



e-submission system for Novel Foods

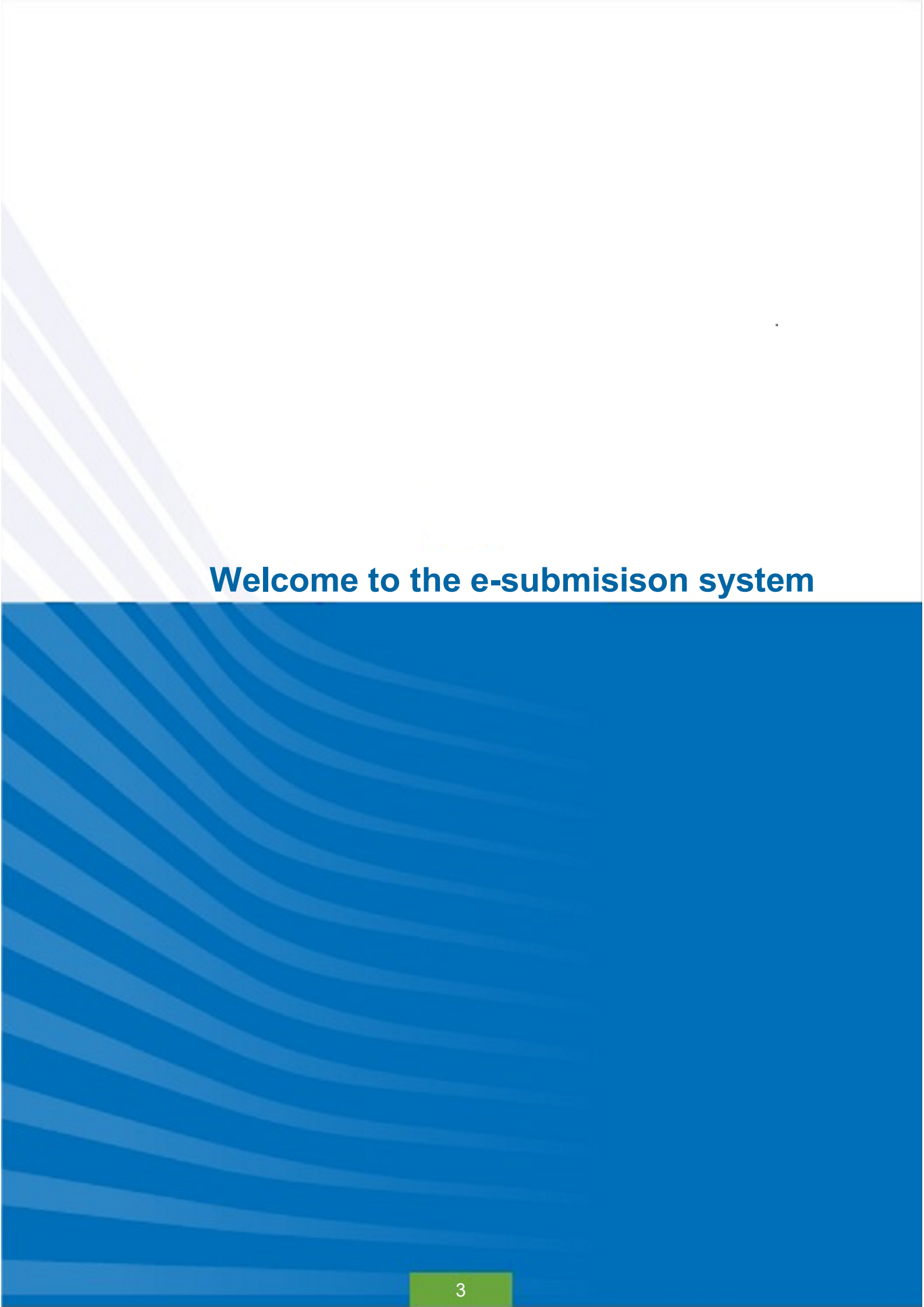
User Guide

Version 1.1



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Welcome to the e-submisison system

e-submission system for Novel Foods User Guide

Welcome to the e-submission system for Novel Foods!

Welcome to the e-submission system for Novel Foods!

The objective of the **e-submission system for Novel Foods** is to automate the authorisation process through an online submission system in the context of the current legislation for each of the relevant Food Sectors (food additives, food enzymes, food flavourings, novel foods, food contact material).

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.

At the moment the system starts with the **Novel foods domain**, but is going to be extended to other domains at a later stage.

Tip: In order to access the system you need an [EU Login account](#).

See also:

- [Create an EU Login account](#)
- [Log into the e-submission system](#)
- [How to create and submit a Novel Food Authorisation](#)
- [How to create and submit a Traditional Food Notification](#)

My 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:

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

EU login - One account, many EU services

English (en)

Sign in to continue

Use your e-mail address

Next

[Create an account](#)

Or

Facebook

Twitter

Google

Or use the eID of your country

Select your country

[About EU Login](#) [Cookies](#) [Privacy Statement](#) [Contact](#) [Help](#)

European Union EU Institutions

5.0.0-d2d | 39 ms

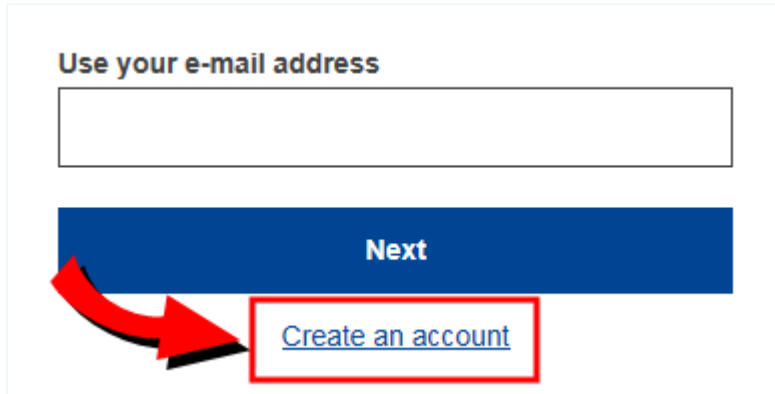
European Commission

Powered by

e-submission system for Novel Foods User Guide

Create an EU Login account

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



Use your e-mail address

Next

[Create an account](#)

3. 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;

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Create an EU Login account

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

privacy statement'. At the bottom is a blue button with the text 'Create an account'."/>

Enter the code



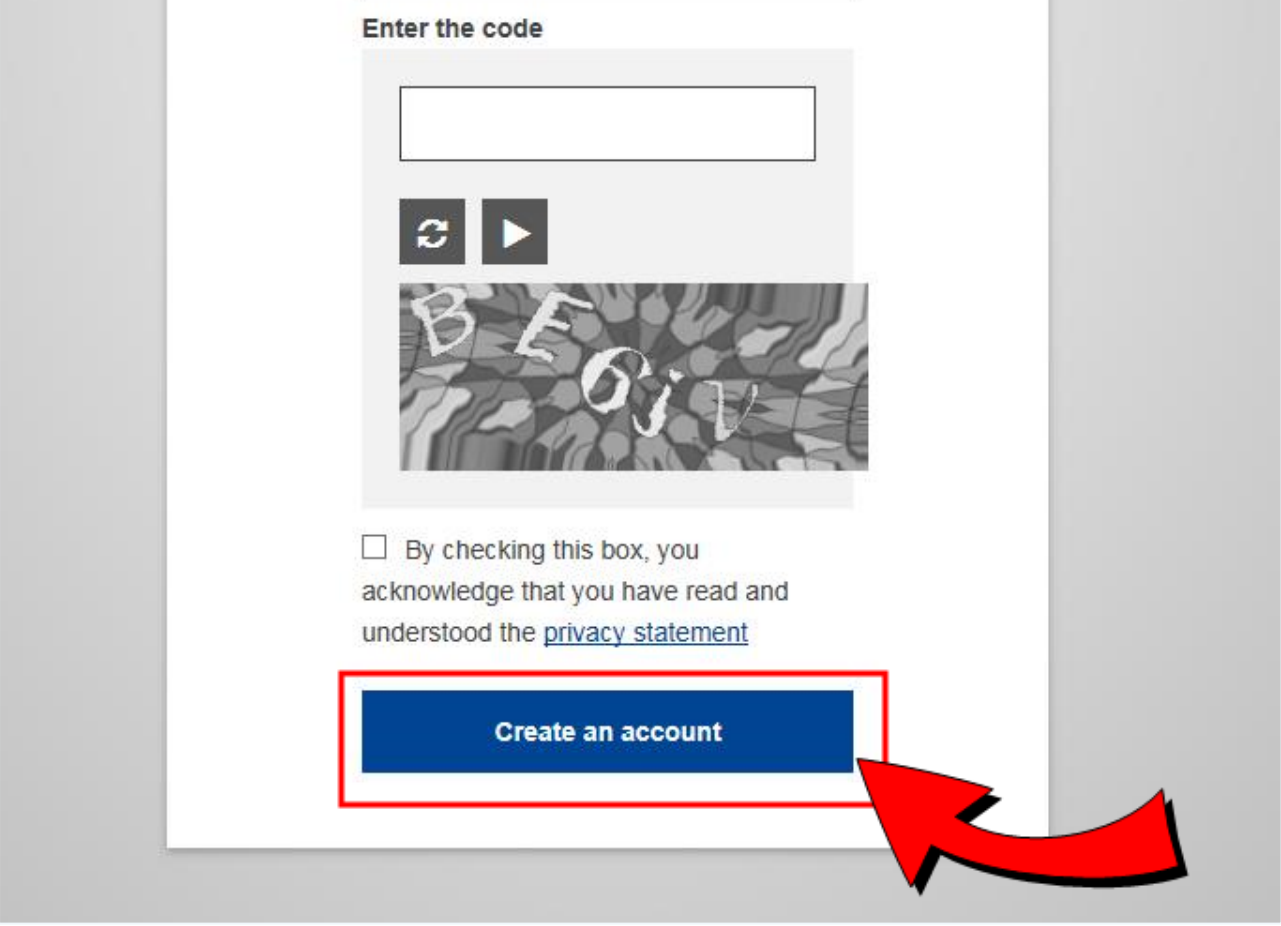
☐ By checking this box, you acknowledge that you have read and understood the [privacy statement](#)

Create an account

e-submission system for Novel Foods User Guide

Create an EU Login account

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



The screenshot shows a web form titled "Enter the code". It features a text input field for the code, a refresh button (circular arrow icon), and a play button (triangle icon). Below these is a CAPTCHA image showing the letters "B E O J V" on a textured background. A checkbox is present with the text: "By checking this box, you acknowledge that you have read and understood the [privacy statement](#)". At the bottom, a blue button labeled "Create an account" is highlighted with a red rectangular border. A large red arrow points from the bottom right towards this button.

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.

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

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Create an EU Login account

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.

e-submission system for Novel Foods User Guide

Create an EU Login account

6. 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 YNKtIKt4nf

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

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

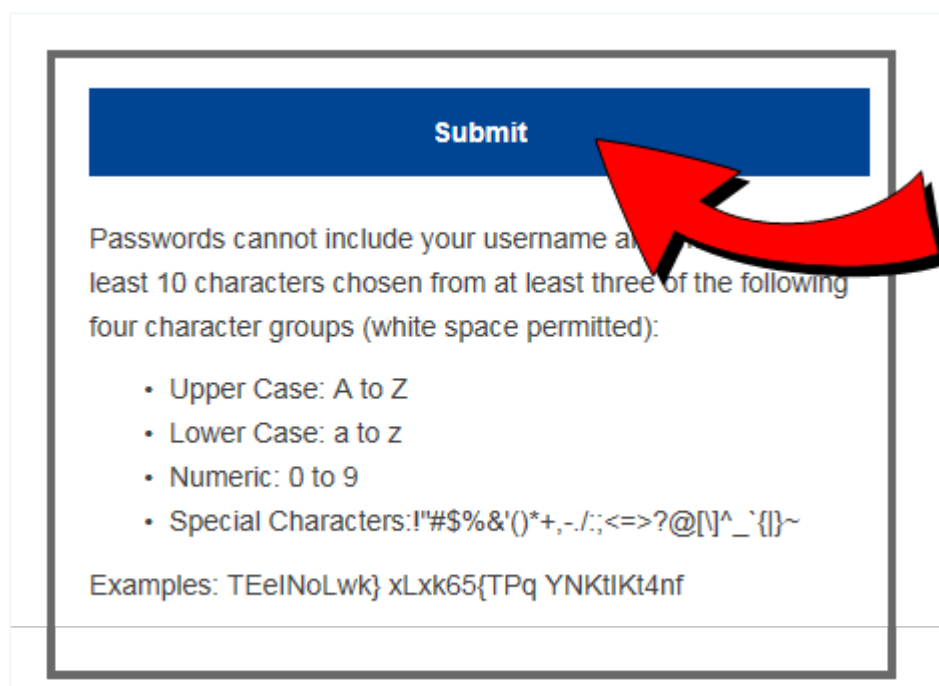
- upper case letters
- lower case letters
- numbers and
- special characters

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Create an EU Login account

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.

7. The system displays a message indicating that your EU LOGIN password has been successfully changed. Click on '**Proceed**' in order to proceed to the service you want to use:



The screenshot shows a web form for password confirmation. At the top is a blue button labeled "Submit". Below it, the text reads: "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):". This is followed by a bulleted list of requirements: "Upper Case: A to Z", "Lower Case: a to z", "Numeric: 0 to 9", and "Special Characters: !\"#\$%&'()*+,-./:;<=>?@[\\]^_`{|}~". Below the list, examples are provided: "Examples: TEeINoLwk} xLxk65{TPq YNKtIKt4nf". A large red arrow points from the right side of the form towards the "Submit" button.

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

See also:

- [Log into the e-submission system](#)
- [How to create and submit a Novel Food Authorisation](#)
- [How to create and submit a Traditional Food Notification](#)

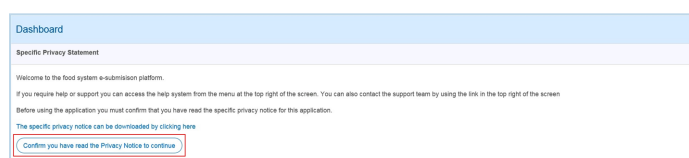
e-submission system for Novel Foods User Guide

Log into the e-submission system

Log into the e-submission system

As soon as you have received your EU Login confirmation email, you can access the [e-submission system](#).

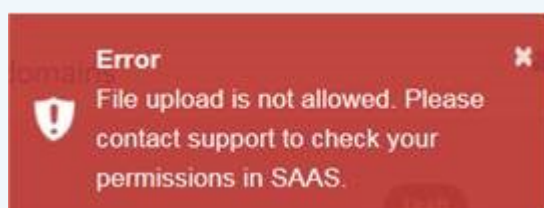
The first time you connect to the e-submission system, it requests to confirm that you have read the privacy note.



Click on the button "**Confirm you have read the Privacy Notice to continue**".

Then access the system and you can proceed with your application.

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



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

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

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

Monday to Friday during the working hours (from 8:00 to 18:00 CET).

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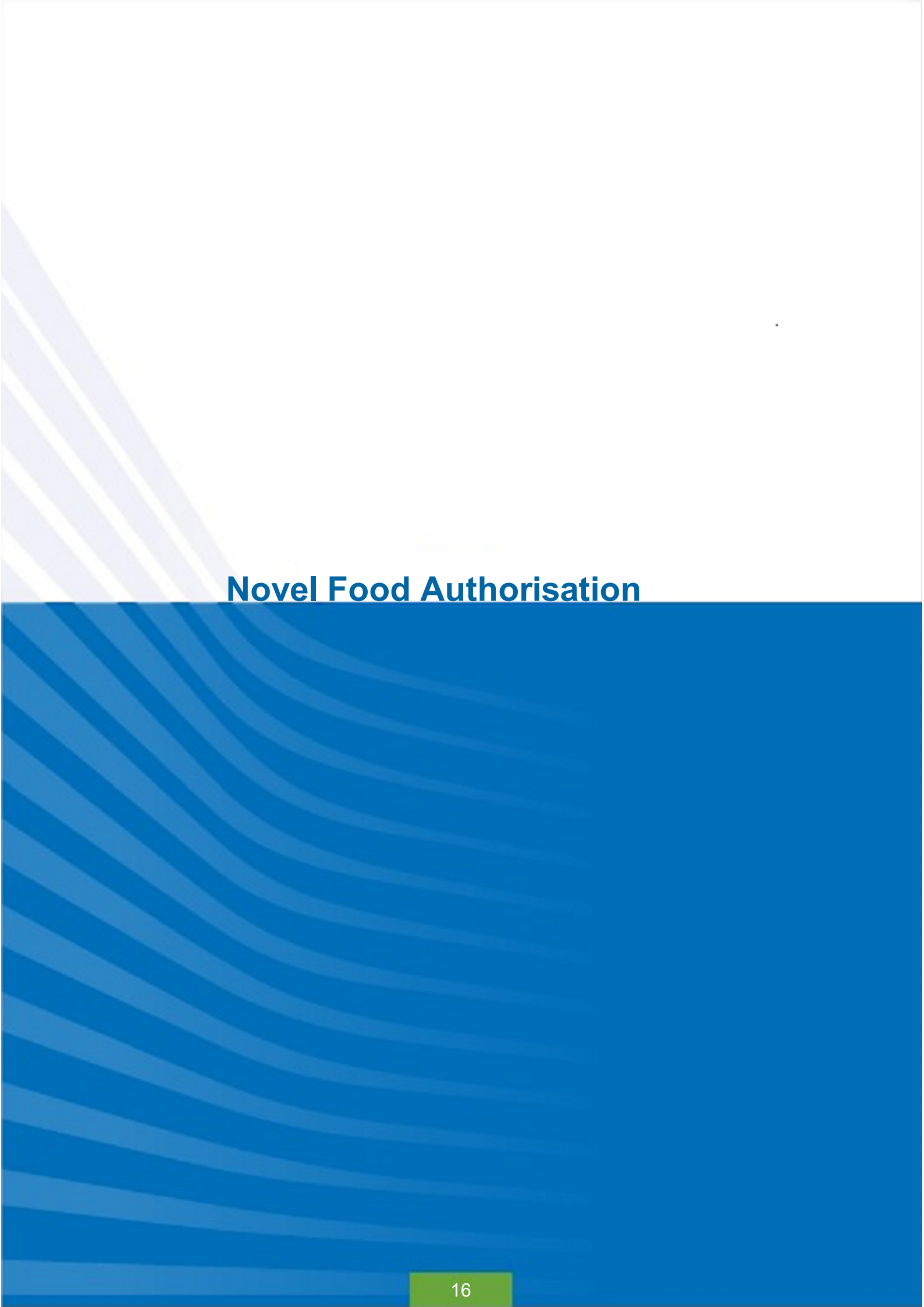
Log into the e-submission system

> If a new user accesses the system for the first time **during the weekend**, he will have to wait until **Monday 8:00** for the setup of his access rights.

> If a new user accesses the system for the first time **outside the working hours**, he will have to wait until **the day after** for the setup of his access rights.

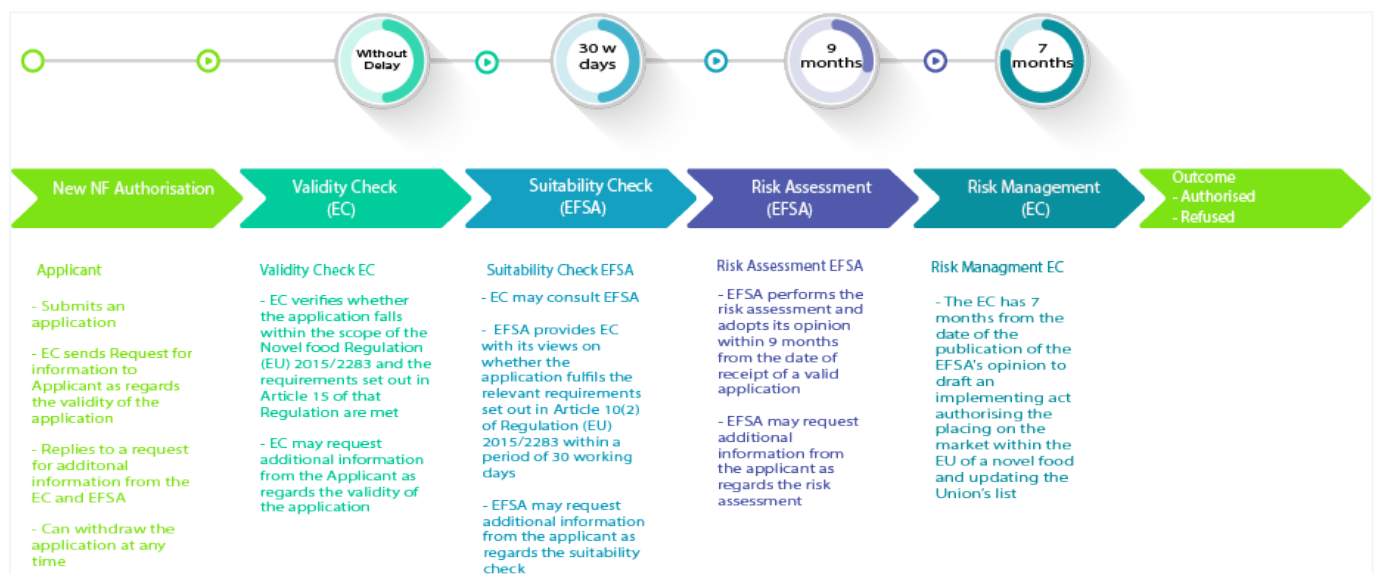
 See also:

- [How to create and submit a Novel Food Authorisation](#)
- [How to create and submit a Traditional Food Notification](#)



Novel Food Authorisation

Novel Food Authorisation Workflow



How to create and submit a Novel Food Authorisation

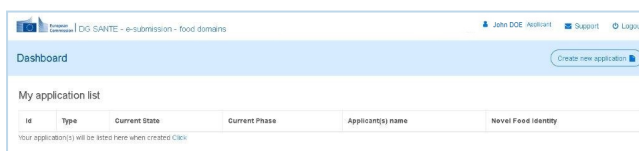
Note: The **Autosave** function ensures that the encoded content is saved automatically. Therefore, there is no button **Save** in the system.



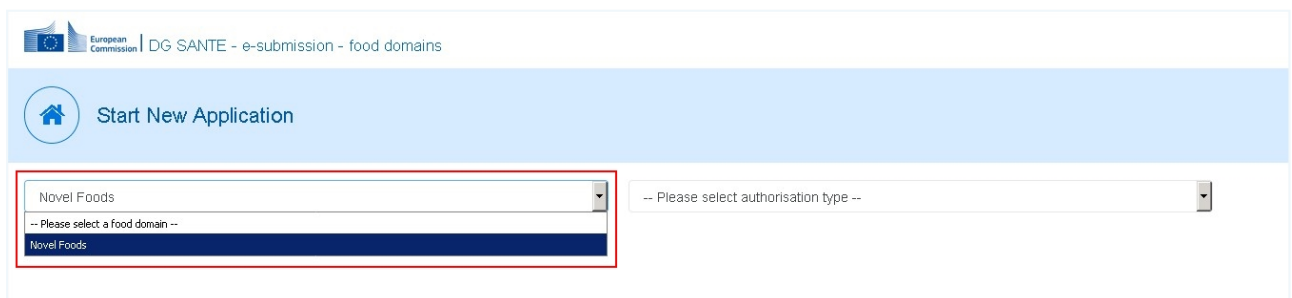
Be aware that while the autosave information message is displayed, the insertions / modifications could not be taken into account. So please make sure that the information is correctly updated.

Detailed steps and more information

1. On the dashboard, click on **Create a new application**.



2. From the drop-down menus, select the **Food Domain** (in this case *Novel Foods*) > the **Authorisation type** and > the **Application Type**.



e-submission system for Novel Foods User Guide

How to create and submit a Novel Food Authorisation

The top screenshot shows the 'Start New Application' page. The 'Novel Foods' domain is selected. The 'Please select authorisation type' dropdown is open, showing 'Traditional food notification' and 'Novel Food Authorisation'. The bottom screenshot shows the same page with 'Novel Food Authorisation' selected. The 'Please select application type' dropdown is open, showing options like 'Modification of labelling requirements of an already authorised novel food', 'Modification of the specifications of an already authorised novel food', 'Modification of the conditions of use of an already authorised novel food', 'Modification of the post market monitoring requirement of an already authorised novel food', and 'New Novel Food'.

3. Click on the button "Start Application Process".

Note: A specific web form appears depending on the selection of the food domain, the authorisation type and the application type.

The Id number of your application is displayed on the upper left corner next to the **Home** button.



4. Fill in the novel food application form.

The following data needs to be encoded:

Administrative Data

In **section 1** type in the Identity of the novel food to be authorised and select the Novel Food category from the drop down menu.

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How to create and submit a Novel Food Authorisation

1. Identify the novel food to be authorised

Novel Food category *

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;

— Please select Food Category type —

Food with a new or substantially 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.

Food consisting of isolated from or produced from plants 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.

Food consisting of, isolated from or produced from material of mineral origin:

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

vitamins, minerals and other substances used in accordance with Directive 2002/46/EC; Regulation (EC) No 1825/2006 or Regulation (EU) No 609/2012, 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) (i) of this paragraph; or — they contain or consist of engineered nanomaterials as defined in point (b) of this paragraph;

Food consisting of engineered nanomaterials as defined in point (b) 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;

In **section 2** fill in the contact details. If there is more than one applicant for your application, you can add another applicant by clicking on the **"Add Applicant button"**.

In **section 3**, fill in the name of the person responsible for the dossier authorised to communicate on behalf of the applicant with the European Commission. If the person in charge for the dossier is the same as the applicant, you can click on **"Copy applicant contact details"**.

Administrative Data Summary * Scientific Data Dossier History

1. Identify the novel food to be authorised *

Novel Food category *

— Please select Food Category type —

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

Applicant Name *

Email *

Phone *

Website *

Address *

Post code *

Country *

— Please Select —

Add Applicant

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

Copy applicant contact details

Applicant Name *

Contact Name *

Email *

Phone *

Website *

Address *

Post code *

Country *

— Please Select —

In **section 4**, fill in the information for the Producer. Click on the **"Add Producer Button"**. If the Producer is the same as the applicant, you can click on **"Copy applicant contact details"**.

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How to create and submit a Novel Food Authorisation

4. Producer (if different from the applicant)

Producer Name *				Copy applicant contact details
Email *	This field is required			Address *
Phone *				Post code *
Website				Country * -- Please Select --

[Add Producer](#)

In **section 5**, state whether the application includes confidential data in accordance with article 23 of Regulation (EU) 2015/2283 by checking the **Yes** or **No** option accordingly.

4. Confidentiality

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

☐ Yes ☒ No

In **section 6 Data Protection**, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283 by ticking **yes** or **no** respectively. If you tick **yes**, a box opens and you have to provide additional information.

In **section 7**, you have to indicate the proposed entry in the union list. Click on the "**Add New Novel Food category**" button to insert your data.

7. Proposed entry in the union list

[Add new Novel food category](#)

Food category	Condition of use	Specific labelling requirement	Post market monitoring requirement	Update	Delete
---------------	------------------	--------------------------------	------------------------------------	--------	--------

Fill in the fields **Food category**, **Condition of use**, **Post monitoring requirement** and **Specific labeling requirement**. The fields marked by a red asterisk are mandatory. Click on **Save to list** to save your entry.

e-submission system for Novel Foods User Guide

How to create and submit a Novel Food Authorisation

7. Proposed entry in the union list

Food Category *	Post market monitoring requirement *
Condition of use *	Specific labelling requirement

[Save to list](#) [Cancel](#)

Note: You can update or delete any entry from the list by clicking on the corresponding icons as shown in the following image:

7. Proposed entry in the union list

[Add new Novel food category +](#)

Food category	Condition of use	Specific labelling requirement	Post market monitoring requirement	Update	Delete
NF	Text		OpenForList		

In **section 8** check **Yes** or **No** for the **Regulatory status** of your product **outside the EU**.

8. Regulatory status outside EU

☐ Yes ☒ No

Note: If you check yes, you will have to select a status from the drop down menu ("**Under consideration**", "**Withdrawn**", "**Authorised**" or "**Rejected**").

8. Regulatory status outside EU

☒ Yes ☐ No

Please select a status

Depending on your selection in the drop-down menu, the system displays a different field underneath allowing you to specify the proposed conditions of use, reasons for withdrawal, reasons for rejection, etc.

8. Regulatory status outside EU

☒ Yes ☐ No

Under consideration

Specify the proposed conditions of use (if they are different), the date of submission, and the recipient regulatory body.

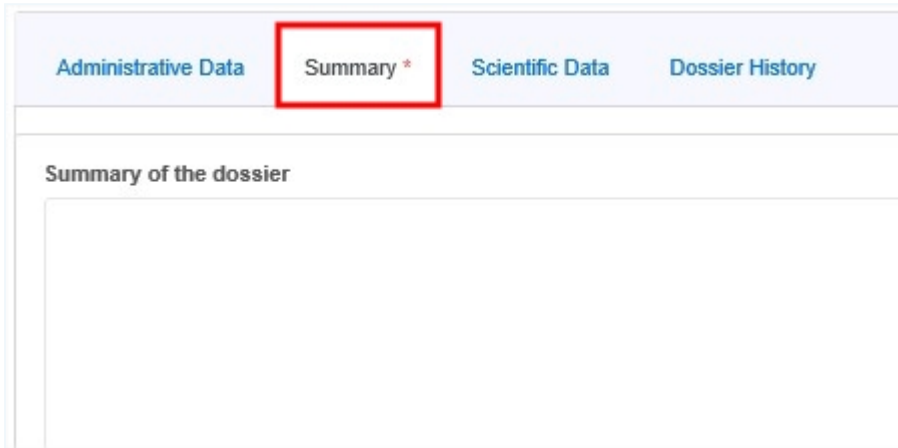
Free text

Summary

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How to create and submit a Novel Food Authorisation

In this tab, you can type in the Public Summary of your dossier.



The screenshot shows a web interface with a horizontal tab bar at the top. The tabs are labeled 'Administrative Data', 'Summary *', 'Scientific Data', and 'Dossier History'. The 'Summary *' tab is highlighted with a red rectangular border. Below the tabs, the main content area is titled 'Summary of the dossier' and contains a large, empty rectangular text input field.

Scientific Data

In this section you can add as many files you want per scientific field. In order to do so, click on the **"Add new file"** button at the top of the list. In the "Scientific field" select a field from the drop down list. Go to **"Browse"** and select the file you wish to upload from your desktop. Once this is done, click on the **"Upload"** button.

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.

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How to create and submit a Novel Food Authorisation

Administrative Data Summary **Scientific Data** Dossier History

i 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

Add new file +

☐ 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
☐ Nutritional information	No Documents
☐ Toxicological information	No Documents
☐ Genotoxicity	No Documents
☐ Subchronic toxicity	No Documents
☐ Chronic toxicity and carcinogenicity	No Documents
☐ Reproductive and developmental toxicity	No Documents
☐ Human data	No Documents
☐ Allergenicity	No Documents
☐ Annexes to the dossier	No Documents
☐ References	No Documents
☐ Concluding remarks	No Documents
☐ Other relevant information	No Documents

Wait a few seconds until a green label indicates that the file has been uploaded correctly and attached to the scientific field you have selected.

The green label indicates that the file has been correctly uploaded and attached to the scientific field you have selected.

Add new file +

Business_Case_Food System_v1.docx **Document uploaded ✓**

Technical field	Not applicable	Not applicable justification
The production Process		

Once your file has been uploaded, a blue label with the number of uploaded documents appears in the list. Click on the plus sign on the far left of the line to state whether your data is Confidential by ticking the "**Confidential**" box. You need to indicate for each file whether it contains confidential elements. If yes, tick the box "**Confidential**" and enter a justification by explaining in detail what the confidential part of the file are in the field foreseen to this effect.

Tip: Should you need to upload **several files**, we recommend uploading them in a compressed (zipped) folder. Should you have several confidential and non-confidential documents, regroup your **confidential data in one zip folder** and

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How to create and submit a Novel Food Authorisation

the **non-confidential documents in another folder** and upload them separately.

Files	Confidential	Justification
Scientific Data Novel Food Application.docx	☐	Provide detailed justification on confidentiality per section and/or annex ...

Note: Should the applicant request confidential treatment of certain sections of the dossier, we kindly request to attach separately the section without confidential information. In case the applicant requests confidential treatment of certain sections of the dossier, we kindly request to attach the section without confidential information separately.

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

Cover Letter Template

Once the notification is fully completed you can upload the cover letter. Click on the button **"Get a cover letter Template"** and save the template on your desktop.

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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):

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 non-core claim.

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.

[Get cover letter template](#) Download the cover letter template. Once it is filled and signed, attach it to your application

Upload signed cover letter

Choose file... Browse

- If you want to replace the document, click on "**Remove**" and upload the correct version of the cover letter you wish to attach to your dossier.

- 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.

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Note: Once you complete a mandatory field, its red star is not displayed anymore.

You can also "**Cancel**" your notification update. **Cancel will only cancel the last actions not yet saved.**

A green notification appears to confirm your cancellation was successful:



Tip: Should some information be missing, **an error message appears** and stating which section needs to be updated.



6. After you click on "**Submit**", the system shows a disclaimer where you need to confirm that the public summary and all attachment documents in the scientific field part of your application (*with the exception of the cover letter*) do not contain any **personal data**.

A screenshot of the 'Novel food application' page (NF 2017/0409) in the e-submission system. The page header shows 'European Commission | DG SANTE - e-submission - food domains' and user links for 'John DOE Applicant', 'Support', and 'Logout'. The main content area has a light blue header with a home icon and the application title. Below this is a disclaimer section titled 'Please Confirm personal data disclaimer' with a text box containing the statement: 'I confirm that the public summary and all the attached documents of my application, with the exception of the cover letter, do not contain any personal data.' A 'Confirm' button with a checkmark icon is located to the right of the text box.

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How to create and submit a Novel Food Authorisation

The **Current State** of your application changes to "**Application Acknowledged**" and the **Current Phase** of your application states "**Perform Validity Check**".

Dashboard Create new application					
My application list					
Id	Type	Current State	Current Phase	Applicant(s) name	Novel Food Identity
NF 2017/0381	Novel Food Authorisation	Draft	With Applicant		
NF 2017/0384	Novel Food Authorisation	Application Acknowledged	Perform Validity Check	Elena Mazza	Algae
NF 2017/0385	Novel Food Authorisation	Draft	With Applicant		

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

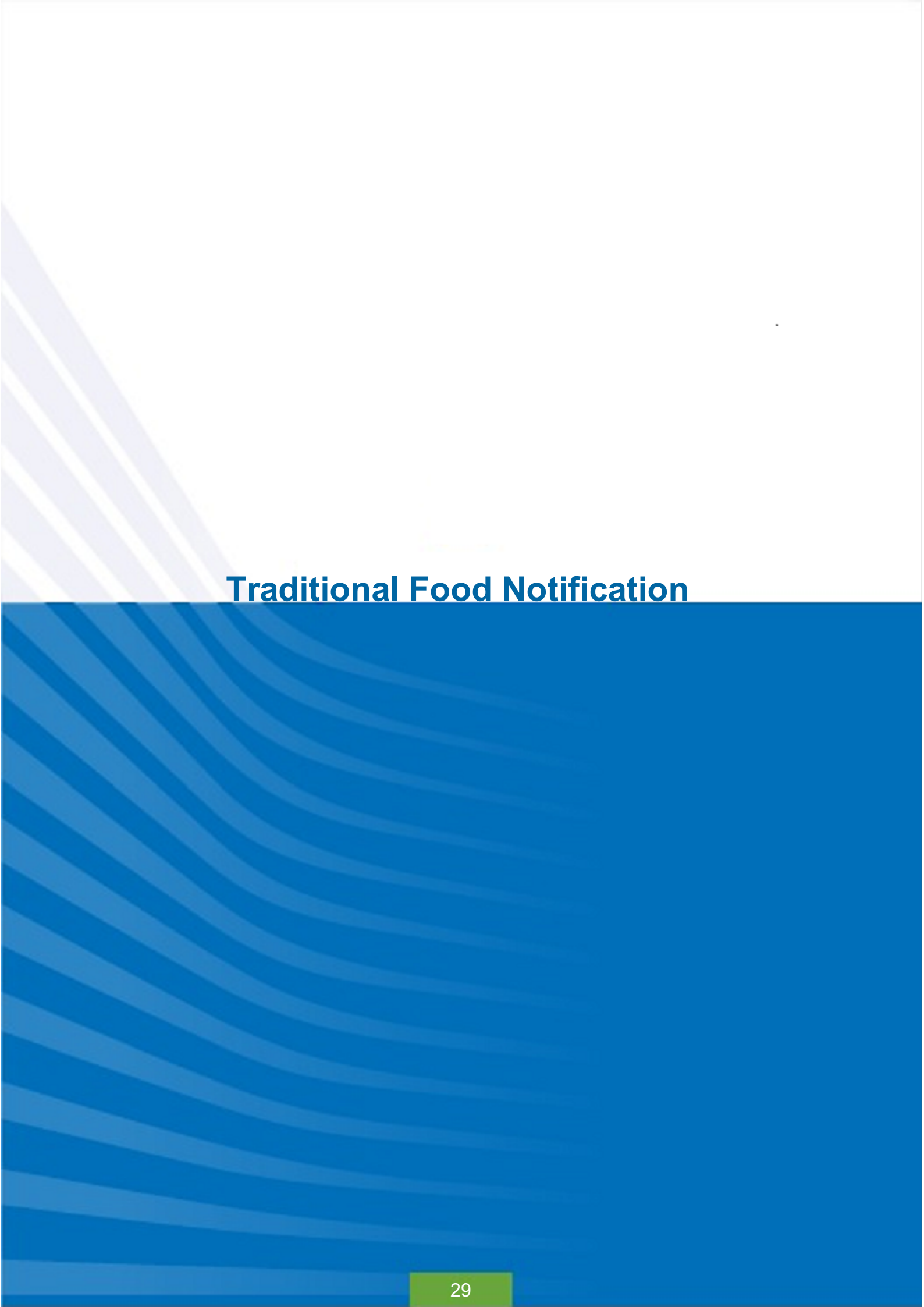
Note: To edit information after having submitted your notification, please send an authorisation request to the [Support Team](#), and specify the **number of your notification** and which **section(s) need(s) to be edited**. The section(s) in question will be editable, whilst the rest of the notification remains in **read-only** mode.

Follow up on your application by using the dashboard. In order to get to the dashboard, click on the "**Home button**" on the upper left corner of your notification.



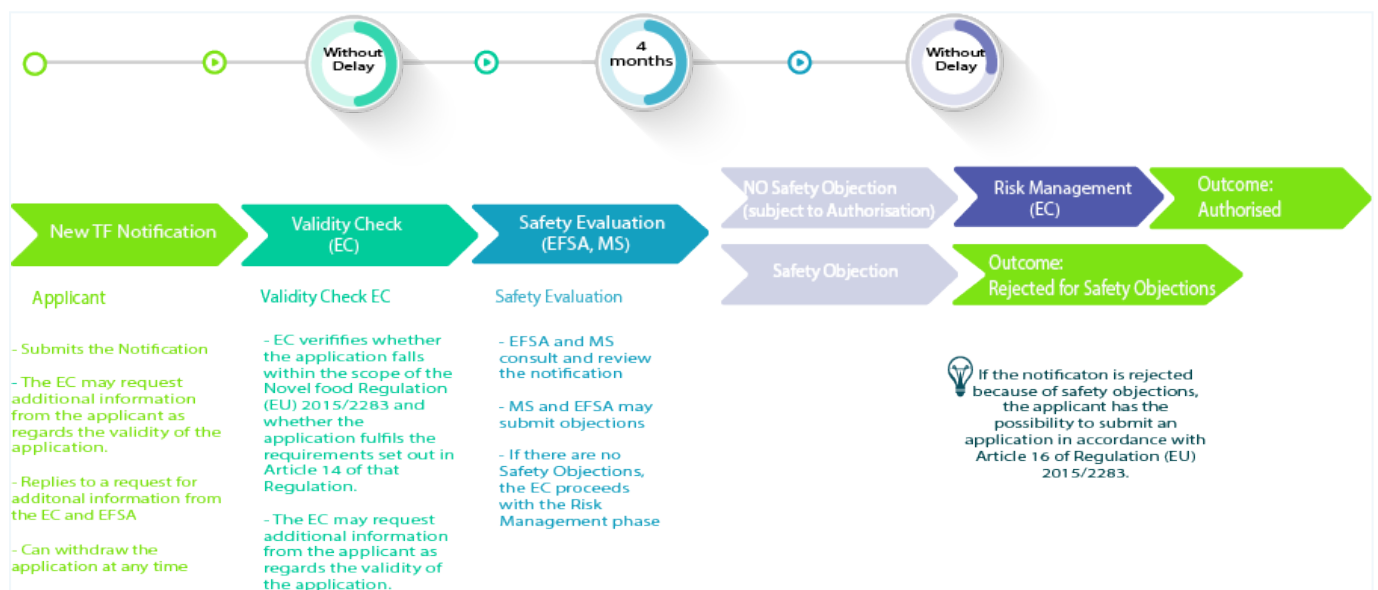
 See also:

- [How to create and submit a Traditional Food Notification](#)
- [How to withdraw an application](#)
- [How to create and submit a Traditional Food Notification](#)
- [Frequently Asked Questions \(FAQs\)](#)



Traditional Food Notification

Traditional Food Notification Workflow



How to create and submit a Traditional Food Notification

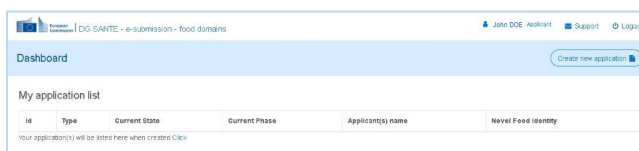
Note: The **Auto save** function ensures that the encoded content is saved automatically. Therefore, there is no button **Save** in the system.



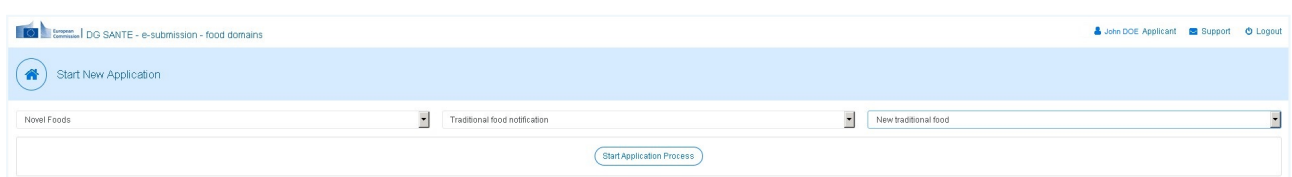
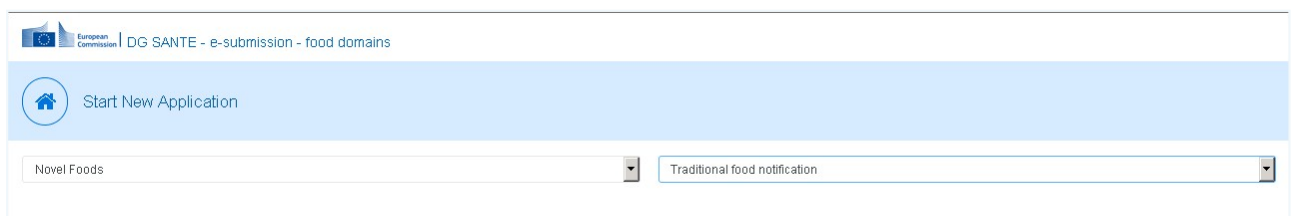
Be aware that while the autosave information message is displayed, the insertions / modifications could not being taken into account. So please make sure that the information is correctly updated.

Detailed steps and more information

1. On the dashboard, click on **Create a new application**.



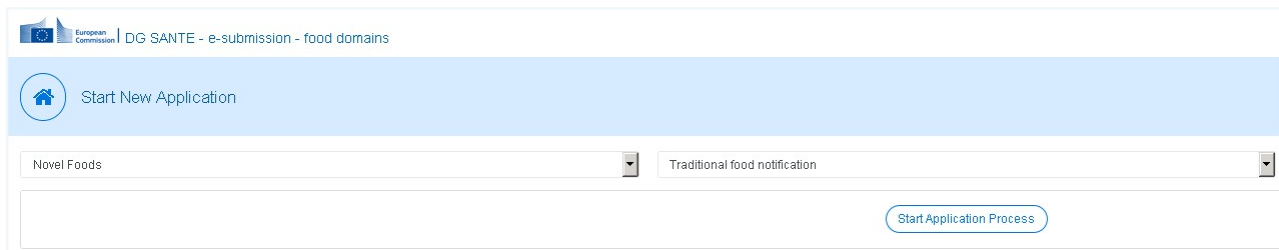
2. From the drop-down menus, select the **Food Domain** (in this case *Traditional Foods*) > the **Authorisation type** and > the **Application Type**.



e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

3. Click on the button "Start Application Process".



Note: A specific web form is displayed depending on the section you chose. The **serial number** of you notification appears on the upper left corner next to the **Home button**.



4. Fill in the **Traditional Food notification** form.

The following data needs to be encoded:

Administrative Data

In **section 1** type in the Identity of the food, select the food category type.



In **section 2** fill in the contact details. If there is more than one applicant for your notification, you can add another applicant by clicking on the "**Add Applicant button**".

In **section 3**, fill in the name of the person responsible for the dossier authorised to communicate on behalf of the applicant with the European Commission.

e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

The screenshot displays the 'Administrative Data' tab of the e-submission system. It contains three main sections:

- 1. Identity of the novel food to be authorised ***: Includes a text field for 'Novel Food category' and a dropdown menu labeled '-- Please select Food Category type --'.
- 2. Applicant(s) as defined in Article 3(2)(b) of Regulation (EU) 2015/2283**: Contains a form for applicant details with fields for 'Applicant Name', 'Email', 'Phone', 'Website', 'Address', 'Post code', and 'Country' (dropdown). A red box highlights the 'Add Applicant' button.
- 3. Person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission**: Contains a similar form for contact details. A red box highlights the 'Add contact person' button.

In **section 4**, state whether the application includes confidential data in accordance with article 23 of Regulation (EU) 2015/2283 by checking the **Yes** or **No** option accordingly.

4. Confidentiality

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

☐ Yes ☒ No

In **section 5**, you have to indicate the proposed entry in the union list. Click on the "**Add New Novel Food category**" button to insert your data.

5. Proposed entry in the union list

A table with columns: Food category, Condition of use, Specific labelling requirement, Post market monitoring requirement, Update, and Delete. A red asterisk is next to 'Food category'. Above the table is a button labeled 'Add new Novel food category +'. The table is currently empty.

Fill in the fields **Food category**, **Condition of use**, **Post monitoring requirement** and **Specific labeling requirement**. The fields marked by a red asterisk are mandatory. Click on **Save to list** to save your entry.

e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

5. Proposed entry in the union list

Food category *

Condition of use *

Post market monitoring requirement

Specific labelling requirement

Save to list Cancel

In **section 6** Check **Yes** or **No** for the **Regulatory status** of your product **outside the EU**.

6. Regulatory status outside EU

☐ Yes ☒ No

Note: If you check yes, you will have to select a status from the drop down menu ("**Under consideration**", "**Withdrawn**", "**Authorised**" or "**Rejected**").

6. Regulatory status outside EU

☒ Yes ☐ No

Under consideration
Withdrawn
Authorised
Rejected

Depending on your selection in the drop-down menu, the system displays a different field underneath allowing you to specify the proposed conditions of use, reasons for withdrawal, reasons for rejection, etc.

6. Regulatory status outside EU

☒ Yes ☐ No

Rejected

Specify the date and the reasons of rejection. Indicate the regulatory body which rejected the traditional food, and if available, provide a copy of the scientific opinion of the regulatory body which rejected the traditional food.

Summary

In this tab, you can type in the Summary of your dossier.

e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

The screenshot shows the 'Summary' tab selected in the top navigation bar, which is highlighted with a red box. Below the navigation bar, the heading 'Summary of the dossier' is visible. The main content area is a large, empty rectangular box for text input.

Scientific Data

In this section you can add as many files you want per scientific field.

The screenshot shows the 'Scientific Data' tab selected in the top navigation bar, highlighted with a red box. Below the navigation bar, there is an information icon and a note: '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'. Below this, there is a table with a red 'Add new file' button at the top. The table lists various scientific fields, each with a radio button and a 'No documents' button on the right.

Field	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
☐ Identity of the traditional food	No documents
☐ Annexes to the dossier	No documents
☐ References	No documents
☐ Concluding remarks	No documents
☐ Other relevant information	No documents

In order to do so, click on the **"Add new file"** button at the top of the list. New fields will be displayed. Select the field in the drop down list and select a topic.

The screenshot shows the 'Add new file' dropdown menu. The menu is open, displaying a list of scientific fields. The first field, 'The production Process', is highlighted in blue. Below it, other fields like 'Compositional data', 'Specifications', and 'Data from experience of continued use' are visible. The dropdown menu is located below the 'Scientific Data' tab in the navigation bar.

Once this is done, click on the **"Upload"** button.

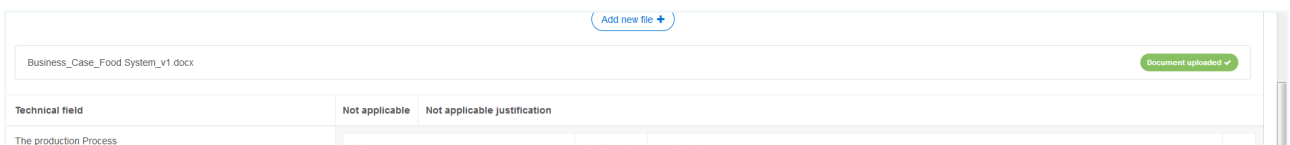
e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

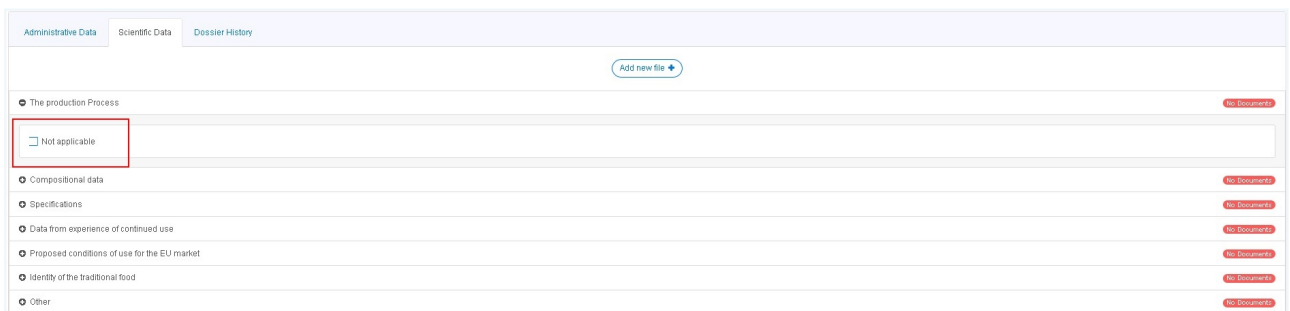


Wait a few seconds until the green label indicates that the file has been uploaded correctly and attached to the scientific field you have selected.

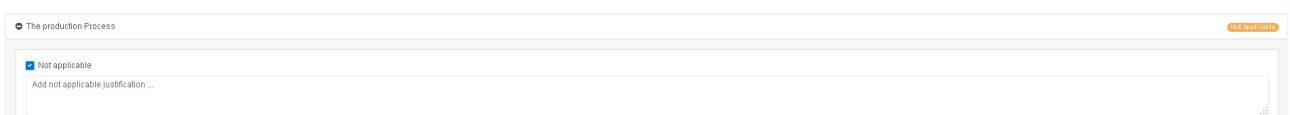
The green label indicates that the file has been correctly uploaded and attached to the scientific field you have selected.



If one of the scientific fields is not applicable for your notification, tick the box **"Not Applicable"** next to it.



For each file please indicate if it contains confidential elements. If not, tick the box **"Not applicable"** and enter a justification by explaining in detail which parts of the file are confidential.



e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

Note: Should you request confidential treatment of certain sections of the dossier, we kindly request to attach the section without confidential information separately.

Tip: Should you need to upload **several files**, we recommend uploading them in a compressed (zipped) folder. Should you have several confidential and non-confidential documents, regroup your **confidential data in one zip folder** and the **non-confidential documents in another** and to upload them separately.

Cover Letter Template

Once the notification is fully completed you can upload the cover letter. Click on the button "**Get a cover letter Template**" and save the template on your desktop.

EN ANNEX ANNEX I										
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: _____ _____ Confidentiality¹. 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 <table border="1"><thead><tr><th>Food category</th><th>Specific conditions of use</th><th>Additional specific labelling requirement</th></tr></thead><tbody><tr><td>-</td><td></td><td></td></tr></tbody></table> 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)		Food category	Specific conditions of use	Additional specific labelling requirement	-		
Food category	Specific conditions of use	Additional specific labelling requirement								
-										

e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

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.



The screenshot shows a user interface for uploading a cover letter. At the top, there is a button labeled "Generate cover letter" with a document icon. To its right, a note states: "Once generated, the cover letter needs to be signed and attached to the application". Below this, the section "Upload signed cover letter" contains a file input field showing "Cover Letter.pdf" and a blue button labeled "Uploading document C".

If you want to replace the document, click on "**Remove**" and upload the correct version of the cover letter you wish to attach to your dossier.

5. 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..



Note: Once you complete a mandatory field, its red star is not displayed anymore.

Cancel will only cancel the last actions not yet saved. A green notification appears to confirm your cancellation was successful.



Tip: Should some information be missing, **an error message appears** and stating which section needs to be updated.

How to create and submit a Traditional Food Notification

Administrative Data Error ✕
Administrative Data Section
producer validation Failed

- The **Current State** of your application changes to "**Application Acknowledged**" and the **Current Phase** of your application states "**Perform Validity Check**".

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

Follow up on your notification(s) by using the **Dashboard**. In order to get to the dashboard, click on the "**Home button**" on the upper left corner of your notification.



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e-submission system for Novel Foods User Guide

How to create and submit a Traditional Food Notification

- [How to withdraw an application](#)
- [How to create and submit a Novel Food Authorisation](#)
- [Frequently Asked Questions \(FAQs\)](#)

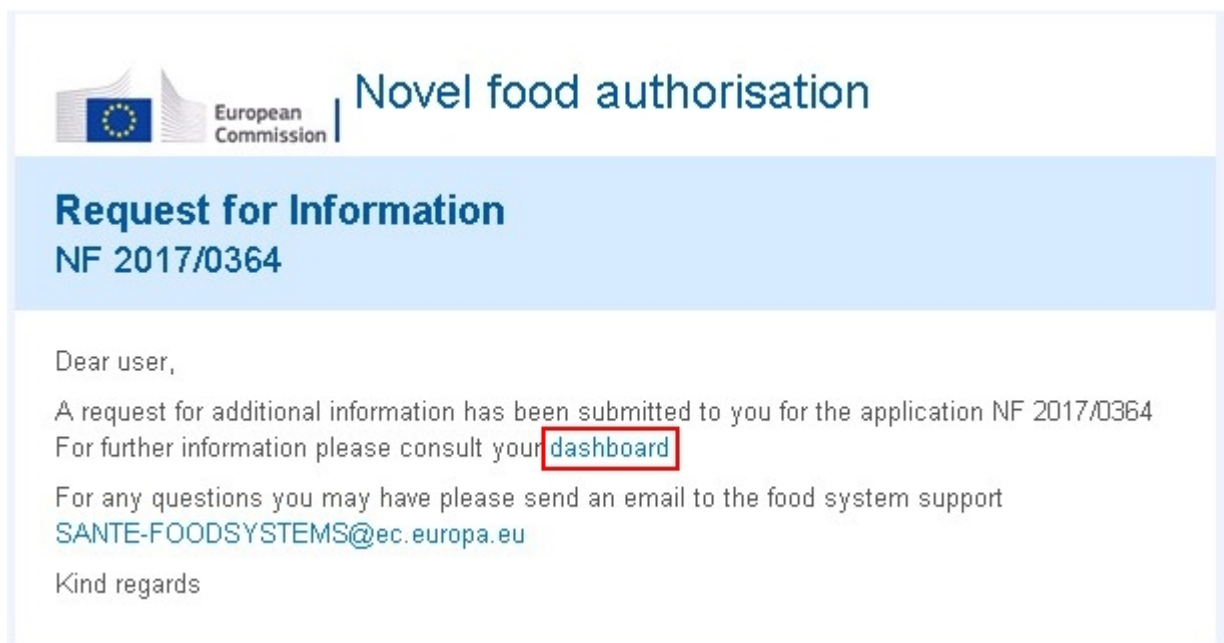


Applications Management

How to reply to an information request

Detailed steps and more information

1. If the EC needs additional information on your application, you receive a **request for information** e-mail asking you to provide additional information on a specific section of your application.



Note: The email contains a link which redirects you to your **Dashboard** page in the system.

Once you click on the link, you can see that the status of your notification has changed to **"On Hold – Additional Information Requested"**.

e-submission system for Novel Foods User Guide

How to reply to an information request

2. Click on the **Id number** of your application to edit it.

EFSA

EFSA

European Food Safety Authority

DG SANTE - e-submission - food domains

John DOE Applicant

Support

Logout

Dashboard

Create new application

My application list

Id	Type	Current State	Current Phase	Applicant(s) name	Novel Food Identity
NF 2017/0383	Novel Food Authorisation	Draft	With Applicant		
NF 2017/0384	Novel Food Authorisation	Draft	With Applicant		
NF 2017/0385	Traditional food notification	On Hold - Additional Information Requested	EC - Provide Additional Information	John DOE	Algae

Warning: Please note that the request for information can be about the Administrative part of your application or the Scientific data panel.

In case the requester would like additional information on the **Administrative part, all fields are unlocked**. You can then respond to the request by editing the concerned field and then resubmit your application.

In case the additional information is requested on one of the **Scientific data fields, the system unlocks only the specific field** for which the requester sent the request for additional information. You can then remove / add new files, and enter comments on the free text box. Then, you can resubmit your application.

Behind the fields requiring additional information, a green label stating "**1 Request(s)**" appears. Only these fields are editable, whereas the other sections and fields appear in read-only mode (see here e.g. Scientific data).

Novel food application
NF 2017/0385

On Hold - Additional Information Requested

Resubmit

Withdraw

Authorization type
Traditional food notification

Application type
New traditional food

Upload signed cover letter
Cover Letter.pdf

Administrative Data

Public Summary

Scientific Data

Dossier History

Analysis of data shall be presented in a clear format, using standardized 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.

Add new file

The production Process

Compositional data

Specifications

Data from experience of continued use

Proposed conditions of use for the EU market

Identity of the traditional food

Other

Documents

1 Request(s)

1 Request(s)

1 Request(s)

1 Request(s)

1 Request(s)

1 Request(s)

e-submission system for Novel Foods User Guide

How to reply to an information request

- Click on the section in question and a field opens with the information needed by the EC.
Click on the button **"Respond to Request for Information"** on the right.

Specifications

Request for information

18 December 2017 2:07 PM - RequestInfoData
We would need this information since it is a new traditional food, could you please provide it?

☒ Not applicable
none

Respond to request for information

- A pop-up window appears into which you can insert the additional information needed.
Once this is done, click on the button **"Add comment"** to add your specific comments in that section of the application.

Add request on Identity of the traditional food

Here is the additional information as requested. |

Add comment

- The additional information you have given appears under the Request of the section in question. If you wish to edit your response, click on **"Edit Response for Information"**.

Specifications

Request for information

18 December 2017 2:40 PM - RequestInfoData
We would also need this information, please clarify
TF.docx

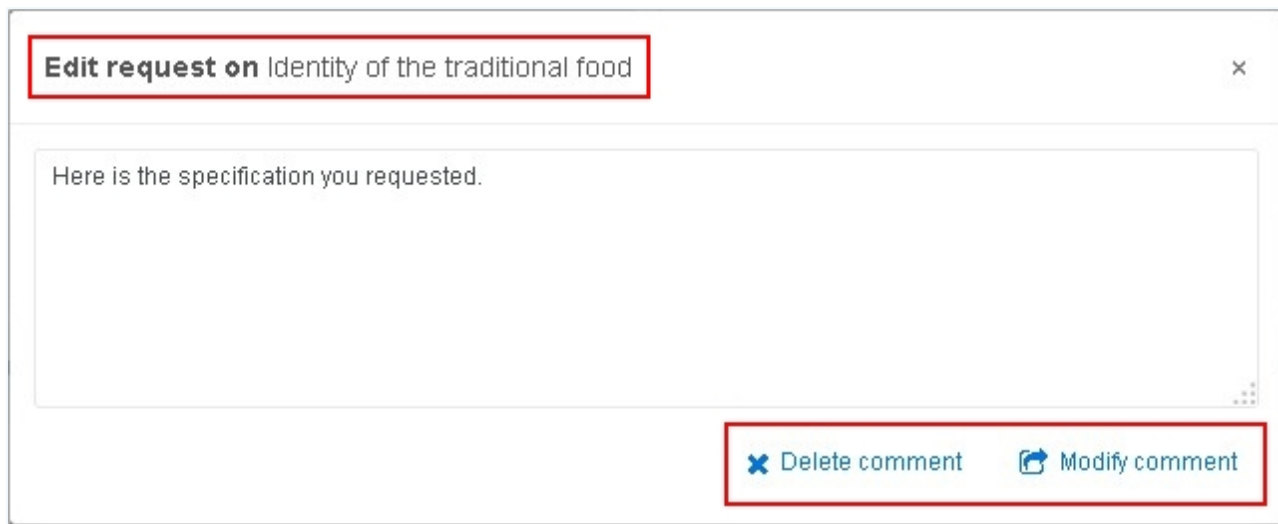
18 December 2017 3:10 PM - RespondInfoData
Here is the specification you requested.

Edit response to request for information

e-submission system for Novel Foods User Guide

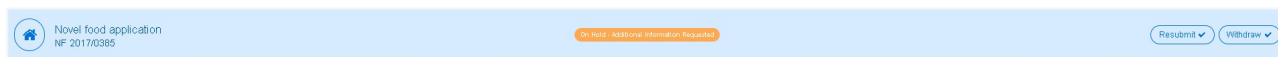
How to reply to an information request

6. You can then either **edit** or **delete** your response.



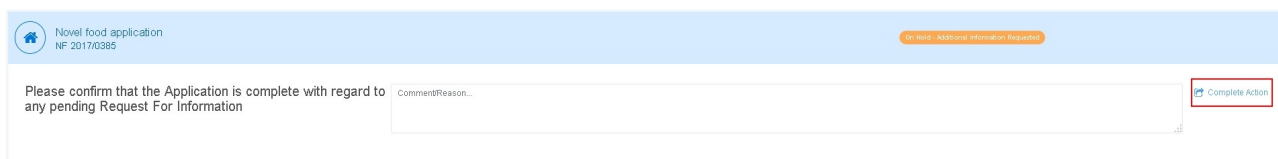
The screenshot shows a dialog box titled "Edit request on Identity of the traditional food" with a close button (X) in the top right corner. Inside the dialog, there is a text area containing the text "Here is the specification you requested." Below the text area, there are two buttons: "Delete comment" with a trash icon and "Modify comment" with a pencil icon. Both buttons are highlighted with a red rectangular box.

7. At this point, if you wish to resubmit your application, click on "**Resubmit**".



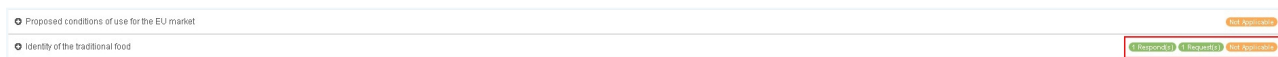
The screenshot shows a horizontal status bar. On the left, it says "Novel food application NF 2017/0385" with a home icon. In the center, there is a yellow label that says "On hold - Additional information requested". On the right, there are two buttons: "Resubmit" and "Withdraw", both with dropdown arrows.

8. In the next step confirm that the application is complete with regards to any pending request and click on "**Complete Action**".



The screenshot shows the same horizontal status bar as in step 7. Below the status bar, there is a text area with the text "Please confirm that the Application is complete with regard to any pending Request For Information" and a label "Comment/Reason...". To the right of the text area, there is a button labeled "Complete Action" with a checkmark icon, which is highlighted with a red rectangular box.

9. Once you have submitted your response, a green label "**1 Respond(s)**" appears next to the "**1 Request(s)**" label.



The screenshot shows the same horizontal status bar as in step 7. Below the status bar, there is a list of items. The first item is "Proposed conditions of use for the EU market" and the second item is "Identity of the traditional food". To the right of the second item, there is a green label that says "1 Respond(s)" and a yellow label that says "1 Request(s)". Both labels are highlighted with a red rectangular box.

10. Your application is now resubmitted and once again in "**Application Acknowledged**" status, therefore not editable anymore.

Note: A request for information can be received at a different stage in the procedure.

 See also:

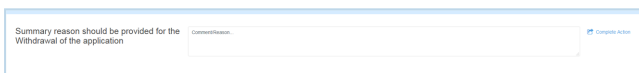
- [How to withdraw an application](#)
- [How to create and submit a Traditional Food Notification](#)
- [Frequently Asked Questions \(FAQs\)](#)

How to withdraw an application

1. If you wish to withdraw your application, click on "**Withdraw**".

A screenshot of the top header bar of the e-submission system. On the left, there is a circular icon with a house and the text "Novel food application NF 2017/0385". In the center, there is a blue button with the text "On Hold - Add more information / Requests". On the right, there are two buttons: "Resubmit" and "Withdraw" with a dropdown arrow.

2. Then confirm your action by explaining the **reason** for withdrawing.

A screenshot of a form for withdrawing an application. It contains a text input field with the placeholder text "Summary reason should be provided for the Withdrawal of the application". To the right of the input field is a blue button with the text "Complete Action".

3. Click on "**Complete Action**".
4. The application status is **Withdrawn** and at this point, the process is stopped.

See also:

- [How to create and submit a Traditional Food Notification](#)
- [How to create and submit a Traditional Food Notification](#)
- [Frequently Asked Questions \(FAQs\)](#)



FAQs

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.

1. 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".
- A separator line with the word "Or" in the center.
- 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 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" and "EU Institutions" logos, the version "5.0.0-d2d | 39 ms", and the "European Commission" logo with the text "Powered by".

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

Sign in to continue

Use your e-mail address

doe7282@gmail.com

Next

[Create an account](#)

Or

Facebook

Twitter

Google

Or use the eID of your country

Select your country

Sign in to continue

Welcome

doe7282@gmail.com
(External)

[Sign in with a different e-mail address?](#)

Password

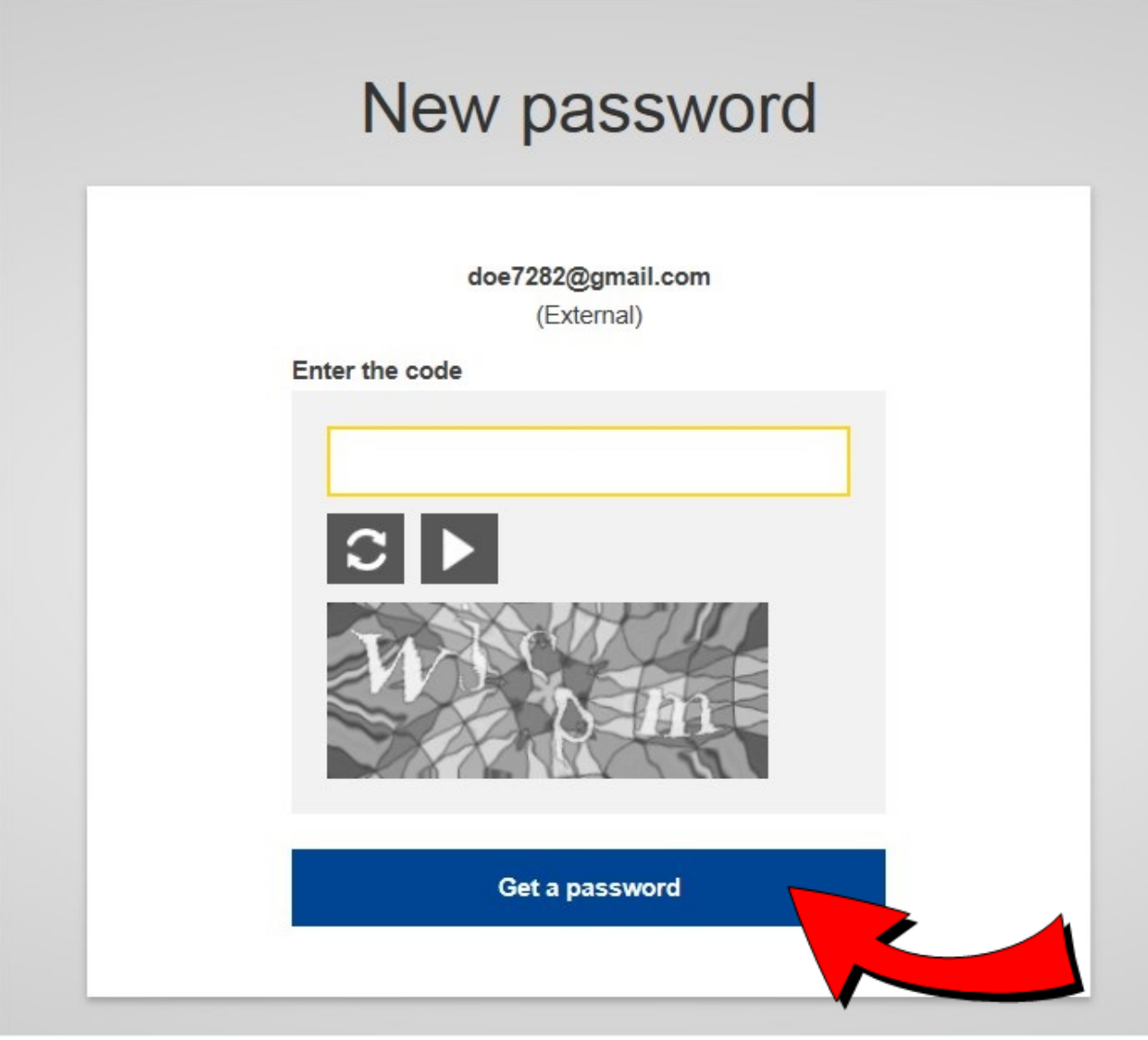
Lost your password?

Choose your verification method

Password

Sign in

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



The screenshot shows a web form titled "New password" on a light gray background. The form itself is white and contains the following elements:

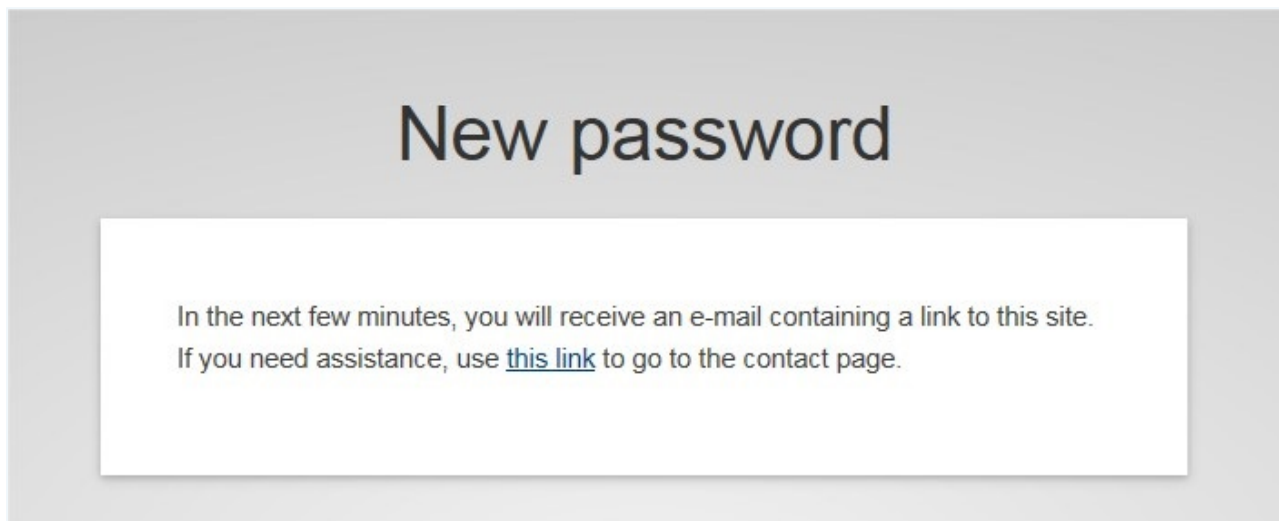
- The email address "doe7282@gmail.com" is displayed, with "(External)" written below it.
- A label "Enter the code" is positioned above a text input field with a yellow border.
- Below the input field are two square buttons: a refresh icon (circular arrow) and a play icon (triangle).
- Below the buttons is a CAPTCHA image showing the word "Wpdm" in a stylized font over a gray, textured background.
- At the bottom of the form is a blue button with the text "Get a password".

A large red arrow with a black outline points from the bottom right towards the "Get a password" button.

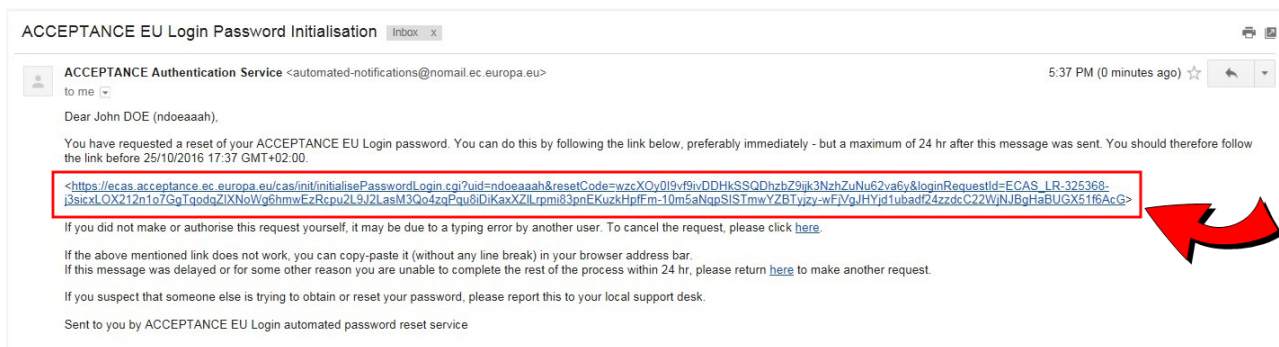
e-submission system for Novel Foods User Guide

Frequently Asked Questions (FAQs)

4. After that, the following information is displayed:



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



5. Follow the link in the email and proceed with changing your password.

Click on '**Submit**'.

New password

Please choose your new password.

Francesca.BOLA@ec.europa.eu
(European Commission)

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: !"#\$%&'()*+,-./:;<=>?@[\\]^_`{|}~

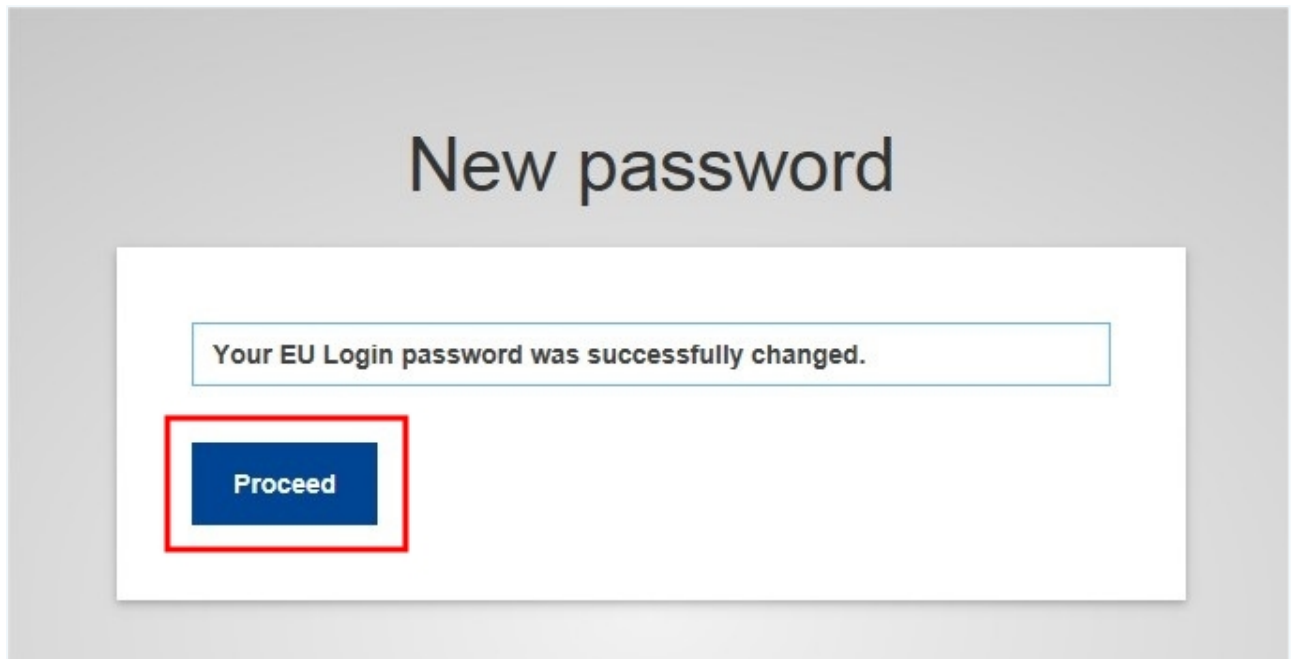
Examples: xej.YXdCyq mNLMwGjas; YBxbsHsbK7

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

Note: Changing this password does **not** affect your Windows or Internet password.

Please take great care in entering your new password. Once you have created it, you will only be able to change or reset it yourself after 24 hr.

6. 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.

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European Commission

Brussels, BE

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