Emergency Authorisations for Plant Protection Products (PPPs)

Guidance for applicants and organisations using the European E-Submission Food Chain (ESFC) platform to submit applications for emergency authorisations of PPPs
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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 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 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, all ESFC users should maintain and monitor a stable IT environment – i.e. following mailbox filtering and email spam protocols etc.
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**.

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](#):

![EU Login login page](image1)

![EU Login sign in page](image2)

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.

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.
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 a request has been sent, the administrator (this may be the European Commission for first requests to set up an Organisation, or the lead user in the selected Organisation or National Competent Authority for subsequent requests) receives a notification to grant access. Access is granted based on your access profile requested and organisation. You will then have access to the Emergency PPP authorisations on ESFC and be able to view / create applications.

NOTE

If you access SAAS directly, you will first be redirected to EU Login to log in your credentials. After entering your EU Login, you will be rooted back to the SAAS homepage.

1. Select 'ESFC' as the intended platform.
2. If you have no profile already set up, you are invited to click Request profile, and then select your organisation.

3. Select the Applicant folder and then open the Applicants-PEST folder to see PPP-registered organisations. You can use the search function to find for your organisation.
Select one organisation.
If your organisation does not appear, it needs to be registered. Click 2a Create organisation (page 9) and proceed. Organisations marked with ‘Request submitted’ can already be used to request access.
Sub-organisations appear within the parent folder, and the ‘Up’ button brings you up the family tree. Click Cancel to return to the start.
4. Click **Select an access profile**.

5. Select the **Applicant** role and click **Step 4: type a comment** – the comment is optional. Click **Submit request access**.

6. The status of the request, and the profile type are displayed. The request is sent to the administrator (EC or organisation) to verify.
Create new organisation in SAAS

If your organisation is not listed in SAAS, you can create a new one, or create sub-organisations underneath existing organisations.

Organisation hierarchies are constructed to limit access at which ever level you require for your own organisation. There is no horizontal access between sub-organisations and users in horizontal organisations cannot see each other’s products and applications.

1. Click the 2b Create organisation tab, and complete the fields. To set your organisation at the correct level, you must open the Applicant folder.

2. If no parent organisation exists, click the radial button Applicants-PEST. If there is a parent (i.e. you are creating a sub-organisation), click the folder and select the parent organisation. Click Step 3 - select an access profile.
3. In the Recap and Submission tab you can see the request summary. Type a comment and click Submit request access. The request is listed and awaiting approval.

**NOTE**
Each time you create a new organisation in SAAS, the initial user is granted the local administrator ('lead user') role. This enables that user to provide access to other users in their organisation, any subsequent sub-organisations, or consultants work for any level of the organisation.

**Applicant profile in SAAS**
Access profiles control what functions you are able to perform within the system. They also influence what information you are able to view. Consultant users have similar or identical access rights to industry users.
Table 1 Applicant profile

| Applicants – industry or consultant users | The 'Applicant' access profile should be selected if you work for a company, organisation or growers association that market, or is directly responsible for, plant protection products. This should also be selected by consultants working on behalf of the organisation. |

Consultants

In order that the company for which a consultant is working can access the applications submitted on their behalf, the consultant must be linked to the parent organisation or its child. If a consultant works on behalf of multiple organisations, a request for access to each organisation must be made.

Consultancy organisations should not be set up as standalone Organisations – they should be linked to a parent organisation that is responsible for PPPs. It is advised that consultants discuss with the organisation for which they will submit applications as to how they should set up and apply for access as it depends on the arrangement between the consultant and the business as to which option would be most suitable. For example, taking into account the number and frequency of applications being made for the parent company.

There are two options:

1. Set up a sub-organisation under the parent organisation and request access to it.
2. Apply directly to the parent organisation.
Access management

The **ESFC dashboard** lists ESFC applications based on EU login and SAAS access profiles. They are searchable by Application number Submission date etc. Your user status appears top right.

Activity notifications are received by users attached to an 'organisation' in SAAS via their registered email address. The email links back to the platform dashboard. Activity is also flagged by the notification bell 📣 in date order.

To add additional users to an application, go to the 'Manage dossiers access' button in the drop-down and enter the new user's email address. Click Add owner. The new user will need to be registered in SAAS to see/access PPP emergency applications in ESFC.
NOTE
The ‘Unsubscribe’ option in the user drop-down list will remove your personal email address as a recipient of notification pings.

IMPORTANT
Multiple users from an organisation can access and work on an application at the same time. 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).

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 status badges denote the current and next phase of the application. The dashboard timeline updates as the application proceeds through each phase.
<table>
<thead>
<tr>
<th>Application</th>
<th>PPP-2023-0021</th>
<th>PPP-2023-0007</th>
<th>PPP-0000-0029</th>
<th>PPP-0000-0029</th>
<th>PPP-2023-0082</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>Authorisation not granted</td>
<td>Application Received</td>
<td>Authorisation Granted</td>
<td>Authorisation Published</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>Date</td>
<td>09/01/2023</td>
<td>26/12/2022</td>
<td>27/12/2022</td>
<td>27/12/2022</td>
<td>10/11/2023</td>
</tr>
<tr>
<td>Time</td>
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<td>20:05</td>
<td>14:00</td>
<td>14:00</td>
<td>26:07</td>
</tr>
<tr>
<td>Action</td>
<td>Application withdrawn by company</td>
<td>Submitted version</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Emergency Authorisations for Plant Protection Products (PPPs)
Completing an application

The top of the left pane shows the application status and phase; upper right shows the auto-save time. Note the left section tabs which need to be completed. The selected MS-CA is shown, but an alternative can be selected before submission, if one exists, via the down arrow. The bottom section displays the authorisation and application type.

Complete the **Administrative Data** and the sections that follow.

![Administrative Data](image)

**NOTE**

Applicants having accounts with multiple organisations, e.g. consultants, are able to select the correct one for which they are submitting in the Administrative Data section.

**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**.
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](http://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).
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.

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 'x' 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.
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**\(^1\) 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.

\(^1\)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.

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

1. Click **Submit**, and complete the message, then **Complete action**. The application is submitted.

2. The application overview and the dashboard updates. EC is informed. The application can still be withdrawn after submission, whether it was created by the Applicant or by the MS-CA on the Applicant's behalf.
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.