Emergency Authorisation for Plant Protection Products (PPP)

ESFC platform guidance for MS users processing emergency authorisations of PPP

Emergency PPP v 9.2.0
November 2023

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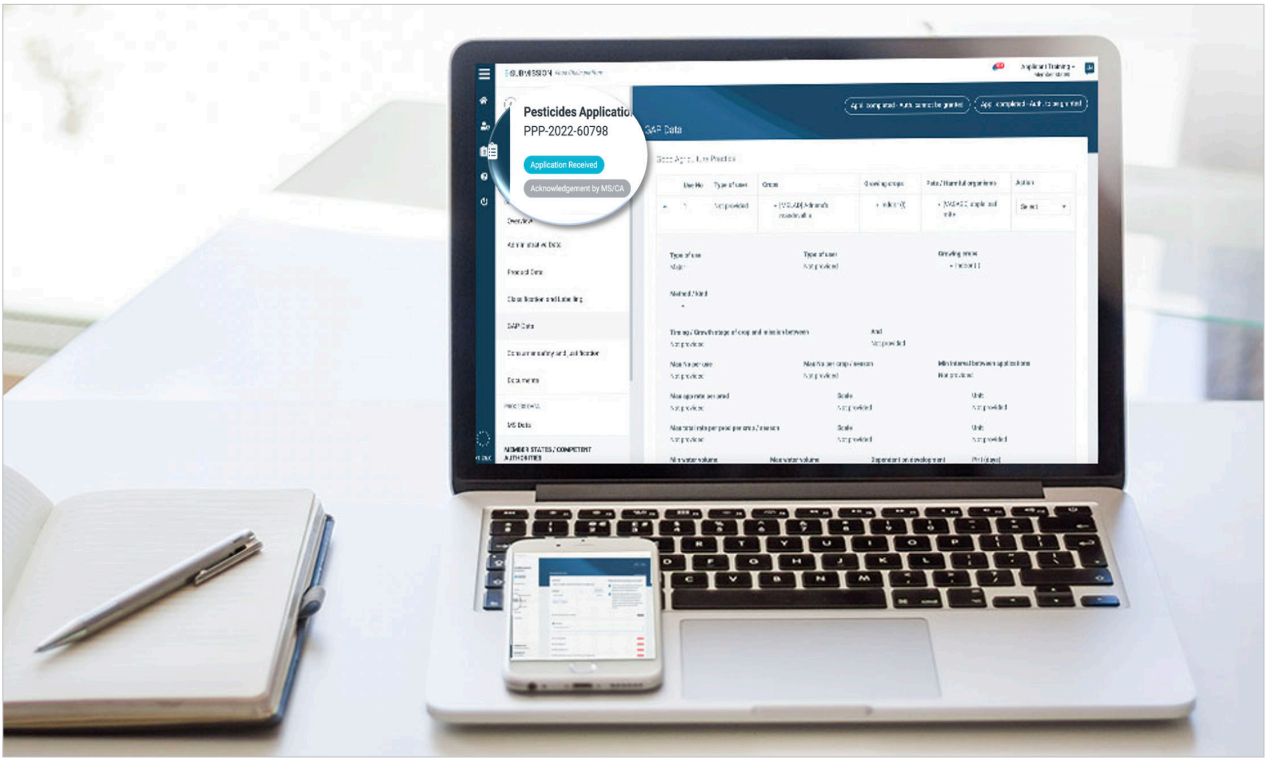
1 Welcome to the ESFC



Article 53 of Regulation (EC) No 1107/2009 allows Member States (Member State Competent Authorities – MS-CA) to authorise the placing on the market of plant protection products, in special circumstances and derogating from the regular authorisation process, for a period not exceeding 120 days and for limited and controlled use, where such a measure is necessary because of a danger which cannot be contained by any other reasonable means.

However, the recipient MS-CA **must inform the Commission and other MS-CAs** when granting or refusing emergency authorisations for PPP in accordance with Article 53. Detailed information about the situation and any measures taken to ensure consumer safety should will be provided. The E-Submission Food Chain platform (ESFC) enables Applicants and MS-CAs to input emergency requests and assessment outcomes. Emergency authorisations granted by MC-CA will be **electronically available** and **publicly accessible** on the EU Pesticides database.

European Commission (EC) and other (non-recipient) MS-CA users have read-only access to all such applications.

OPEN THE PLATFORM: ESFC

NOTE
Paragraphs 1 to 3 of Article 53 of Regulation (EC) No 1107/2009 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

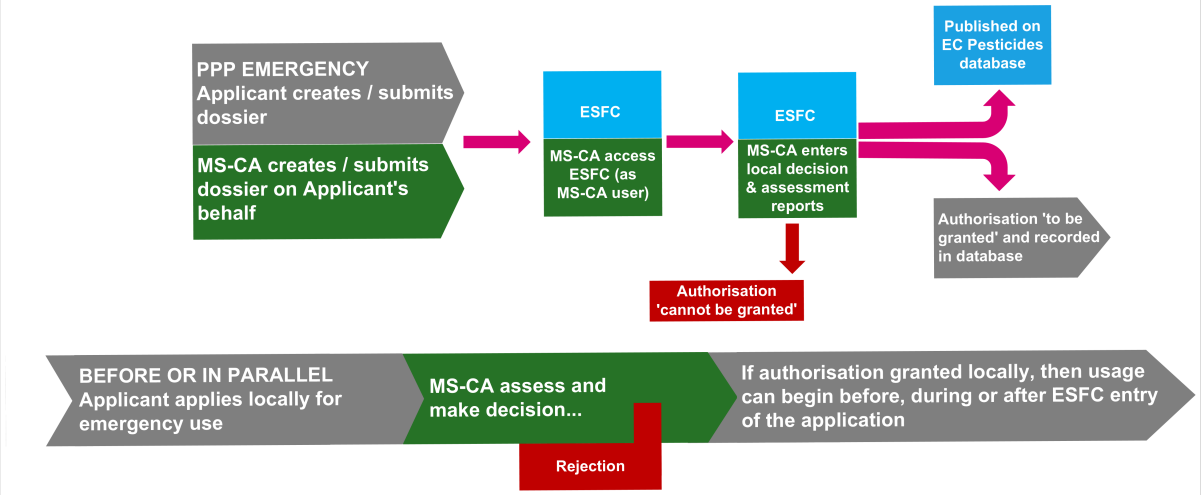
Authorisation process principles

1. ESFC ensures there is transparency across the EU for emergency PPP authorisations and related substances.
2. The **Applicant-selected 'recipient' MS-CA** are responsible for PPP emergency authorisations, managed on their local systems and assessed locally.
3. While the recipient MS-CA receive applications submitted directly by an Applicant in ESFC, in certain cases they may also create and submit applications on behalf of the Applicant.
4. When emergency authorisations are **repeated**, a clear reasoning should be provided why no other solution has been found. Applicants should use the regular authorisation process to seek a longer-term solution to a recurring danger.

IMPORTANT
Go to the European Commission's Procedure to apply for authorisation of a PPP for details on all authorisations.

ESFC process principles

1. When starting an application, only applicants users with a PPP profile in **SAAS** will be able to view the emergency authorisation PPP domain option in the food domain drop-down list.
2. Since there is no standard EC-wide dataset for PPP emergency applications, to simplify the input process not all ESFC fields are set as 'mandatory'.
3. The ESFC platform enables an audit trail and central data storage, and it also shares certain communications between actors.



TIP

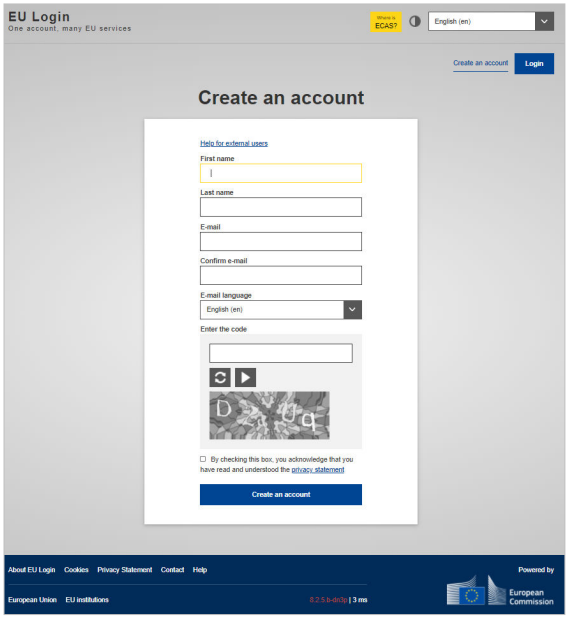
Because notifications arrive by email, to minimise avoidable delays or missing an applicant interaction, all ESFC users should maintain and monitor a stable IT environment – i.e. following mailbox filtering and email spam protocols etc.

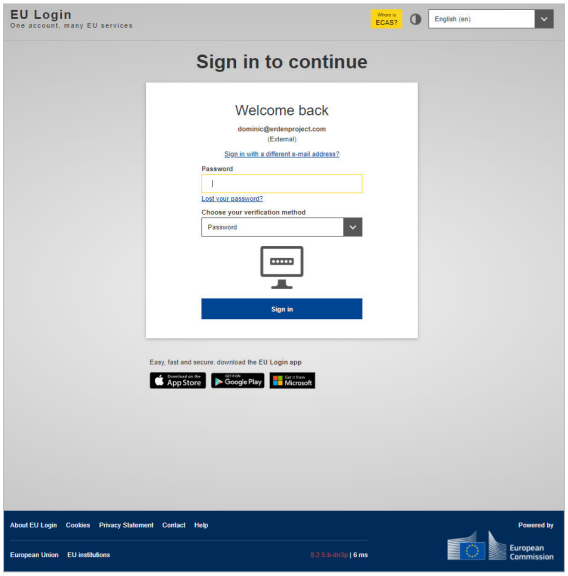
2 Logging in

To access the ESFC platform, you need an **EU Login**. The European Commission Authentication Service (ECAS) allows users to access a wide range of Commission information systems and services, using a single username and password. If you do not have an EU Login account linked to your work email address, please follow the instructions here.

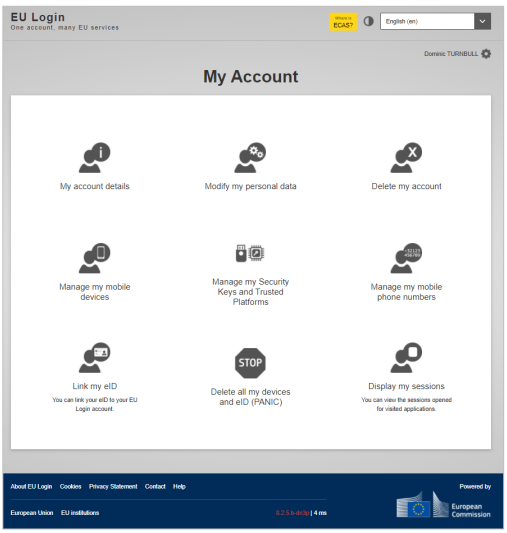
IMPORTANT
To access the Emergency PPP domain on ESFC, you need to have or create your profile in SAAS [6].

To set up your new EU Login account, begin here. If you already have a user account for EU Login, you can log directly into the ESFC platform via this link:





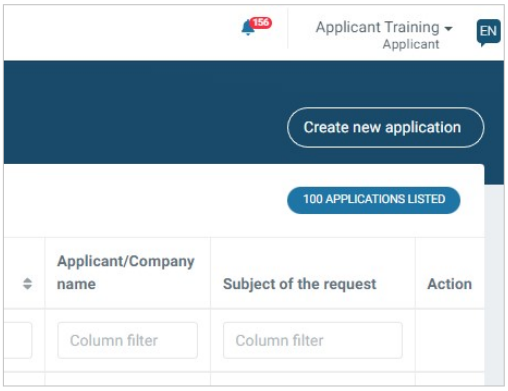
To change your EU Login password or edit your EU authentication login account, click here.

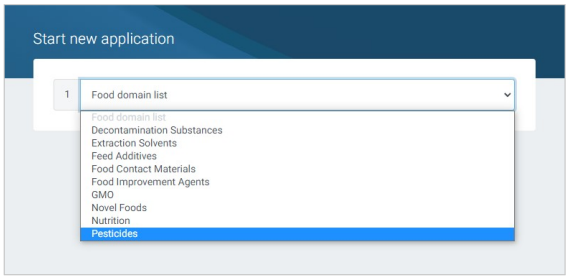


NOTE
The account will become inactive after six months if not used, but still accessible. You will be prompted to create a new password.

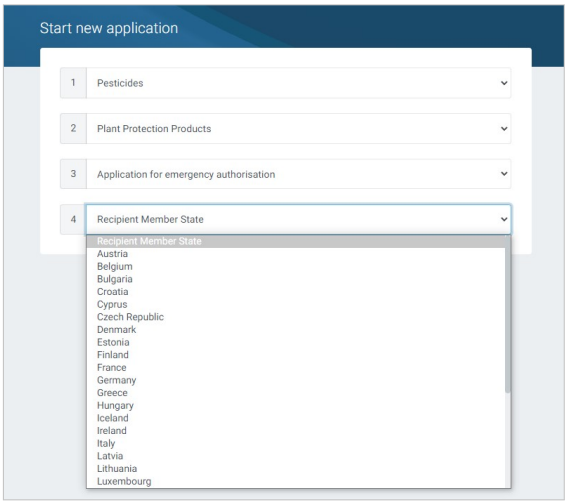
2.1 Log into ESFC

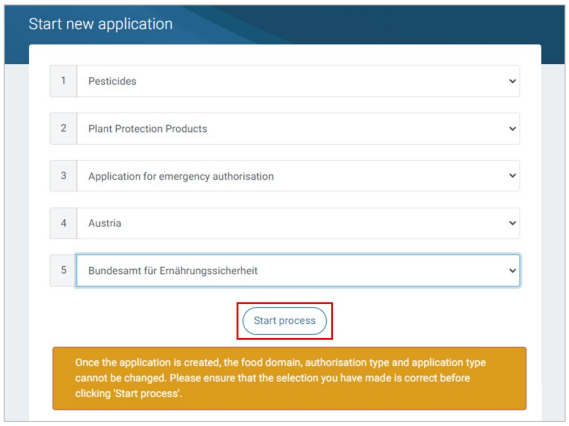
1. Click **Create new application** and select **Pesticides** from the domain dropdown.





2. Select **Plant Protection Products**, **Application for Emergency authorisation** and the **Member State**. Select the competent authority and click **Start process**.



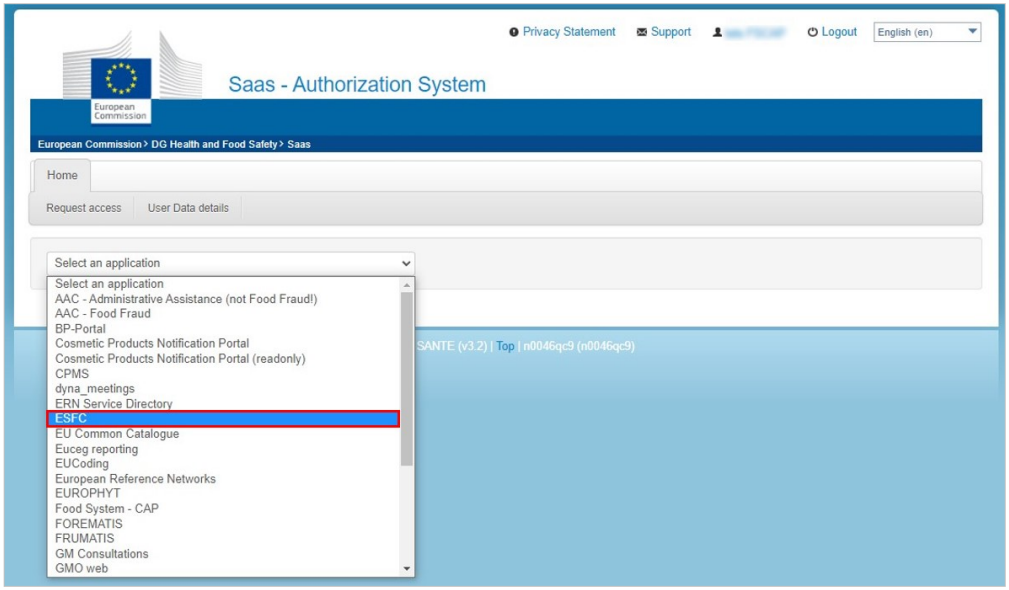


2.2 SAAS registration

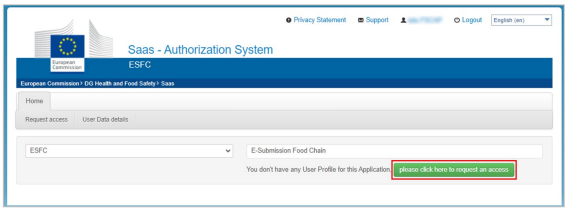
Go to the SANTE Authentication and Authorisation System (SAAS). SAAS links your EU Login account to the ESFC platform by assigning a User Access Profile. After you are successfully authenticated by EU-Login and your SAAS 'PEST' access profile **is verified**, you will have access to the Emergency PPP authorisations on ESFC and be able to view (or create) applications.

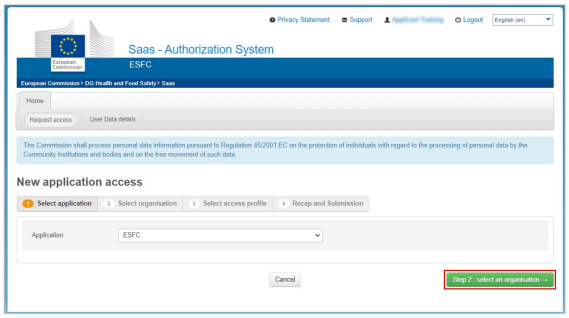
NOTE
To log into SAAS, you will first be redirected to EU Login to log in your credentials. After entering your EU Login, you will be redirected back to the SAAS homepage.

1. Select 'ESFC' as the intended platform.

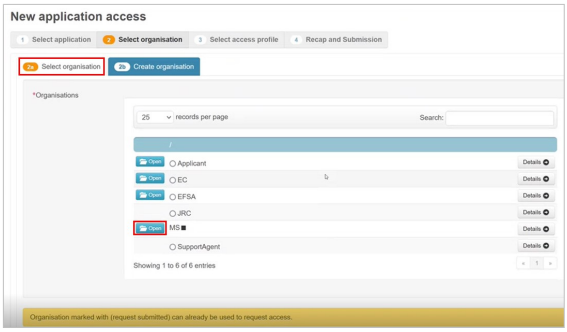


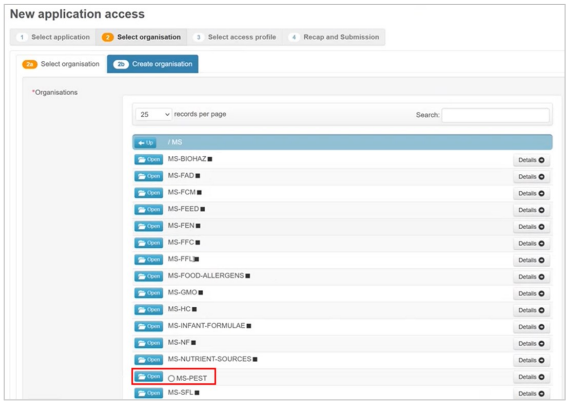
2. If you have no profile already set up, click 'Request profile', and then select your organisation (i.e. your MS-CA).



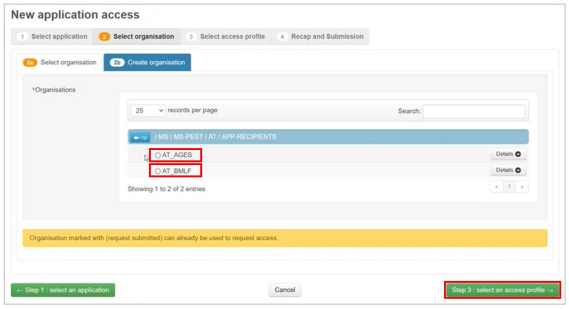


3. Select a **MS** folder (note the EC, EFSA and Applicant paths), then select **MS-PEST**.



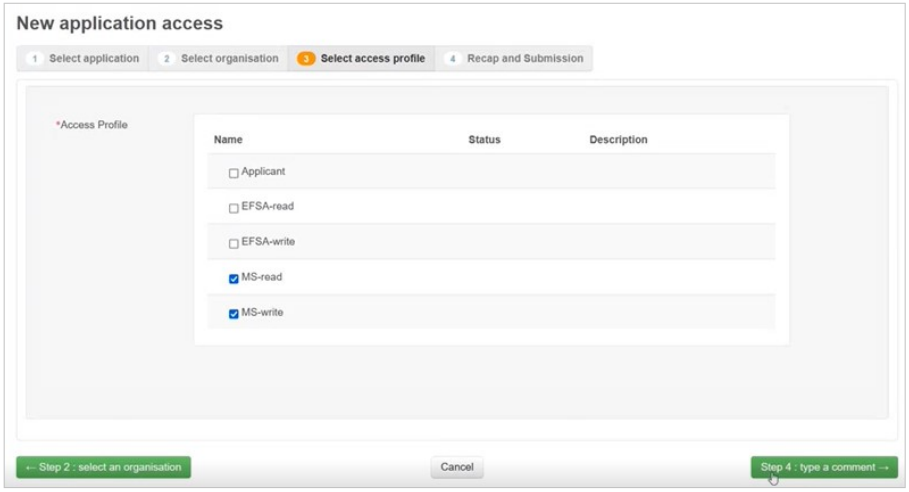


4. Now within Pesticides, request access to your **Member State**, and select the appropriate MS-CA, if registered. Click **Select an access profile**.

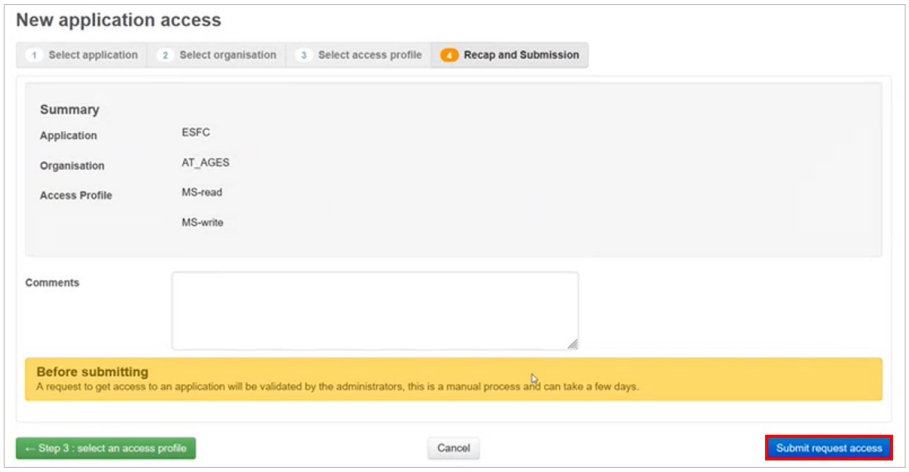


> **NOTE**
> If your 'organisation' (i.e. your Competent Authority) is not registered, please contact Support who can add it.

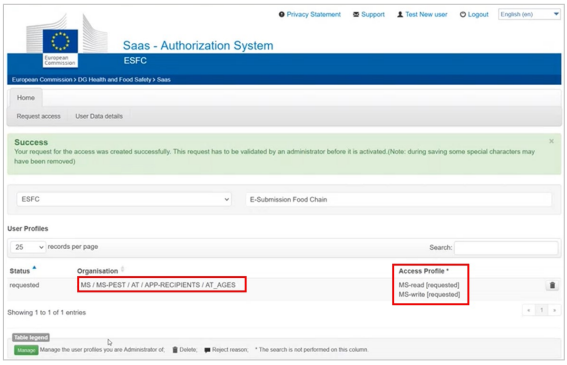
5. Select the access rights you need. Click **Type a comment**.

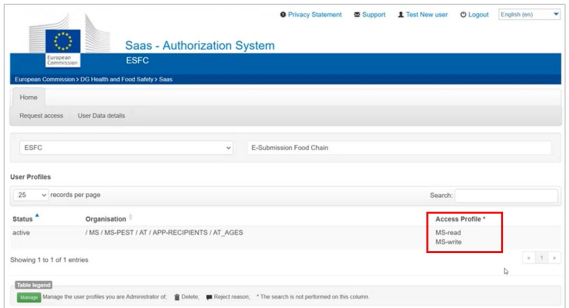


6. Enter an optional comment. Click **Submit request access**.



7. Your request screen shows. Once access has been granted, you'll see your updated profile screen. We recommend you return to the page after 48 hours if you receive no notification. For significant delays, contact Support.





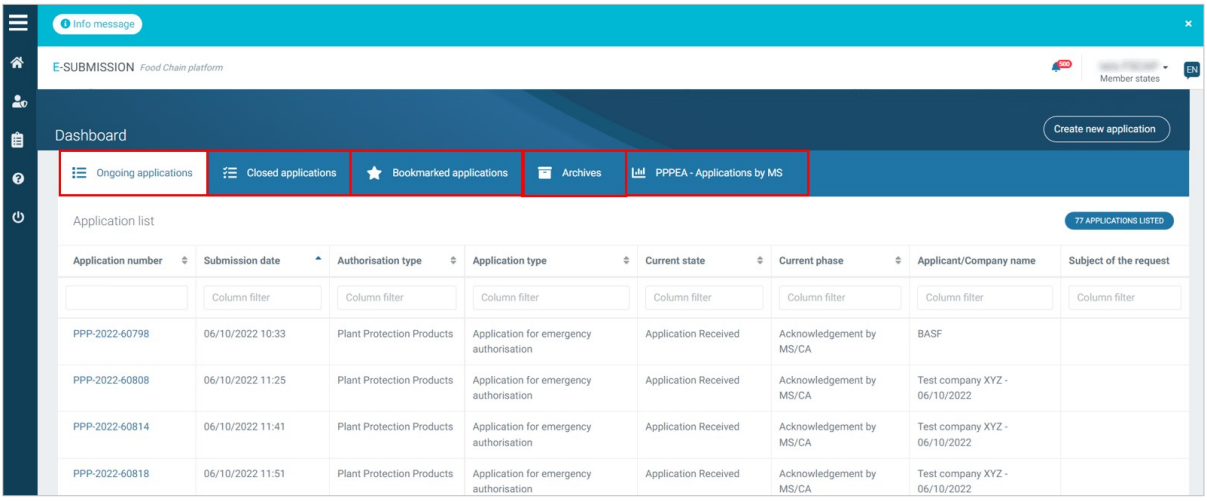
NOTE

For technical issues regarding the functioning of SAAS, please contact: **SANTE-SAAS2DEV@ec.europa.eu**

For issues related to EU Login, please contact the IT Helpdesk of DG SANTE: **ec-helpdesk-IT@ec.europa.e**u

For PPP support, please contact: **sante-e-submission-food-chain@ec.europa.eu**

3 Access management

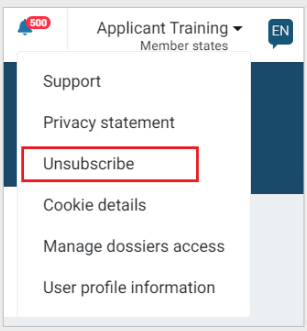


The **ESFC dashboard** presents users with all ongoing, withdrawn and closed applications based on the domain selection in SAAS (with bookmark, archive, closed applications and PPPEA listings available to MS-CA and EC users).

Each recipient MS-CA has a functional mailbox which receives notifications of activity. Also, individual users attached to that 'organisation' in SAAS receive notifications via their own email address. To add additional users to an application, email the ESFC support team directly on: sante-e-submission-food-chain@ec.europa.eu. (The 'Manage dossiers access' button only applies to the Applicant user.)

NOTE

The '**Unsubscribe**' option in the user pull-down list will remove your personal email address as a recipient of notification pings. It **does not** effect the functional mailbox reception of the notifications.

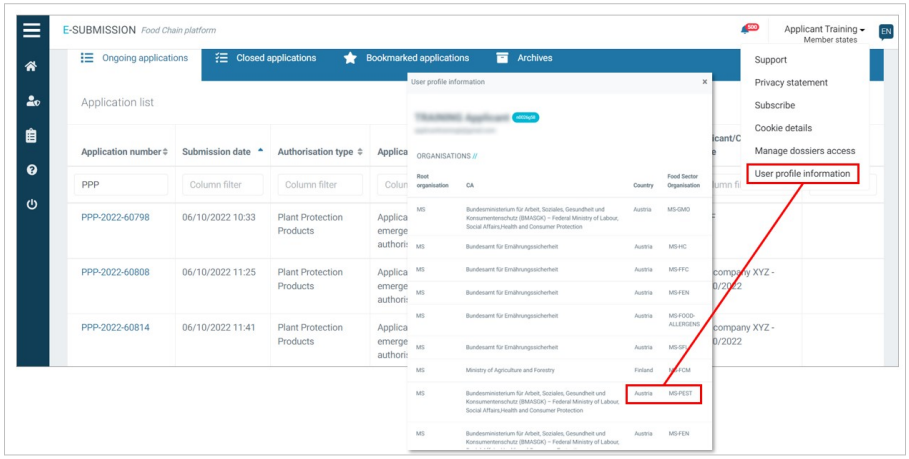


IMPORTANT
Multiple users from the same MS-CA can access and work on the same application at once. It is important that there is some coordination because the platform currently does not limit access or flag parallel inputs. This means that for now, there is a risk of input overlaps (when the application is not in read-only mode).

3.1 Manage your profile

If you have logged into the ESFC platform successfully, but you do not see the correct (or any) applications, check that your profile is correct. Are you associated with the correct organisation and domains – i.e. MS-CA and PEST?

1. Check that your profile is correctly listing the appropriate domains. This can be done at the application library screen, or within an application.
   - Click the top-right corner and select '**User Profile Information**'.

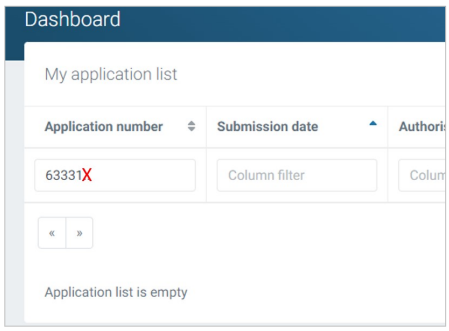


2. To amend the information, email a request to: **sante-e-submission-food-chain@ec.europa.eu**

3.2 Tracking applications

Before submission, the application is automatically saved as *draft* and appears in the dashboard. Its content is viewable by the Applicant (and the recipient MS-CAs after its submission). Its content can be developed by the MS-CA after authorisation is granted with follow-up data until publishing.

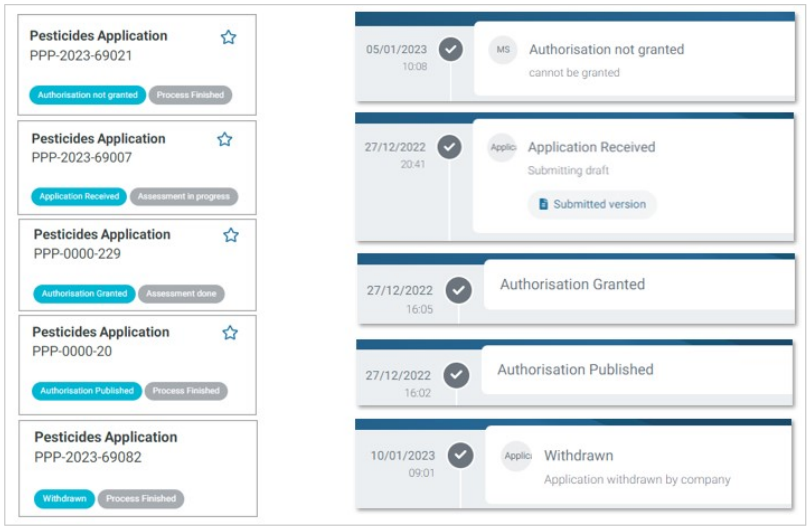
When searching in the dashboard for an application, be sure to remove any spaces around the application number.

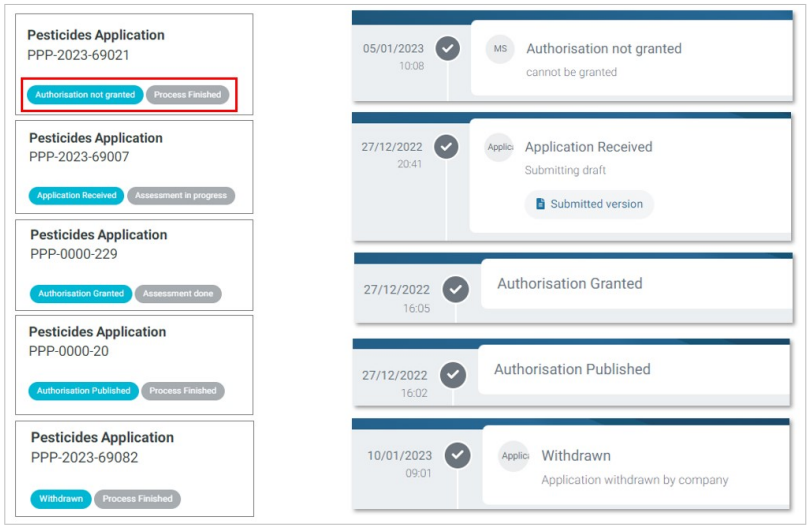


The search can also be made by product name.

Throughout the submission process, users who are connected to an application receive notification emails indicating activity. The email links back to the platform dashboard. Activity is also flagged by the notification bell , in date order for all your ongoing applications.

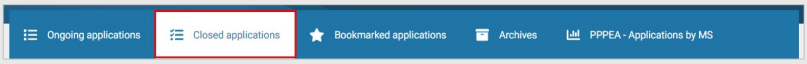
The status badges denote the current and next phase of the application. The dashboard timeline updates as the application proceeds through each phase. Note the possibility of bookmarking an application by clicking the star ' ☆ '.





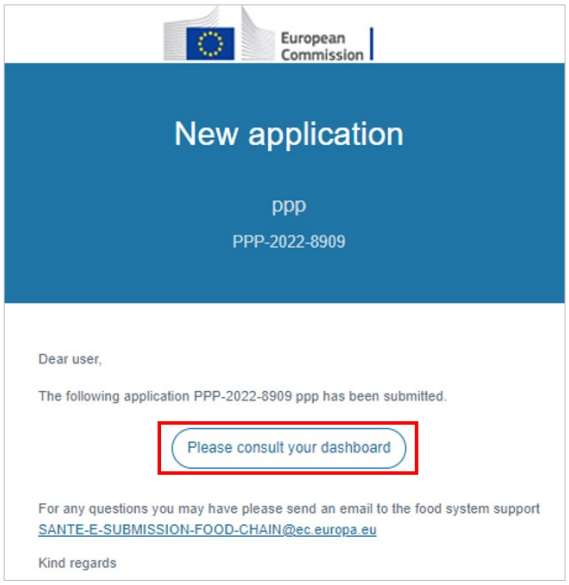
TIP

A completed or withdrawn application can be found in the '**Closed applications**' folder. Your bookmarks will appear in the bookmark folder (based on your log-in).

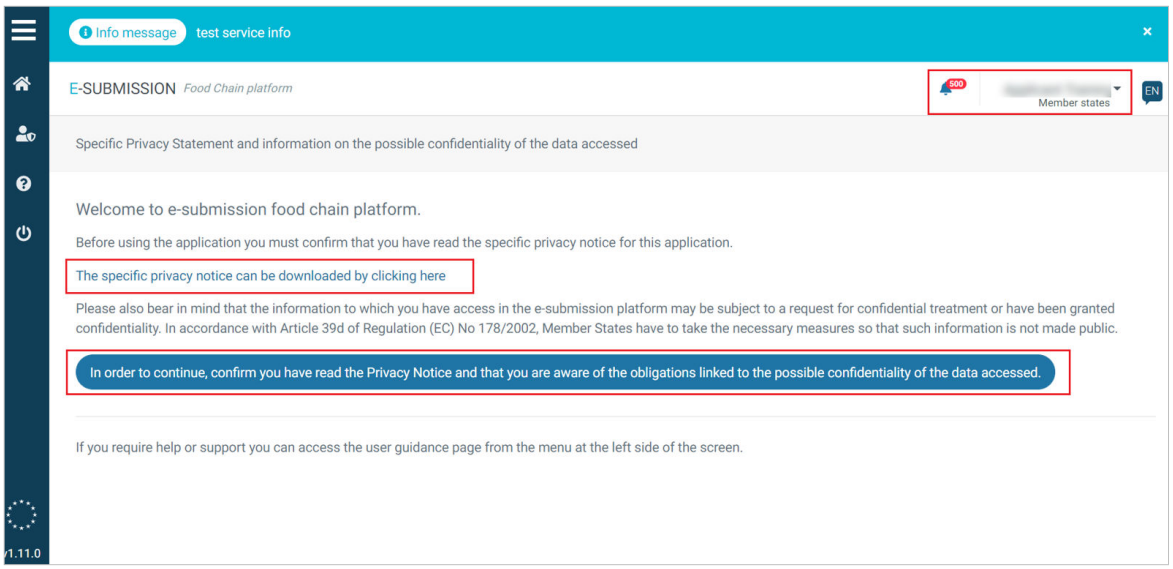


4 Using the ESFC platform

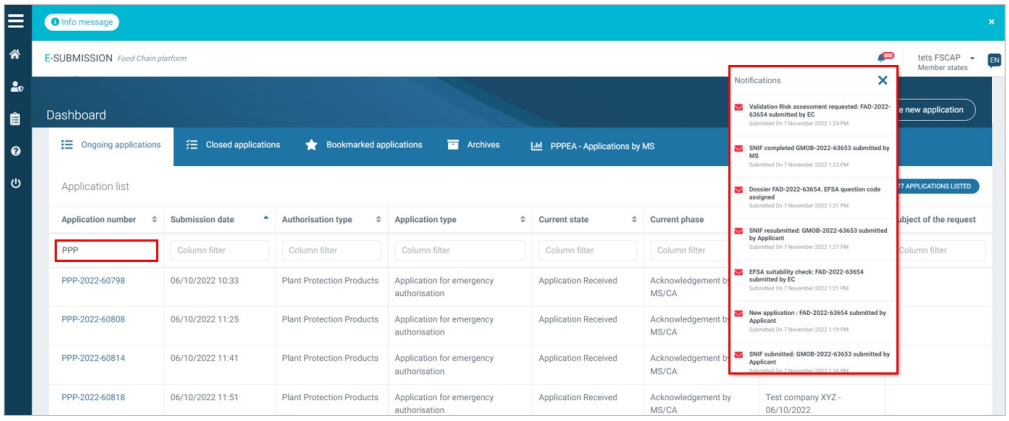
1. An emergency authorisation application is submitted via the ESFC platform. Recipient MS-CA users receive an email notification linking to the ESFC dashboard.
   EC are not yet informed of the application submission. Other MS-CAs are not informed.



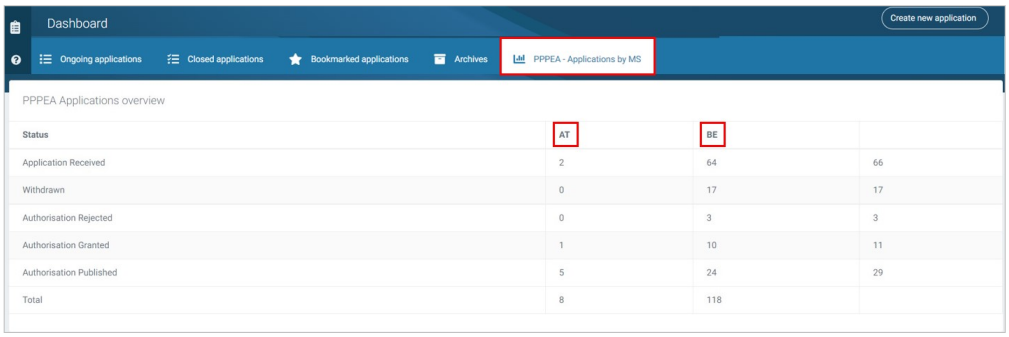
2. In order to access the platform, all MS-CA users must confirm that they have read the **Privacy Notice**. This agreement is because applications may contain confidential data, personal information, or content provided without Applicant-owned intellectual property rights.
   - Remove the top blue info-bar maintenance messaging by clicking the '**x**'.
   - Click the confirmation that you have read the Privacy Notice. This requirement applies to all MS-CA users, not just those from the recipient member state.



3. The user's profile determines which submitted application are displayed. You can sort the dashboard content using the top-row fields.
   - Either type the application number, or click on the application in the notifications dropdown.



4. The **PPPEA Applications overview** tab displays the EC-wide statistics, as captured by ESFC, for dossiers received and managed by each MS-CA.



5 MS-CA initiates application

The MS-CA may create an application on behalf of an applicant.

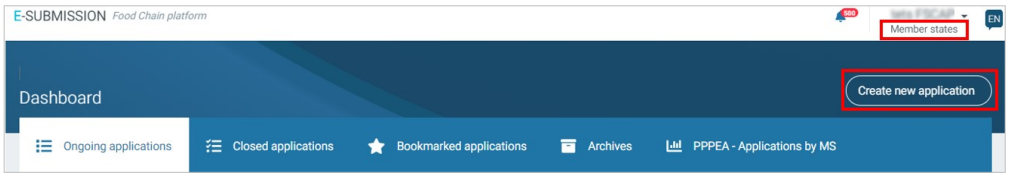
If an applicant cannot enter its application into ESFC (for various reasons, e.g. the applicant is not expected to submit future applications and therefore setting up an account is considered unnecessary) the MS-CA can instead create the application on the Applicant's behalf, using the information already submitted through their local process.

This could take place in parallel with the assessment, after it, or even after the product has been used.

1. Create a Pesticides profile in SAAS. See SAAS registration [6].
2. Log in as MC-CA, then create and submit the application in ESFC on behalf of the **Applicant**. See How to create an application [16].
3. To receive and manage the application in ESFC, log in as the recipient **MS-CA**, then follow the steps for approval or rejection, depending on your local assessment outcome. See Manage application [29].

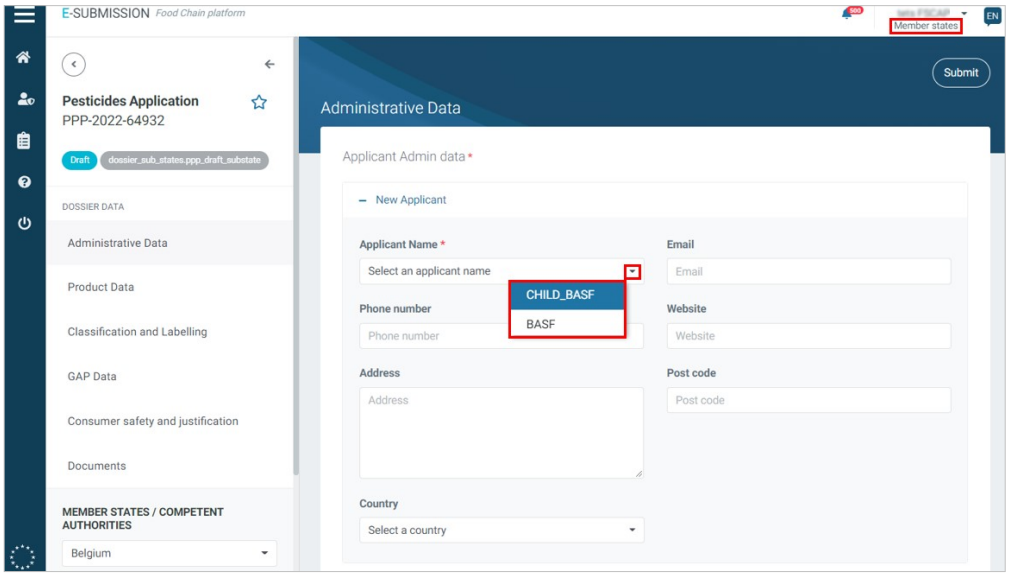
5.1 How to create an application

1. Once logged in, click **Create new application**.



2. The top of the left pane shows the application status and phase. Note the sections list, and your MS-CA details below. The bottom section displays the authorisation and application type.

   Now select the Applicant for whom you are creating an application. Use the ' ▾ ' arrow. The fields are populated with data held in SAAS.



   If the Applicant does not appear in the dropdown list, it can be **manually entered**, but the details will not be stored in SAAS and will only exist for that application. Alternatively, the Applicant can register itself directly in SAAS.[1]

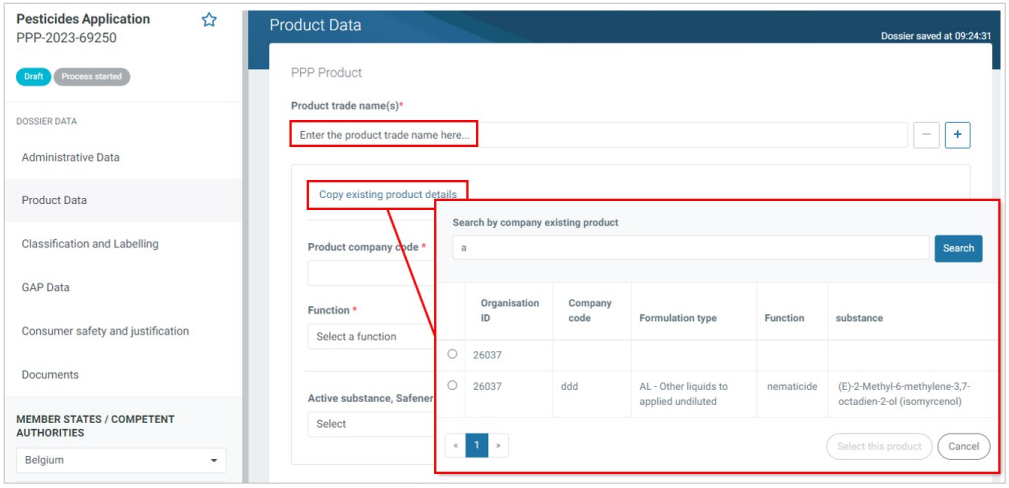
3. Complete the application, inputting information/files already received by your local system.

> **NOTE**
> To avoid possible duplication, the MS-CA user should first search in the dashboard for an existing emergency submission before proceeding. Note that an applicant-created **draft** application will **not** appear, so coordination may be necessary.

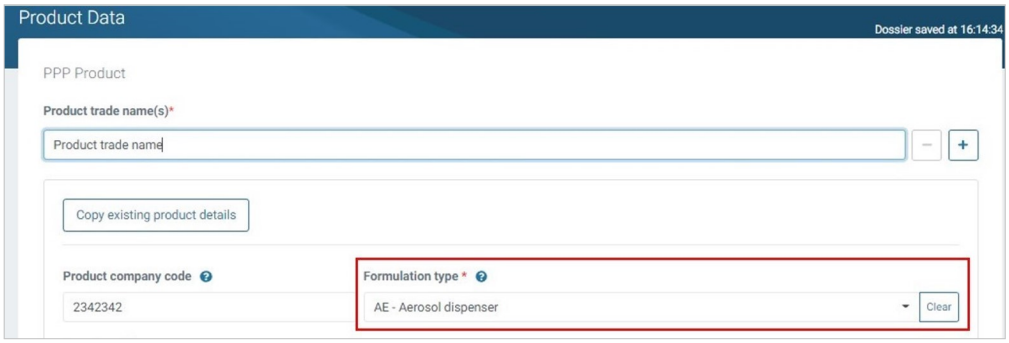
5.1.1 Product data

1. Provide the **product trade name** – if there are multiple, click '**+**'. Complete the fields manually if it is a new product.
   You can search the database if it already exists. Click '**Copy existing product details**'. In the pop-up, provide the company code or (partial) name, click '**Search**', and select from the displayed list. Click '**Select this product**'.

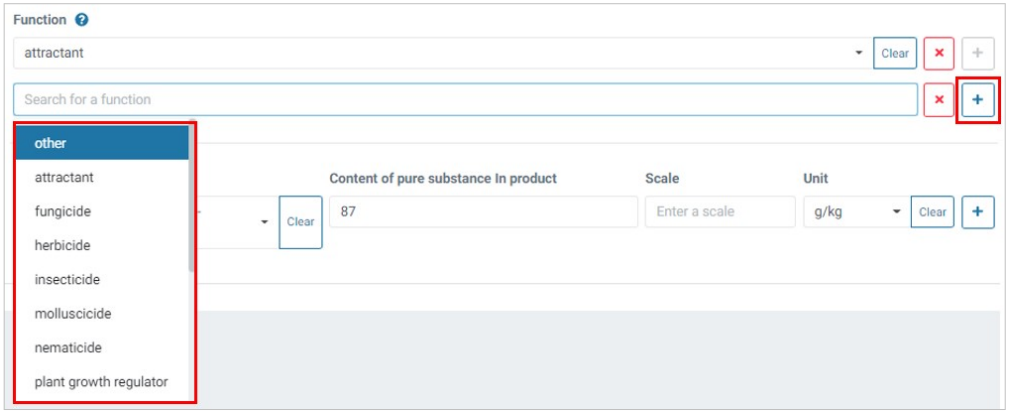
[1]For more information, visit PPPAMS (europa.eu).



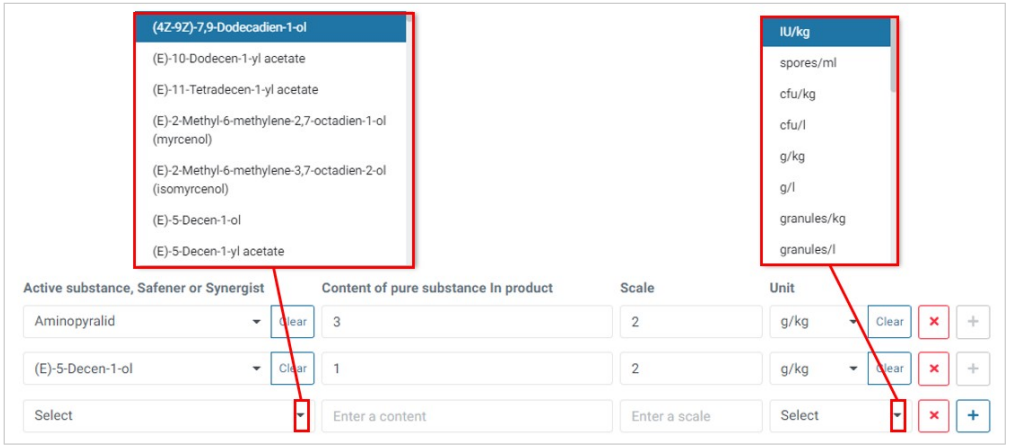
2. The product details are populated. The **Formulation type** drop-down list is based on the 'Catalogue of Pesticides Formulation types and International Coding Systems' GCPF (GIFAP). Revised in May 2008 (www.croplife.org).



3. Click the '**+**' to select one or more Functions from the drop-down list. Tick the relevant check boxes next to each relevant function. If you can't see a function that you wish to use within the list, select '**Other**' and the field allows a free-text entry. '**Clear**' and '**x**' delete and remove your selection.



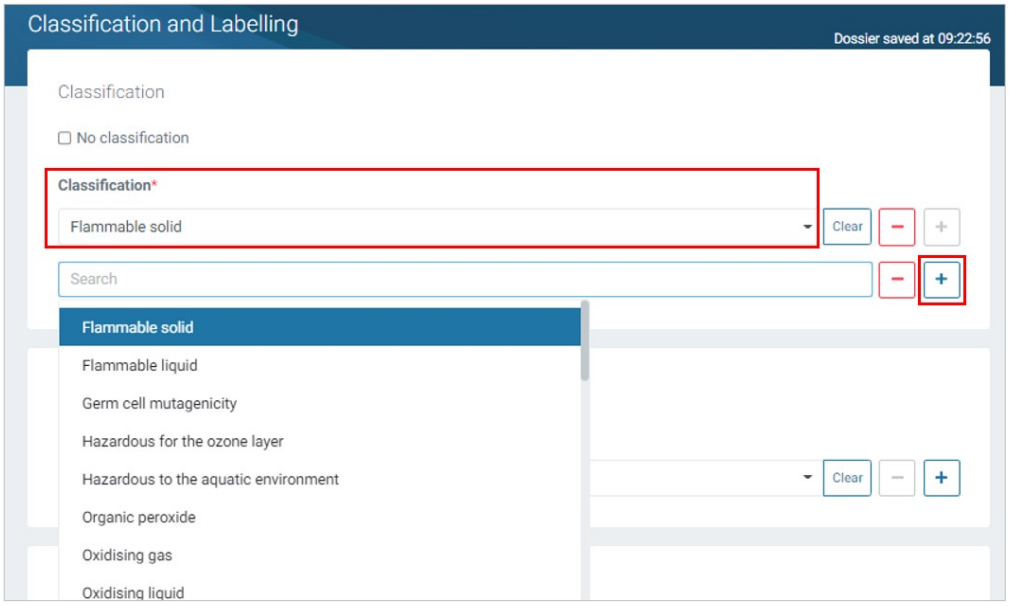
4. Select one (or multiple) active substance(s). You can '**Clear**' your Substance data and, using the arrow, select differently from the list. Similarly with the Unit type. You can select multiple substances using the '**+**' button. The **Content of pure substance in product** field will pre-populate the **Max app rate per prod** fields in the GAP Data section (Step 6).



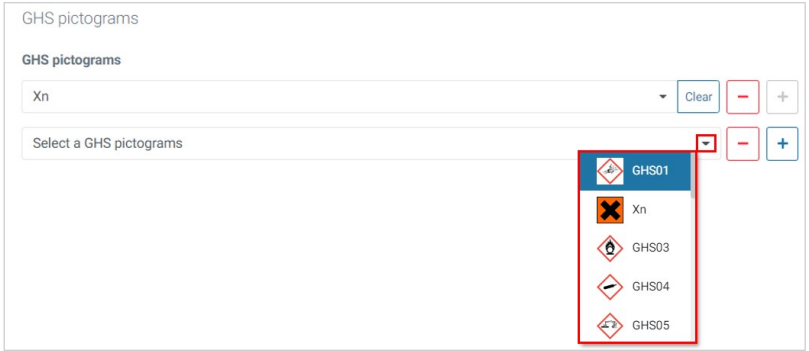
5.1.2 Classification and labelling

The classification fields and the product creation are combined in the ESFC flow – i.e. no longer are there two distinct phases for this, as was the case in PPPAMS.

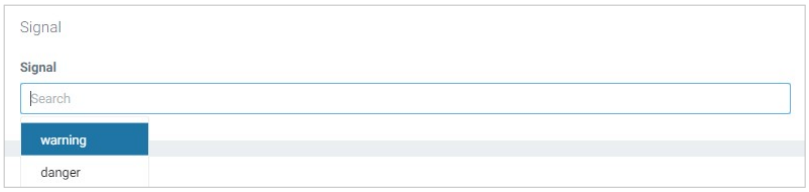
1. If there is no classification required, click '**No classification**' and the selection field disappears. Otherwise, that selection is mandatory. Multiple are possible by using the '**+**'.



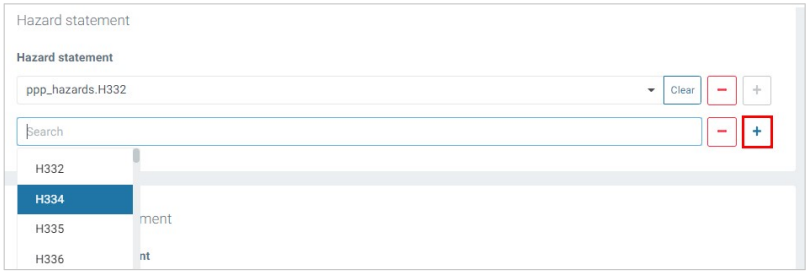
2. Select one (or multiple) **GHS pictograms** from the icon list. Values can be found in Regulation (EC) No 1272/2008.



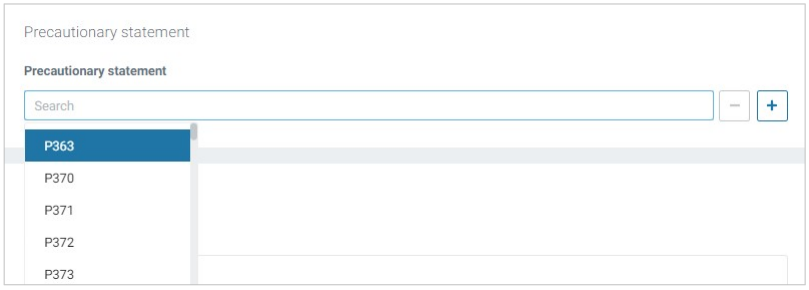
3. Select an optional **Signal**, indicating the relative level of severity for hazards of the product.



4. Select one, or multiple, hazard statements(s).



5. Select the optional **Precautionary statement** from the drop-down list, advising on precautionary measures to prevent or minimise adverse effects on humans or the environment.



6. Provide an **additional statement** if necessary.

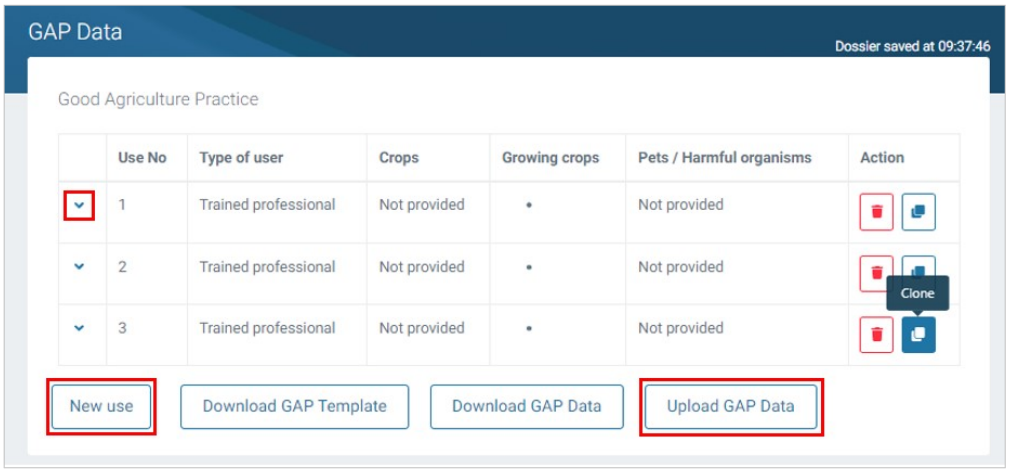
5.1.3 GAP Data

Define how/when the product will be used, according to Good Agricultural Practices.

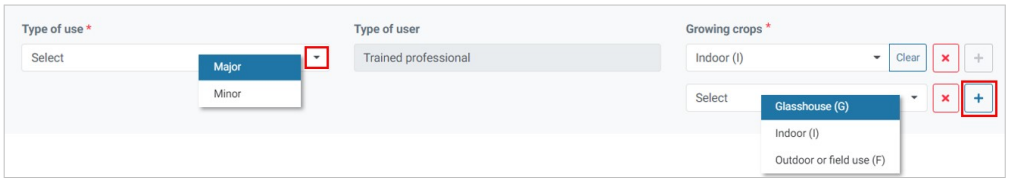
IMPORTANT
You can **shortcut the data entry process** by uploading an excel with the values, which ESFC will parse and pre-populate if formatted correctly. Click **Upload GAP Data**.

1. Provide the use(s) of the substance. Click **New use** if there are multiple uses.

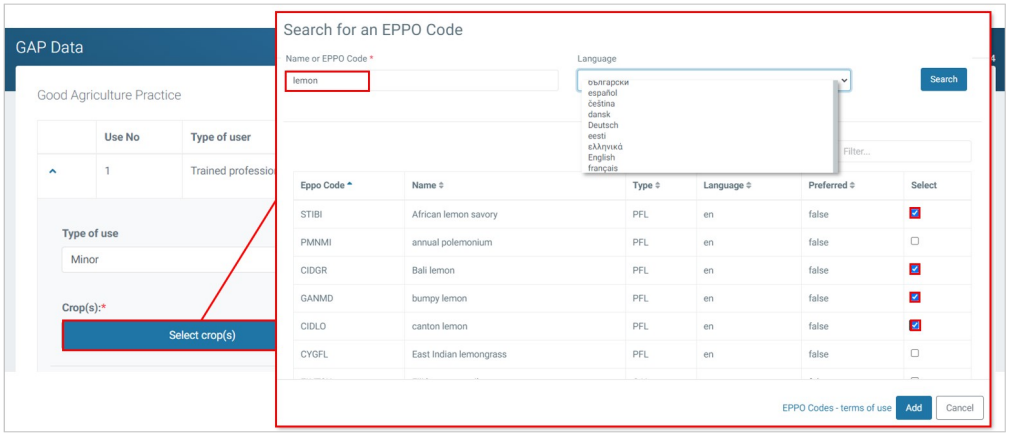
The ' ⌄ ' arrow **minimises** the data fields for each use type. Click the ' ⧉ ' icon to create a duplicate (clone) use type.
Alternatively, download the **GAP Template**, then via the **Upload GAP Data** button provide all the information in an excel file.



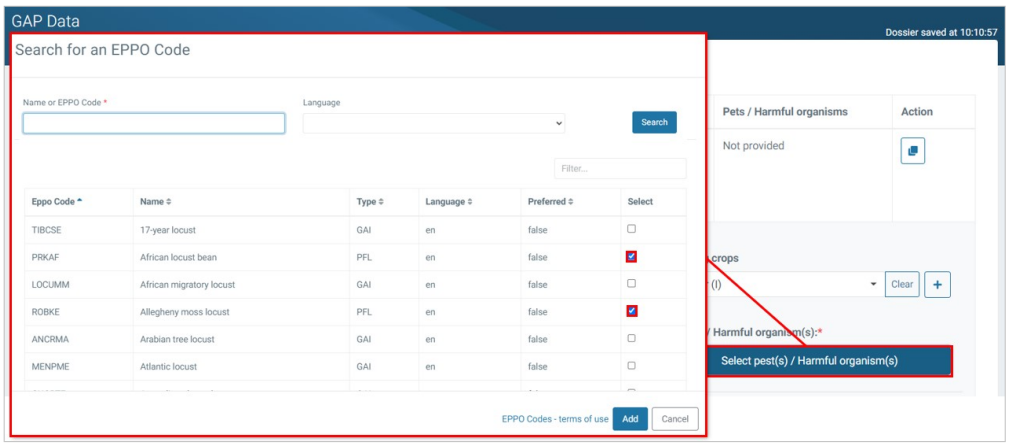
2. Now complete the fields within each use. All emergency applications assume a '**Trained professional**' as the default.



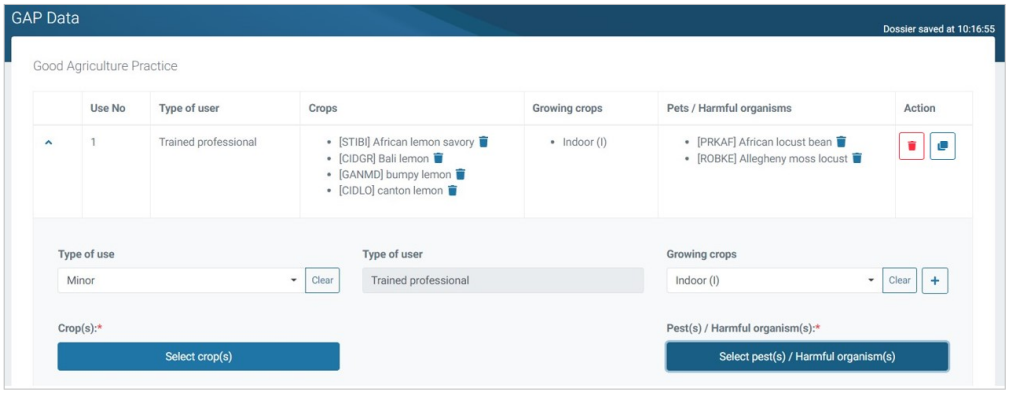
3. Using the European & Mediterranean Plant Protection Organisation database (EPPO), define the crop. Input a keyword or code into the **Search** field, and select the appropriate language. Select the relevant crops and click '**Add**'.



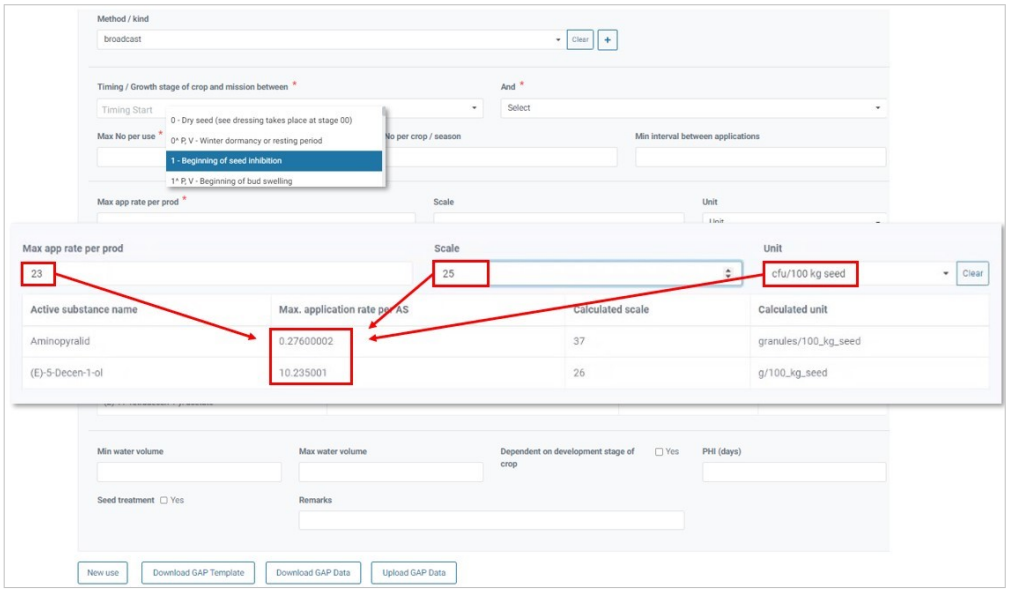
4. In the same way, search and add the pest(s) for which the product will be (has been) used.



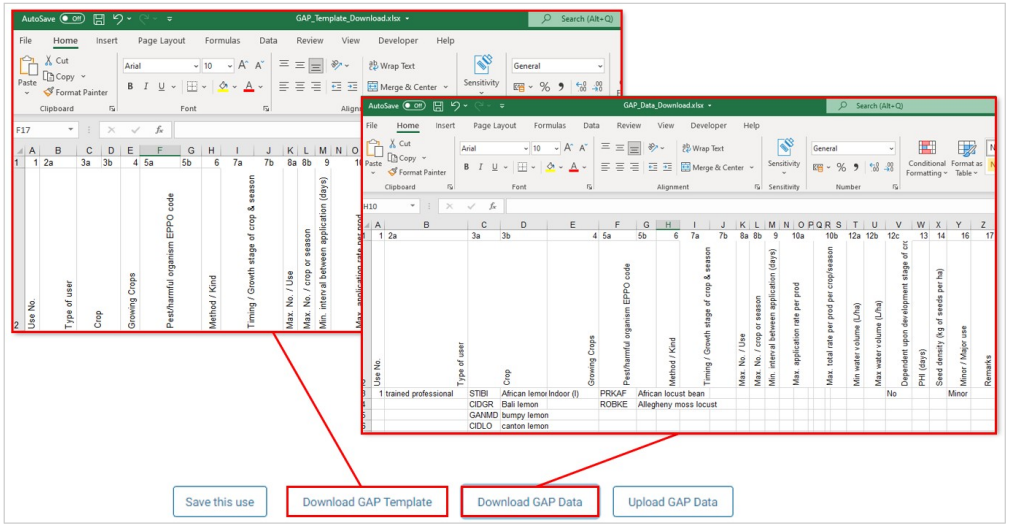
5. The selections are displayed for each use type. Click the '🗑' bin icon to remove a selection.



6. Complete the remaining (mandatory) fields. Note that the **Maximum application rate per AS** value is based on the Product Data provided and will be re-calculated if the **Max app rate per prod**, **Scale** and **Unit** values are changed.

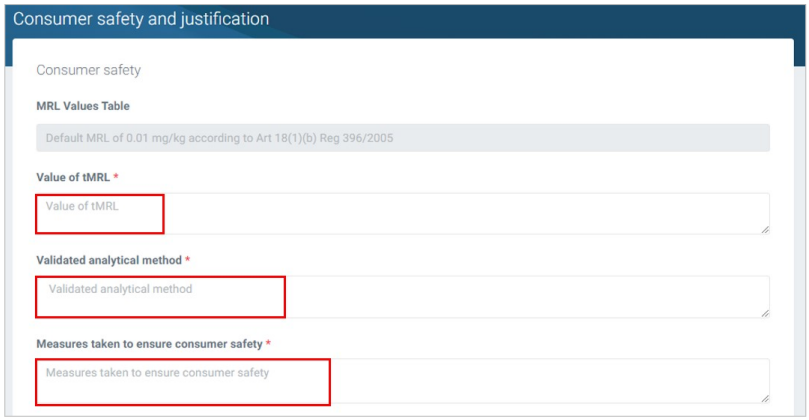


7. To enable wider team input and for convenience, you can download your supplied GAP data in excel format, share it for modifications, and re-upload. Alternatively, you can download the raw GAP template, complete it and re-upload.



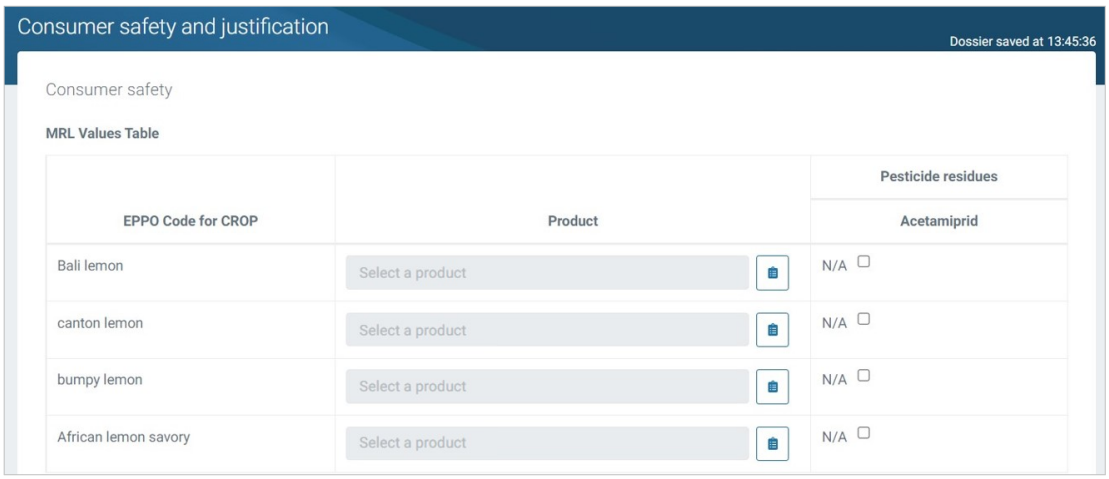
5.1.4 Consumer safety and justification

This data is unique to the emergency authorisation process. You can refer to named files you provide in the Documents section.

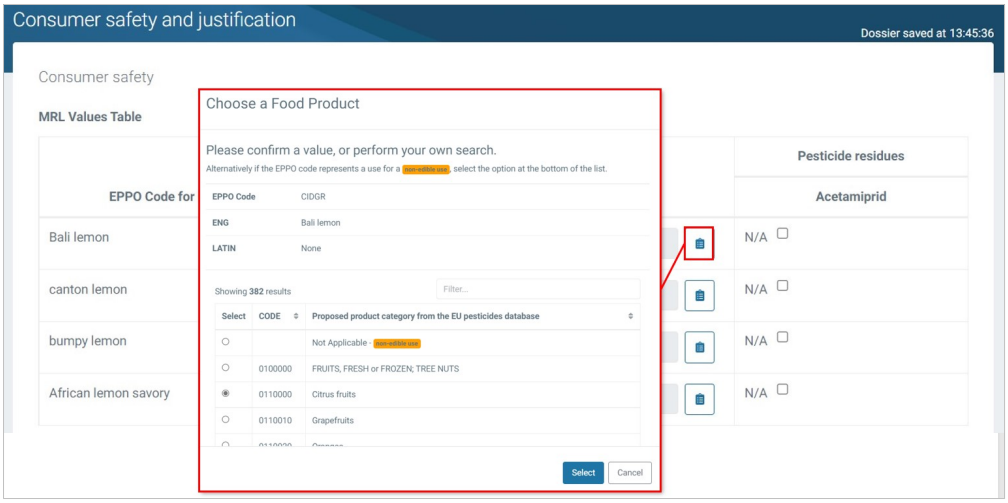


1. **Consumer safety**: The Maximum Residue Level (MRL) Values Table is set to the default maximum level. However, if an **active substance**[2] in the Product Data section is selected (in this case "Acetamiprid"), the MRL Values Table expands so you can identify the corresponding Food Product and its pesticide residue, as regulated across the EU.
   Note that the active substance name and its residue name may be different.

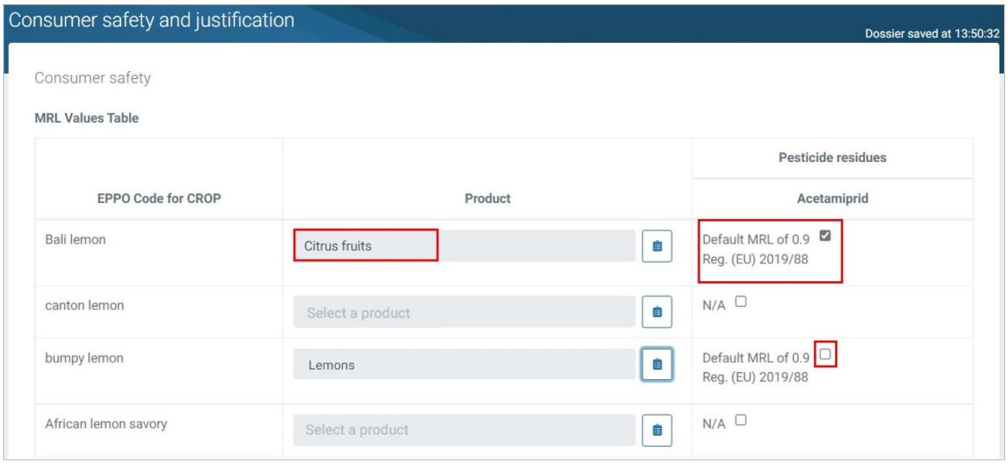
[2]See Active substances, safeners and synergists



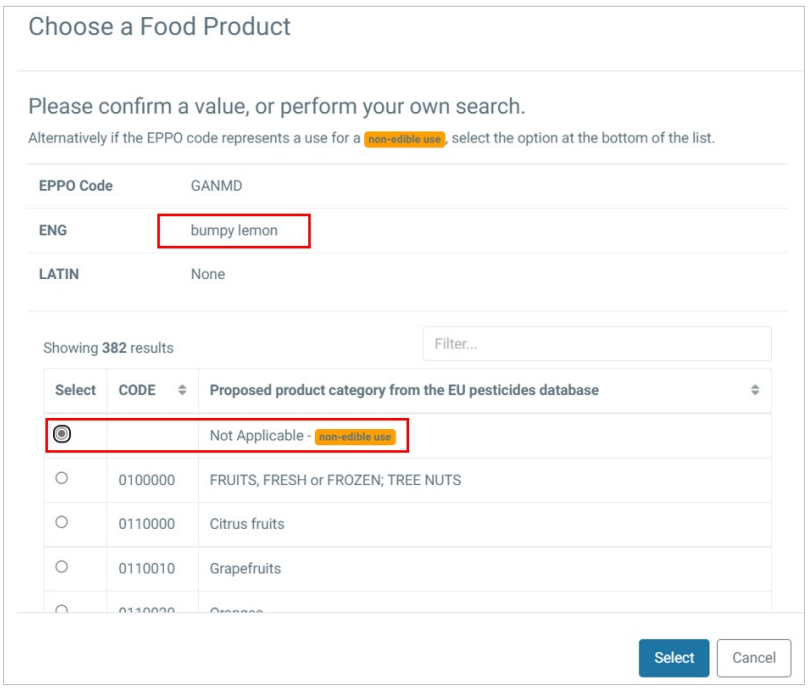
a. Click the '' list icon to select the Food Product for your crop, as selected in the GAP Data section. The PIMS database will display most food products and/or food families. Click the radial button next to your selection, then '**Select**'.



b. The corresponding MRL will display, with the appropriate regulation. Confirm the food type complies with this level using the check box.



c. If the MRL is not relevant to a crop or food product, click 'N/A' in the 'Pesticide residues' column. You can also remove a selection using the 'Not Applicable' radial button within the list screen (in this case "bumpy lemons").

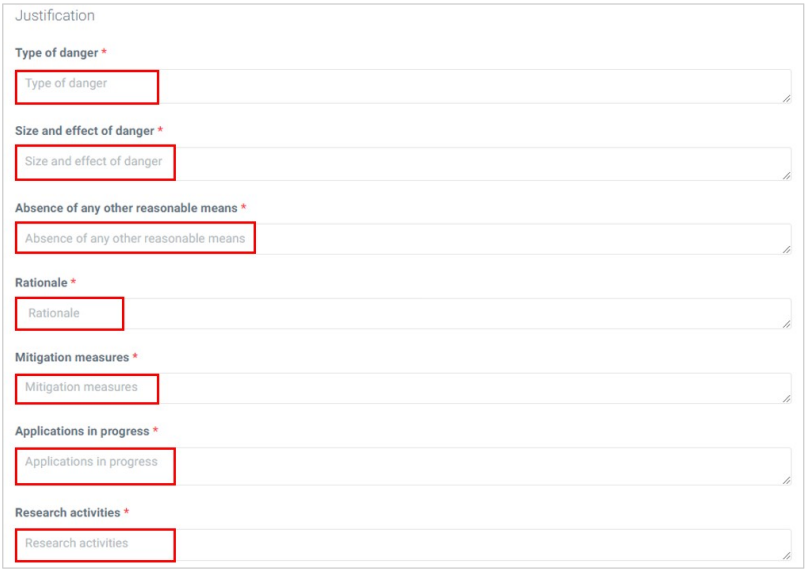


2. **Value of tMRL**: Include information on the measures taken to confine the commodities resulting from the treated crop to the territory of the notifying MS, pending the setting of a tMRL at EU level.

3. **Validated analytical method**: Provide details of the availability of the method for monitoring of residues in plants and plant products.

4. **Measures taken to ensure consumer safety**: Describe the consumer safety measures taken, indicating if the active substance(s) contained in the PPP being authorised is listed in Annex IV to Regulation (EC) No 396/2005, or would be expected to be listed in that Annex.

Provide the justification behind the emergency authorisation request.



1. **Type of danger**: Provide reasoning for what category the 120-day authorisation is given. Whereas reference to the EU quarantine legislation may suffice for quarantine pest, elaborate reasoning should be provided for the 'Any harmful pest' category.

2. **Size and effect of danger**: Describe the area affected, the development over time of the infestation, and the agronomic and economic effects it has.

3. **Absence of any other reasonable means**: Describe the alternative control measures (chemical, non-chemical and cultural) and indicate why they do not (in combination) suffice. Describe which, if any, authorisations for the pest to be controlled exist in other Member States.

4. **Rationale**: Provide the rationale based on the available information to justify the emergency authorisation. A description of the consequence if authorisation is not given (e.g. crop losses, costs, environmental risks) should be considered. Describe what measures are taken to limit and control use.

5. **Mitigation measures**: Describe what mitigation measures are taken if needed for minimising risk to humans, animals, and the environment – attach summary risk assessment in the Documents section. Describe what measures are taken to limit and control use.

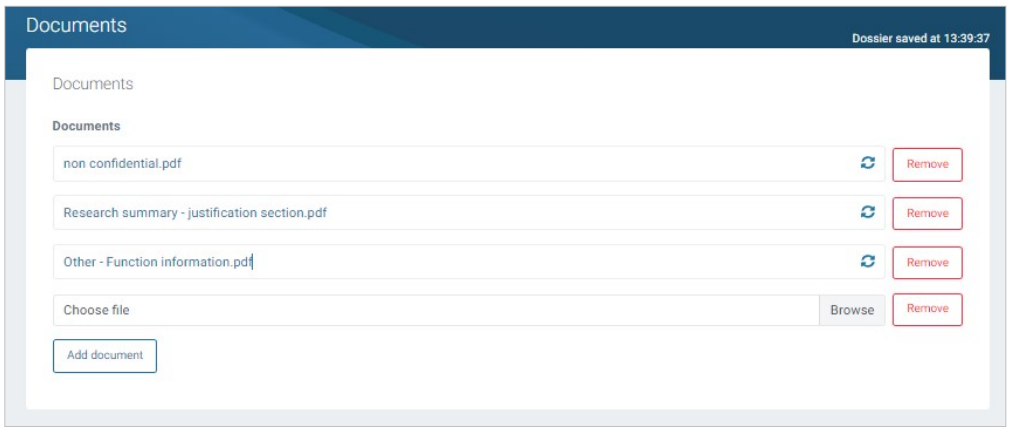
6. **Applications in progress**: The use notified may have been applied for already, or a suitable alternative PPP may be in the process of authorisation. Describe such applications, including a possible date of authorisation. For emergency authorisations that are in fact extensions of already authorised uses of products containing approved substances, reference to an ongoing Article 51 (minor use) or Article 33 (other uses) or Article 40 (mutual recognition) procedure should be given, where applicable.

7. **Research activities**: Describe the research efforts undertaken and/or in progress, their aims, their expected date of results.

NOTE
Enter "n/a" if a mandatory field is not applicable.

5.1.5 Documents

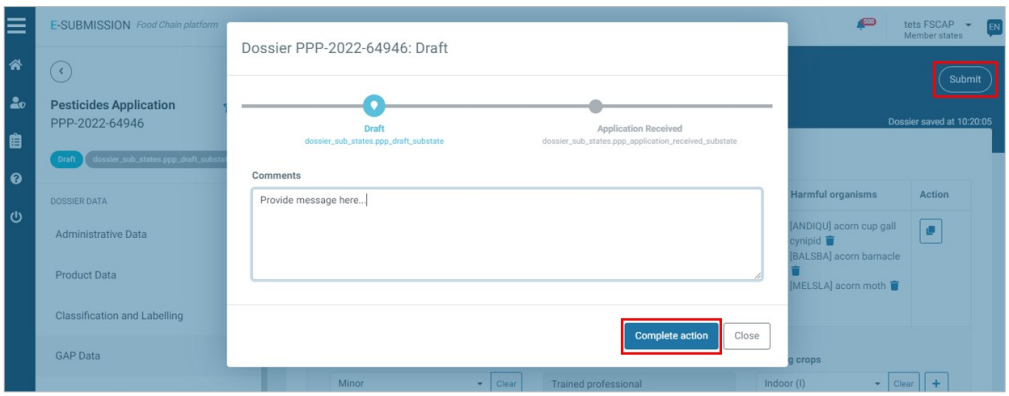
Upload any supporting documents, or documents referred to in the free-text fields, and label them accordingly. Make sure the content does not contain personal or confidential information.



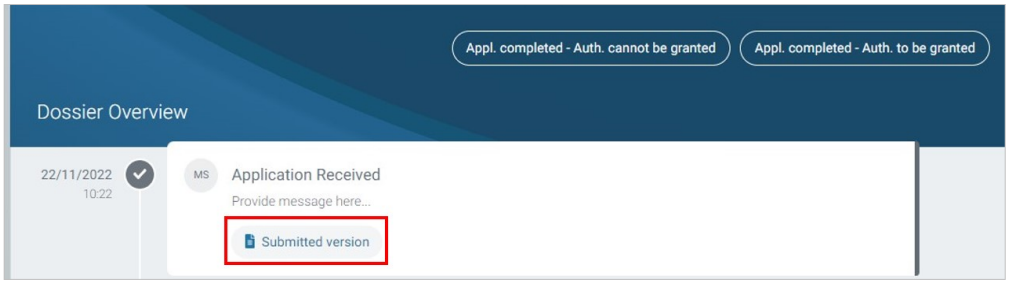
5.2 Submit application

When all application sections have been completed, click '**Submit**'. If mandatory fields remain incomplete, error messages will appear. These needs to be addressed.

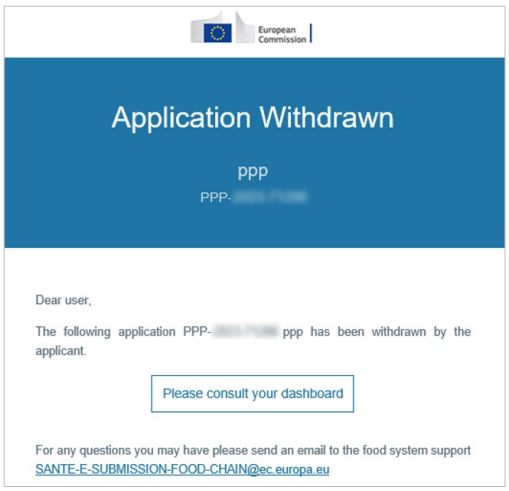
1. Complete the message displayed. Click '**Complete action**'.



2. Once submitted, the application process labels update in a new **application overview** screen. The icon allows a download (currently in excel format) of the application details.



3. The application can be withdrawn after submission, whether it was created by the Applicant or by the MS-CA on the Applicant's behalf. A notification is sent.



4. Now proceed as the recipient MS-CA to process the application.

6 Manage application

A notification is received by the MS-CA after an application is submitted (by Applicant, or on behalf of the Applicant). The MS-CA needs to:

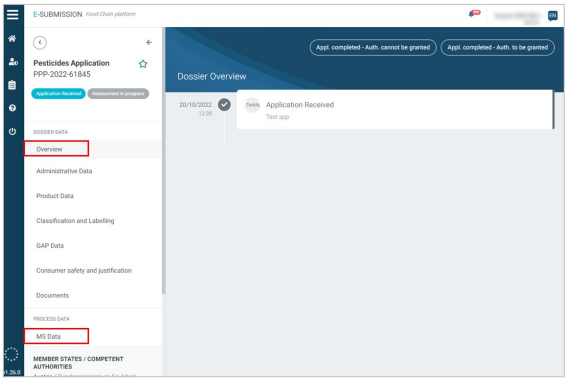
- Process the application, including checking and modifying information in the dossier data section (C&L, GAP, Consumer safety and justification).

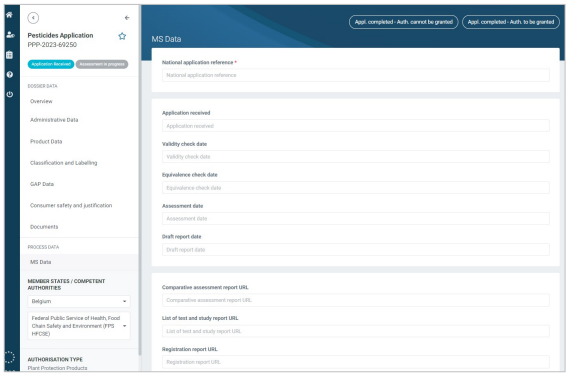
> **NOTE**
> It is essential that the MS-CA carefully checks and amends all information in the application, since this will be published if the authorisation is granted.

- Specify if an authorisation is granted or not granted.
- MS-CA can **develop the application** GAP Data right up until publishing, and specify the authorisation decision for each 'Use type'.
- Input the authorisation information/dates etc.
- Publish the application.
- Post-authorisation actions.

6.1 MS Data section

1. Log in as the MS-CA.
   The **Overview'** tab shows the application's progress. Click the '**MS Data**' tab to access the application processing fields.





2. Provide the **National application reference**, as assigned in the national system.

3. Complete the date information fields.

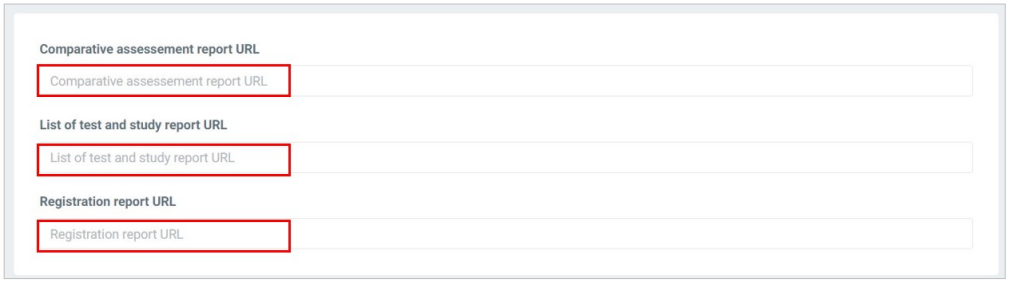
Supply the date when the application was received and select the validity check date, if relevant.

4. **Equivalence check** date.

5. The '**Assessment date**' refers to the date the assessment was finalised.

6. **Draft report** date.

7. Now provide links to the documentation hosted on the MS-CA's PPP system. Please only use **http://** or **https://** so the database can automate the link correctly.

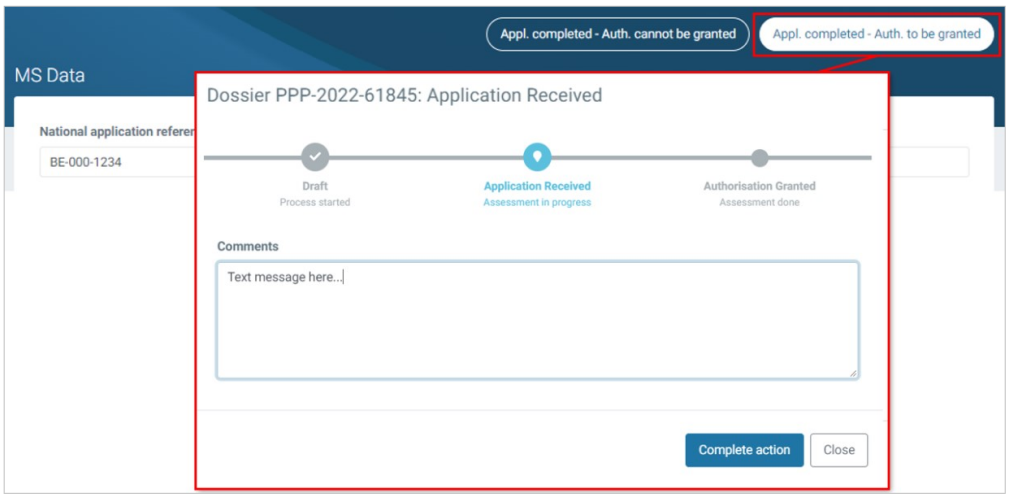


URL link to the **Comparative assessment report** URL.

8. URL link to the **list of test and study reports** used to support the application.

9. Provide the **Registration report** URL.

10. Finally, select the MS-CA assessment outcome, either '**Authorisation cannot be granted**' or '**Authorisation to be granted**', and complete the message pop-up. Click '**Complete action**'.

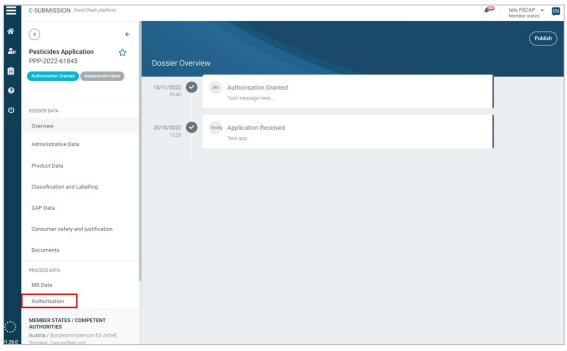


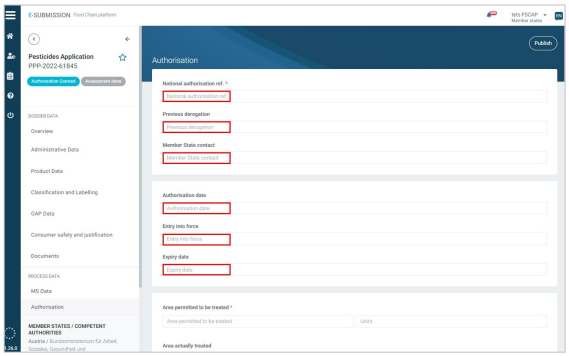
The authorisation phase begins, go to the Authorisation overview screen.

IMPORTANT
To enable correct URL code behaviour, please ensure you only supply **http://** or **https://**

6.2 Authorisation overview

1. The Authorisation overview shows application path.
   Click '**Authorisation**' tab to provide the authorisation background, dates, details, limitations and authorisation excel and pdf.





2. Provide the **National authorisation reference** number.

3. Select any **previous derogations** of the emergency authorisation, if any, from the dropdown list, in case the authorisation that you are creating has already been granted for this application for a period of 120 days and now needs to be extended.

4. Identify a **contact person** responsible for the authorisation at the MS-CA from the dropdown list, if any, with email/phone information (i.e. not a generic mailbox).

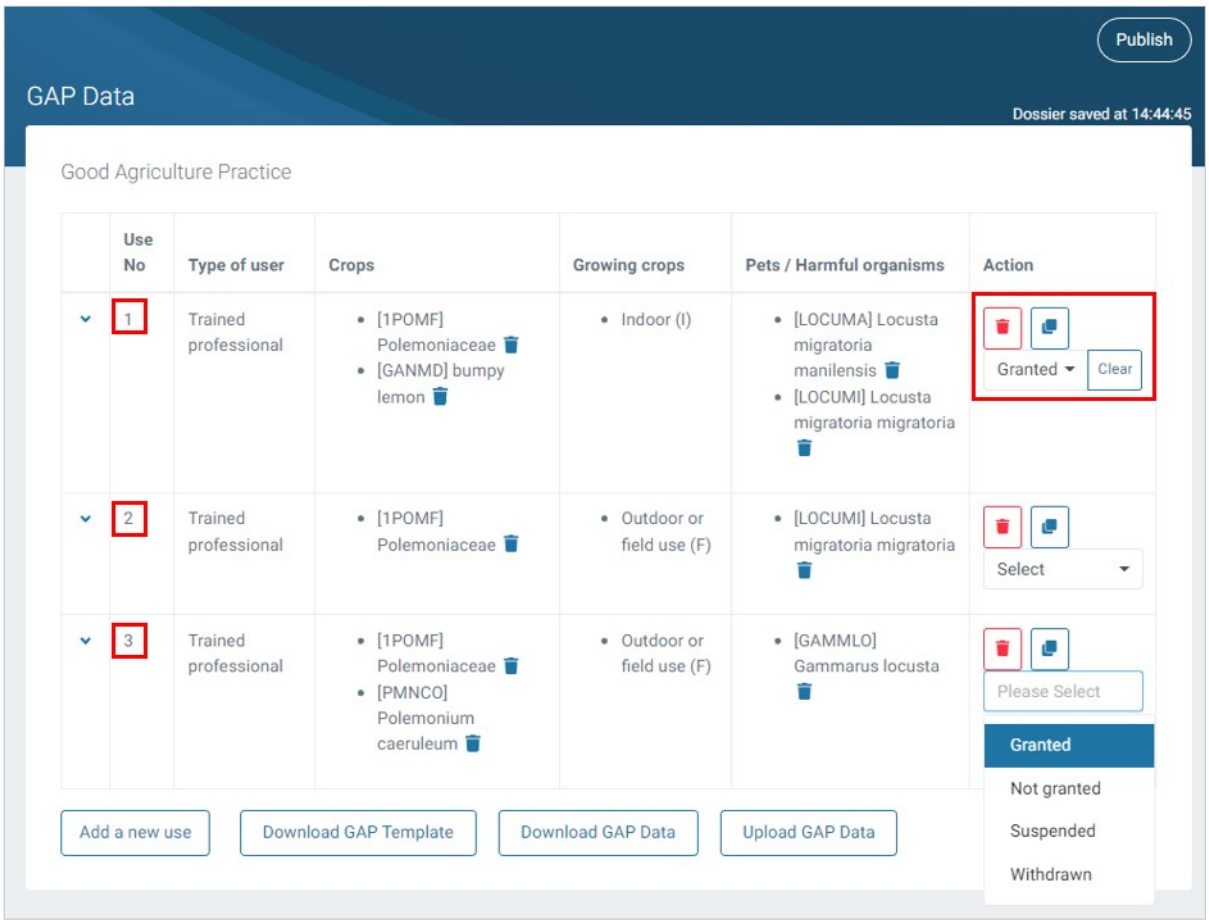
5. **Authorisation date**
6. **Entry into force**
7. **Expiry date**
8. Complete the fields for the area permitted to be treated, i.e. the size in your chosen units where the product will be used. The area **actually treated** is completed after the treatment with the product, see Post-authorisation actions [34]).

9. The system imports the authorisation details in **excel** and **PDF** formats. These will appear on the public PPP database after publication.

6.3 Decision for each use

Until publishing, the application can be developed by the MS-CA.

1. In the **GAP Data** section, new 'Use types' can be added using the **Add a new use** button. Alternatively, the clone ' ' button will duplicate an existing 'Use type', which can then be edited. Each can also be deleted, ' '.

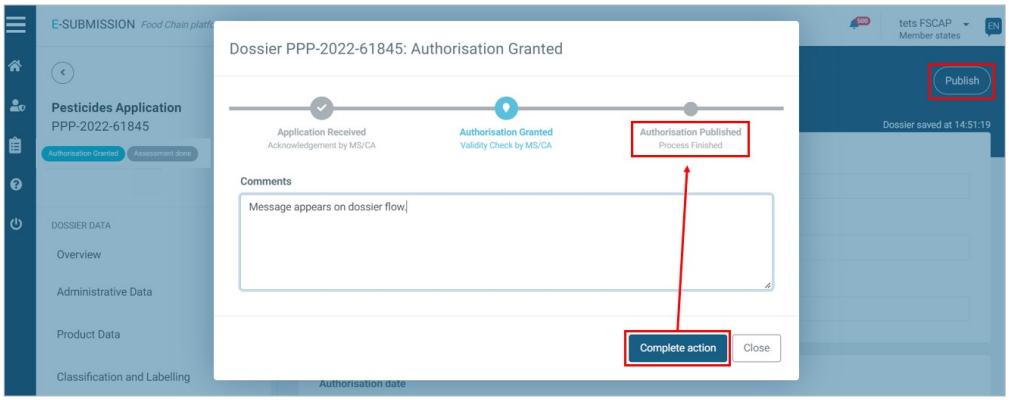


2. You have the option to download the existing dataset in excel format – or download the blank GAP template – which enables you to build the dataset 'offline', then re-upload it using the **Upload GAP Data** button.

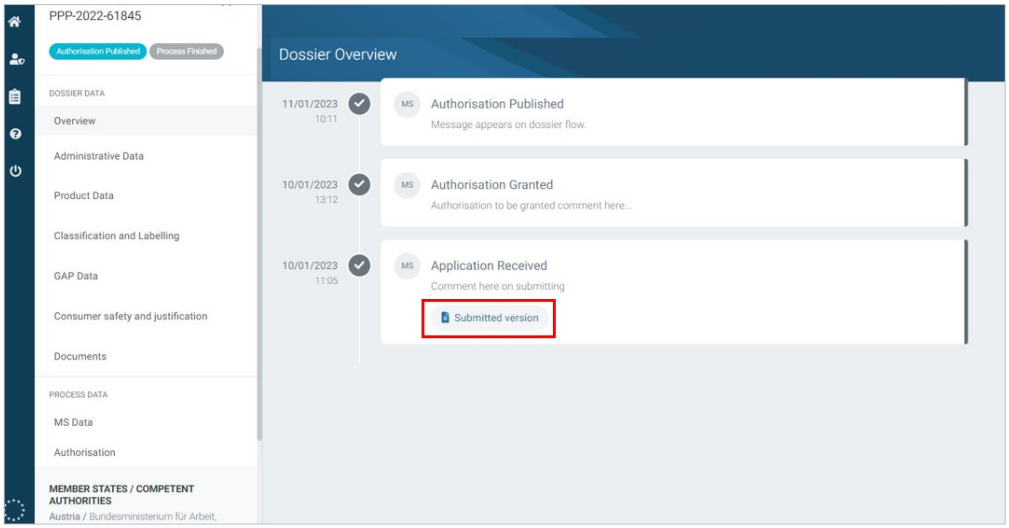
3. Each 'Use type' requires a decision in the Action column. Click the **Select** dropdown: **Granted**, **Not granted**, **Suspended** or **Withdrawn**.

6.4 Publish authorisation

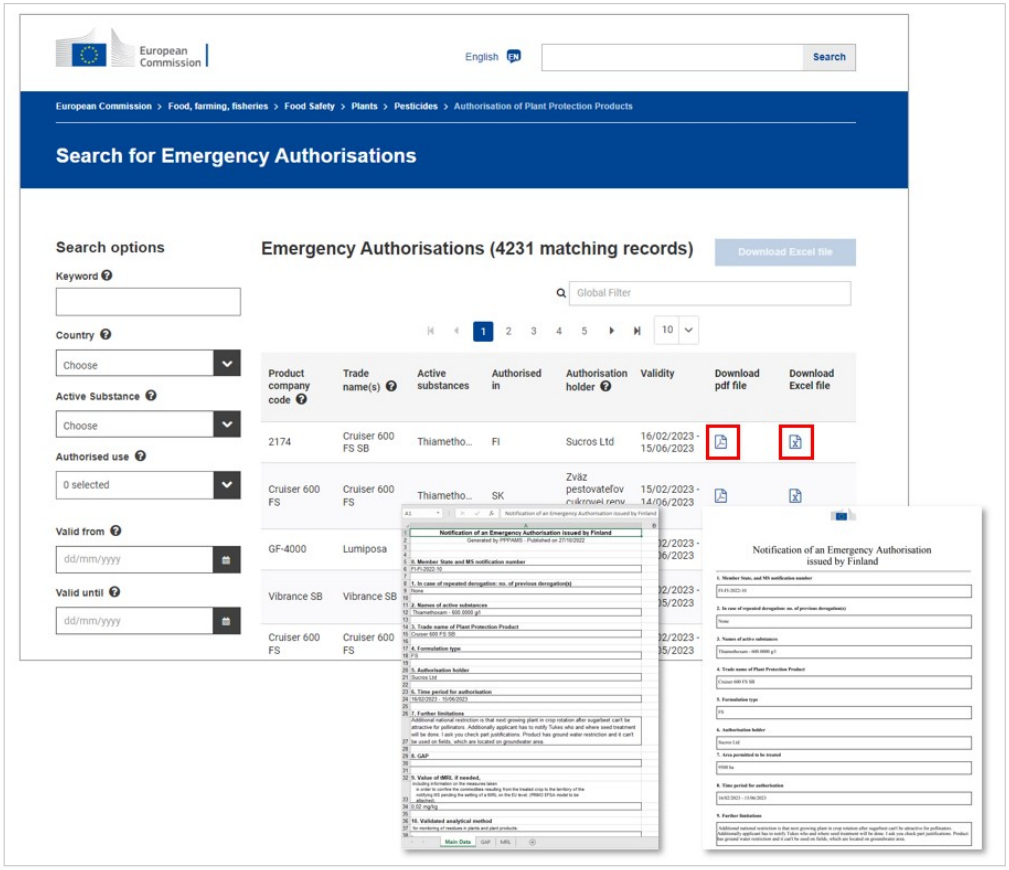
1. Click '**Publish**' and provide a message in the pop-up. The dossier enters the end phase.



2. Once you click '**Complete action**', the authorisation outcome and details are published. The dossier status is now **Process Finished**. Applicant, all MS-CAs and EC are notified. The original application can be downloaded from the icons displayed, the authorisation information can be obtained via the EU Pesticides database.

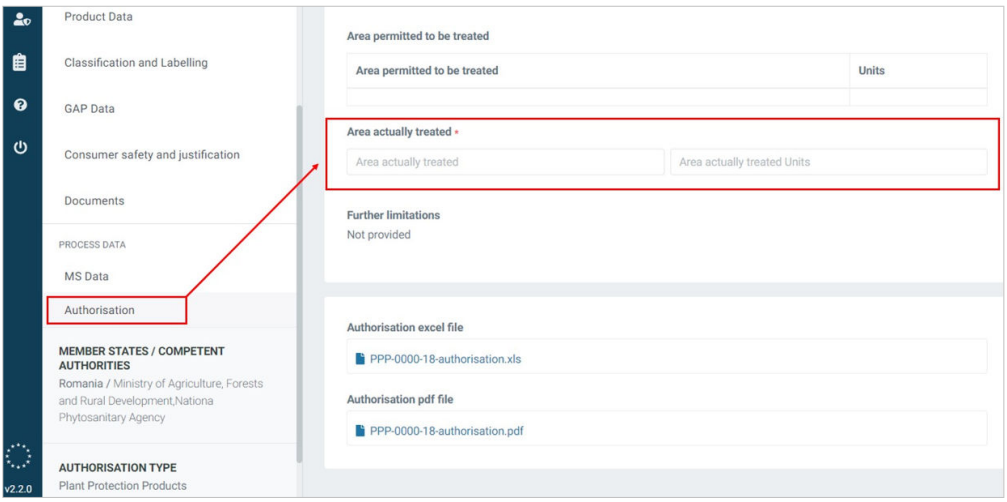


3. All elements of the authorisation are publicly accessible and downloadable on the Emergency Authorisations database.



6.5 Post-authorisation actions

The MS-CA must enter the **Area actually treated** after the authorisation has expired. The system will send a reminder email to the MS-CA user one month after that expiry date.



The PDF in the public database will be replaced with a new version.

7 Commission & EFSA's role

The Standing Committee on Plants, Animal, Food and Feed, Section – Phytopharmaceuticals Legislation, will be informed about authorisations granted by Member States. The Commission and Member States may discuss and scrutinise notifications, including the justifications underpinning the emergency authorisation, where appropriate. Member States are also invited to analyse and comment on the notifications provided by other Member States. Where the justification provided by the Member State is not considered complete or acceptable, the Member State may be asked by the Commission to provide further information.

In cases where a Member State proposes to set a temporary MRL, such proposals will be referred for discussion to the Standing Committee on Plants, Animal, Food and Feed – Section Phytopharmaceuticals – Pesticides Residues.

Furthermore, following the notification of emergency authorisations in accordance with Article 53(1) of the Regulation, in accordance with Article 53(2), the Commission may consult EFSA for an opinion or for scientific or technical assistance – in particular, this may be done in case of repeated emergency authorisations. If so, EFSA shall provide its opinion or results of its work within one month of the request.

Where, based on EFSA's advice, the Commission concludes that an emergency authorisation is not justified, it may present a proposal to the Standing Committee in accordance with Article 53(3) providing that the Member State may not extend the duration of the authorisation or may not repeat it, or requiring the Member State to withdraw or amend it.

European
Commission