What is this document for?

This quick reference guide gives a brief introduction and overview on the process for emergency authorisations and how to submit applications for them (in accordance with Article 53 of Regulation 1107/2009) via the Plant Protection Products Application Management System (PPPAMS).

What is an Emergency Authorisation?

The agronomic and environmental field situation in respect of plant protection continues to present emergency situations that pose a danger to plant production and ecosystems that cannot be contained by any available reasonable means (as cited in recital 32 of Regulation (EC) No 1107/2009). These emergencies demand quick and effective responses that cannot await the outcome of the normal authorisation process. Recital 32 recognises that certain exceptions are possible, and this materialises in Article 53. In these special circumstances, National Competent Authorities can authorise placing a PPP on the market for a maximum period of 120 days for a limited and controlled use.

Applications for emergency authorisations are made via the PPPAMS. The applications are made either by the Applicant (an industry or consultant user in PPPAMS) or by the National Competent Authority (in cases where the applicant is a grower, trade organisation or National Competent local authority, for example).

The Commission and all other National Competent Authorities must be informed when an emergency authorisation is granted, and if required the Commission may ask the European Food Safety Authority for an opinion or scientific/technical assistance.

Who creates an application for emergency use of a Plant Protection Product (PPP)?

As mentioned above, applications for emergency authorisations should, in most situations, be created by an applicant such as an agrochemical company, growers’ association and individual farmers or their authorised consultant operating on their behalf. If the application is made by an individual grower and is expected to be a one-time event then there is the possibility that the National Competent Authority creates a product in PPPAMS and submits an application on behalf of an applicant. Applicants should discuss with the National Competent Authority about what to do in these cases.

PPPAMS is able to facilitate both situations and therefore the system allows applications to be submitted by:

1. Applicants and their consultants (industry or consultant profile in PPPAMS.)

2. National Competent Authorities who act on behalf of minor growers or individual farmers who for one reason or another are unable to create their own accounts or whereby it is not practical to create an account.
How to submit an application for emergency use of a plant protection product (PPP)

This can be completed in 3 simple steps:

**Step 1. Create or select an existing PPP.**

Defining a product is very simple. The user simply inputs some key details about the product in the ‘Product>Create a product’ screen. Applicants should check before creating a new product to see whether the PPP already exists in PPPAMS. If so you can proceed directly to Step 2.

Enter the following details:

- Company code
- Formulation type
- Function
- Click the ‘Add substance’ button and add the active substance (s), safeners and synergists (if applicable.)

If an active substance is not in the EU Pesticides Database it will not appear in the list. Email the details to SANTE-PPPAMS@ec.europa.eu and it will be checked and added. The EC will contact you to tell you this has been completed and you can then continue to define your product.

**Step 2. Create and submit an application for the PPP.**

Once you have created a record for your product and defined its composition you can then create the emergency application for this PPP following these simple steps (also see the online user help in PPPAMS for further details.)

- In the PPPAMS menu click ‘Applications’ and then select ‘Create an application.’
- Search for and select the product you wish to authorise then select the ‘create application’ icon next to it – this opens the ‘create application’ screen.
- Under application type select ‘create emergency application.’
- Complete the other fields, including the applicant details and then click ‘save.’
- If multiple identical products are being authorised (products with the same Authorisation Holder) then add the other product trade names.
- The tabs for C&L, GAP and Justification are activated. All mandatory fields (those marked with a red asterisk) need to be completed as a minimum but if possible, all relevant GAP fields should be completed. To support your application, ensure that the fields within the Justification tab are sufficiently completed, providing the required information in a concise manner. In the MRL selection in the Justification tab, confirm if the established MRL for the use applied for is complied with. If an MRL is not complied with then a full consumer risk assessment and a tMRL need to be provided to the National Competent Authority and a tMRL should be indicated in the ‘tMRL’ field in the Justification tab.
- Next, go to the workflow tab and change the status to ‘submitted.’ The application is then submitted to the NCA in the Member State where authorisation is requested.

Tips:

1. If you wish to create an application for an emergency authorisation for multiple products (with the same use) but these are from different Authorisation Holders then you should create a separate application in PPPAMS per Authorisation Holder.
2. If you wish to create an application for an emergency authorisation for multiple products (with the same use) and the same Authorisation Holder, then you can create a single application in PPPAMS and include the various trade names of the PPPs.
3. If there are multiple applicants you can include details of the others in the ‘additional information’ box just before submitting the application. This box appears when you change status from ‘draft’ to ‘submit application’.
Step 3. Keep track of an application once it has been submitted.

Through the PPPAMS built in email notification system you can keep track of a submitted application, respond to any additional information requests if needed and see the application status and possible eventual authorisation.

Once an application is submitted, National Competent Authorities will carry out an assessment to determine if an authorisation can be granted, taking into account information and data submitted – this takes place outside of PPPAMS.

There are two possible stages where additional information may be requested:

1. At validity check stage
2. During the assessment

In both cases you will receive a message for action if a request is made. You should respond as appropriate inside/outside of the system (e.g. in PPPAMS if you need to amend the C&L, GAP or Justification sections or outside of PPPAMS if you need to submit required data.) Then you can change the status back to ‘validity check’ or ‘assessment by RMS’ in PPPAMS. The National Competent Authority would then continue with the application.

What happens if an emergency authorisation is granted?

You will receive a notification informing you if an authorisation is granted. The National Competent Authority will also issue their necessary documents outside the PPPAMS e.g. legal certificate of authorisation. The authorisation in PPPAMS does not have a legal status. National Competent Authorities, the Commission and EFSA users are also notified via PPPAMS when an emergency authorisation has been granted.

Can I update an application after it has been submitted?

Changes are not permitted in the system by applicants once applications have been submitted apart from during a request for additional information during the processing of the application by the NCA. If further changes are required then you should discuss this with the relevant evaluating National Competent Authority and see if a change can be allowed during their assessment. The National Competent Authority would then make the change/s in PPPAMS to ensure the correct information and

Reminder – Accessing PPPAMS

Each organisation set up in PPPAMS has been allocated at least one lead user who can provide access to other users within their organisation. New users simply need to have an EU Login and need to follow the instructions to request access to the system by going to:

https://webgate.ec.europa.eu/pppams

Further advice can be found on the PPPAMS webpages on Europa:


Need more help?

A dedicated support desk service is also available to all users by contacting:

SANTE-PPPAMS@ec.europa.eu