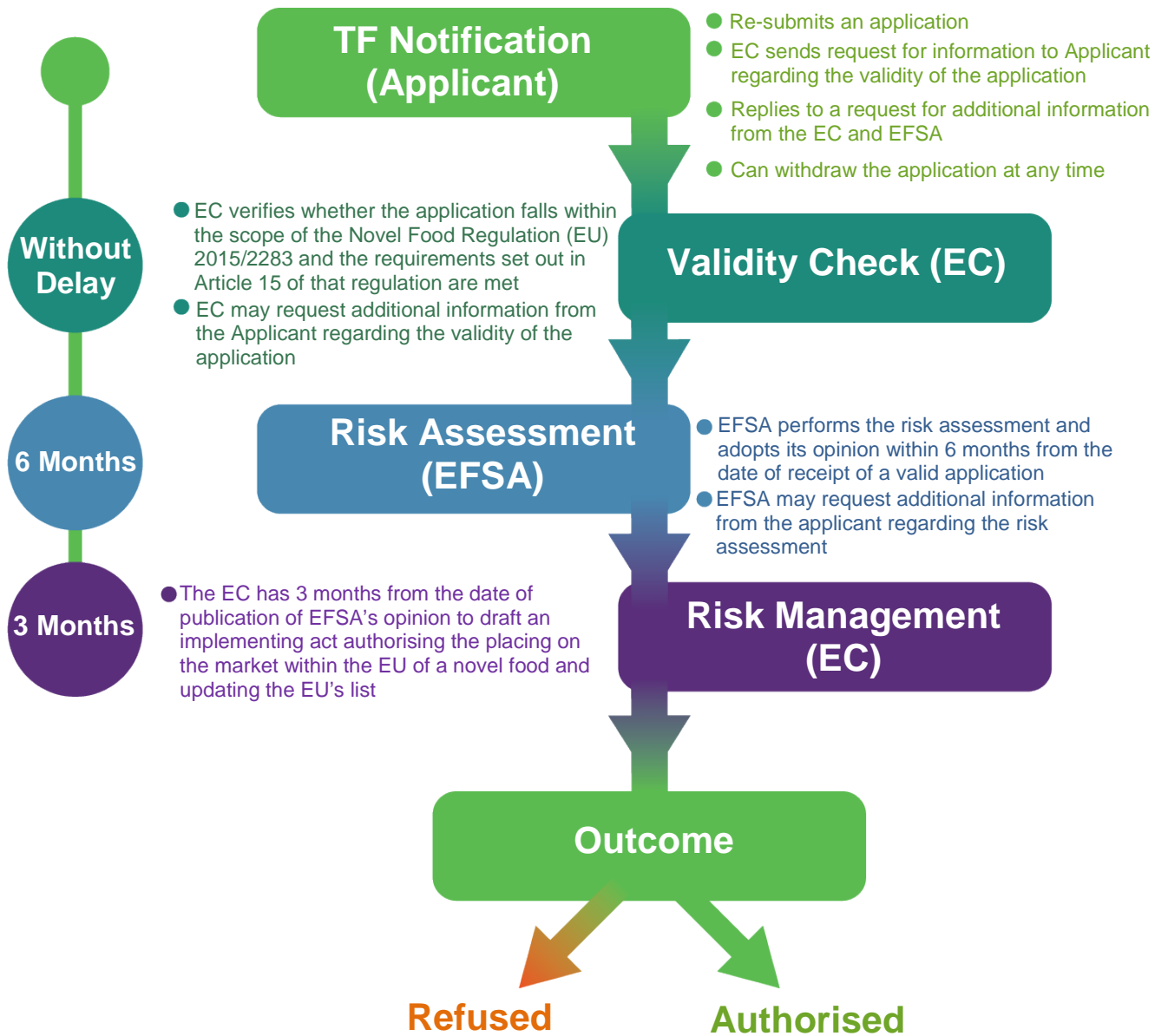
A lot of new features

Close release notes

Contact Details

If you have any questions regarding your application, do not hesitate to contact the dedicated support team at: SANTE-FOODSYSTEMS@ec.europa.eu

Traditional Food Application Workflow



What to do if the traditional food notification is rejected for duly reasoned safety objection(s)

Note: In case of refusal of a traditional notifications for safety objections, an applicant may resubmit an application to the conditions as outlined in article 16 of the Legal reference: **Legal reference, Article 16** : Application for the authorisation of a traditional food from a third country where the Commission, acting in accordance with Article 15(5), does not authorise the placing on the market within the Union of a traditional food from a third country or update the Union list, the applicant may submit an application including, in addition to the information already

provided in accordance with Article 14, documented data relating to the duly reasoned safety objections submitted in accordance with Article 15(2).

Once a Traditional food notification has been refused for duly reasoned safety objection(s), you may submit an application (once a Commission Decision not authorising the placing on the market within the Union of the TF concerned has been adopted and subsequently addressed to the concerned applicant) by clicking on the "Apply for application in accordance with Article 16" button, displayed at the top of the application detail of the notification.

Note: The button allowing you to create a Traditional food application in accordance with article 16 of the regulation will be visible only after a traditional notification has been rejected for safety objection(s) reason. This type is not visible in the drop down list when you start a new application.

- ➔ By clicking on this button, a pop-up window appears and asks you to confirm the creation of the draft traditional food application.

If you click on No, nothing happens, the draft is not created and you are back at the traditional food application form. If you click on Yes, the system starts creating the draft. While the draft is being created no action can be taken on the traditional food notification and a pop-up window will inform you that the process of creating the new traditional food application might take some time. You will be alerted once it is done by an email notification (sent to the email address specified in your ECAS account). You will find the reference number of the draft traditional food application in the email.

The whole notification content is copied into the new draft traditional food application. This action might take some time, as the dossier can contain a lot of documents.

All the data from the administrative part and the scientific part are copied. Two new items are requested to be provided on the scientific part: I) Duly reason safety objection(s) II) Response to duly reason safety objection(s)

Frequently Asked Questions (FAQs)

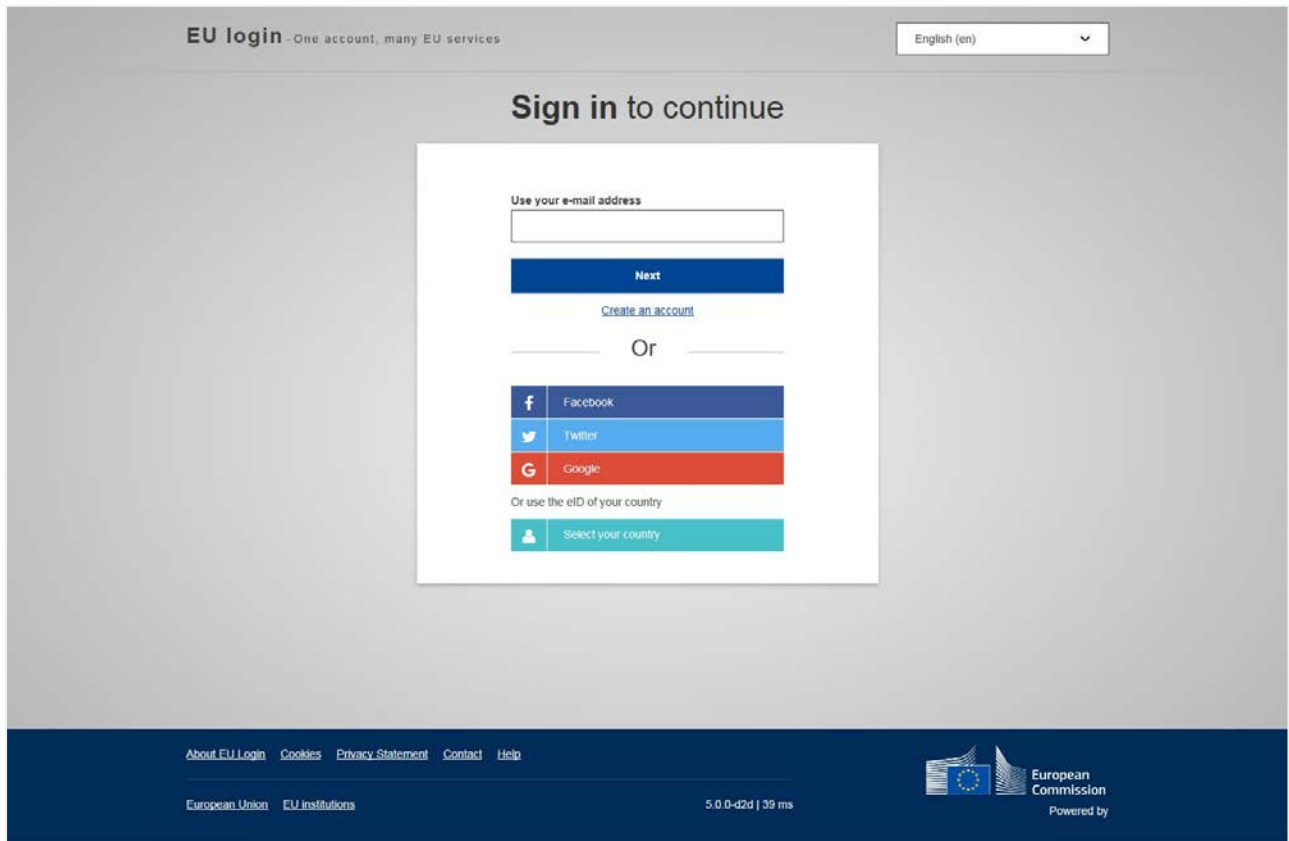
How do I know when the status of my application changes?

You will receive an automatic email when the status changes.

How do I reset my EU Login password?

If you have forgotten your password or cannot log into EU Login, please follow the below steps in order to request a new password.

- ➔ Go to EU Login by entering the following address in the browser:
<https://webgate.ec.europa.eu/cas/login>



The screenshot shows the EU Login sign-in interface. At the top, it says "EU login - One account, many EU services" and "English (en)". The main heading is "Sign in to continue". Below this, there is a form with the following elements:

- A text input field labeled "Use your e-mail address".
- A blue "Next" button.
- A link labeled "Create an account".
- The word "Or" centered between two horizontal lines.
- Three social media login buttons: Facebook (blue), Twitter (light blue), and Google (red).
- A section labeled "Or use the eID of your country" with a teal button labeled "Select your country".

The footer contains links for "About EU Login", "Cookies", "Privacy Statement", "Contact", and "Help". It also includes the European Union logo, "European Commission", "Powered by", and technical information: "5.0.0-42d | 39 ms".

- ➔ Click on '**Lost your password?**' in order to request a new one.

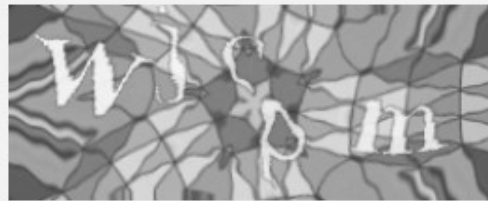


➔ Fill in the requested information and click on 'Get a password'.

New password

doe7282@gmail.com
(External)

Enter the code



Get a password

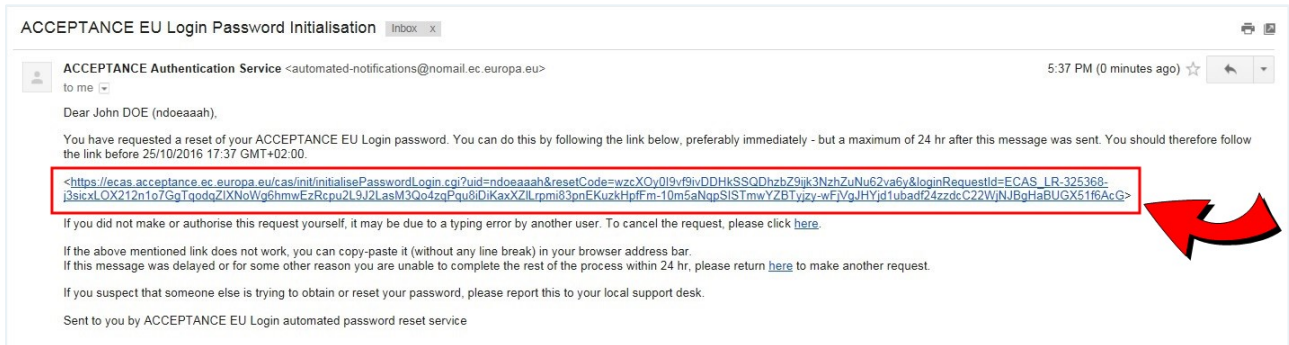


➔ After that, the following information is displayed:

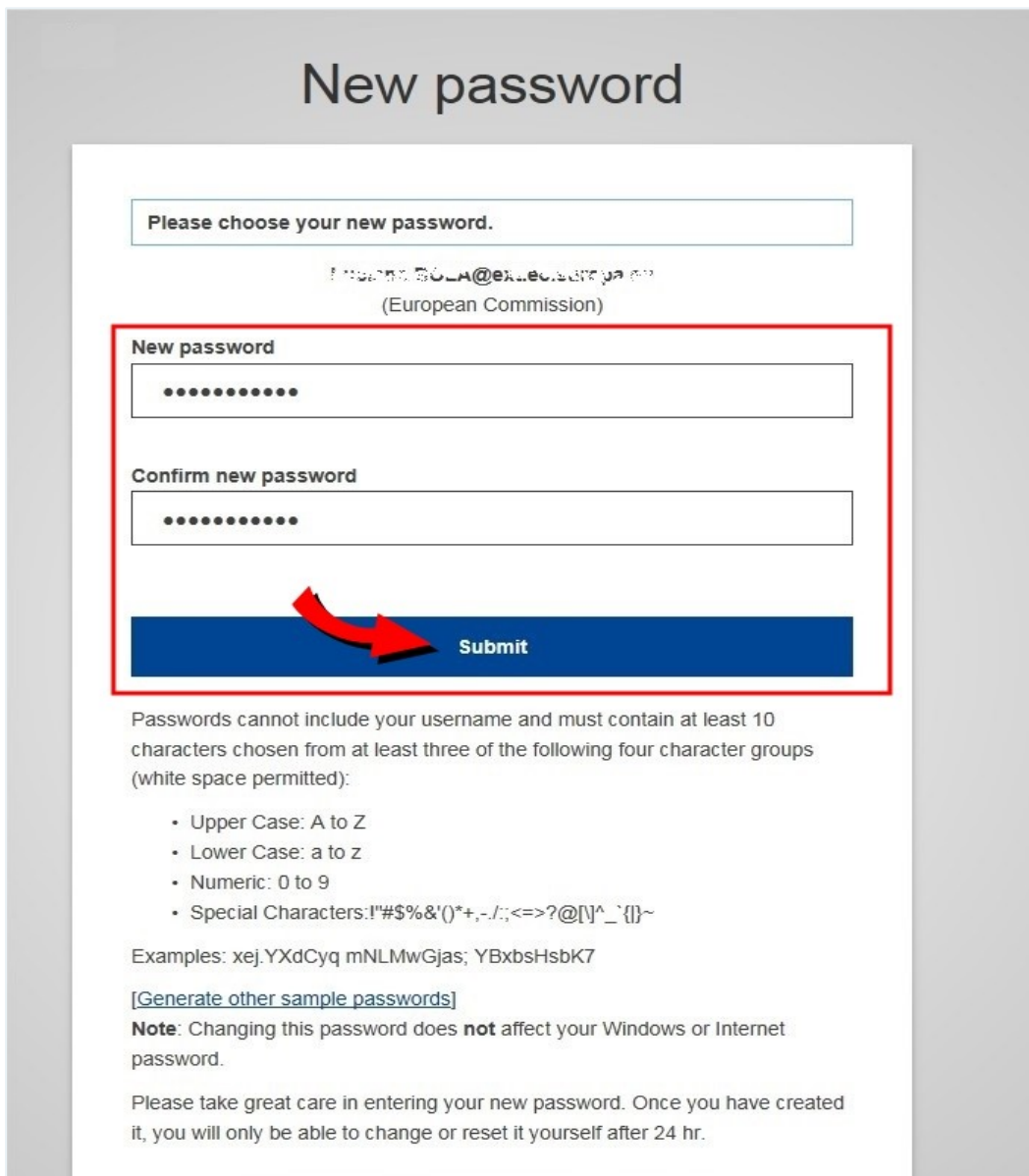
New password

In the next few minutes, you will receive an e-mail containing a link to this site.
If you need assistance, use [this link](#) to go to the contact page.

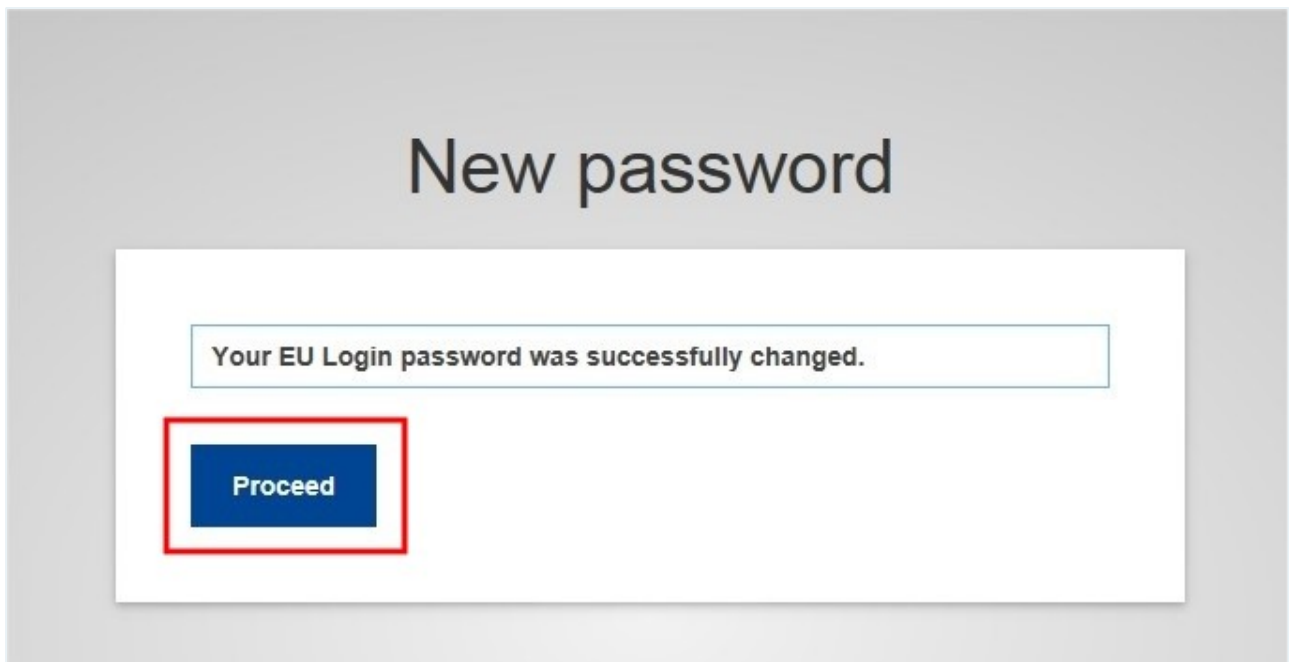
- ➔ And you get an e-mail from EU Login allowing you to reset your new password in the system.



- ➔ Follow the link in the email to change your password.
- ➔ Click on '**Submit**'.



➔ The following message is displayed. Click on '**Proceed**' to login:



How to edit an application after it has been submitted?

To **edit** your application (NF Authorisation or TF Notification) after submitting it, you must send a request to the Support Team. Specify the application **number** and the **section(s) you need(s) to edit**. The EC will then unblock the section(s) in question and you will be able to update them accordingly. You will receive an email notification.

Note: Your application is put "*On Hold*" for the duration of the editing process.

What can I do if my Traditional Food notification is rejected?

You can Re-submit your notification as a new application but in this case, as a **Novel Food authorisation**.

What Email does the system use to send me Updates and Requests?

The system will always send notifications to the email specified in the EU login form.

If you need to change this email, please check the section "*how to change my EU login contact details*".

What happens if I withdraw my application?

By **withdrawing your application** the procedure will be stopped.

Who do I contact if I wish to erase my Personal Data?

If you wish to erase your personal data from the EC's databases, please contact the [Support Team](#).

Also, read the **privacy statement** containing more information regarding the processing of your personal data within the context of the novel food system.

What happens if the application is not created correctly?

You will receive a notification email explaining that the process was not successful. In this case, we suggest that you contact the [Support Team](#) directly, indicating the reference of the traditional food notification for which you want to re-apply.

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