Plant Protection Products Application Management System (PPPAMS)

Applications for Emergency Authorisations –
Quick Reference Guide for National Competent Authorities

▶ What is this document for?

This quick reference guide gives a brief introduction and overview on the process for emergency authorisations – how to submit applications and create authorisations 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 the 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 onetime 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 4 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. Users 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.

It is also important to know that all National Competent Authorities can create emergency authorisations for the same product and duplicates should not be created if a product already exists.

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 the product.

Step 2. Create and submit an application for the PPP on behalf of an applicant.

Once you have created a record for the 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 the 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 should be provided by the applicant 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 you as the National Competent Authority responsible and you can continue the process.

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.

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

Normally the applicant has submitted the application, which means that as a National Competent Authority you only need to check the information that has already been completed. Here you would only need to confirm the C&L, GAP and Justification information. In the Workflow tab you can change the status of the application. It is possible to change the status directly to 'application completed' or 'application rejected.'

Important: Once the status 'application completed' has been selected, you must continue to Step 4 and create the authorisation. If you refuse the application you do not need to do this.

Benefit: Once an application has been submitted all National Competent Authority users are able to view the application. This improves transparency and allows all National Competent Authorities to have a clear overview of ongoing activity.

Step 4: Create the emergency authorisation

After the application has been completed the National Competent Authority user can create an authorisation within PPPAMS.

- On the main PPPAMS menu click 'Authorisations' and select 'Create emergency authorisation'.
- Search for the completed application for which you wish to authorise and click on the blue star on the right-hand side to 'create authorisation'.
- Fill in the general details regarding the authorisation. If the authorisation holder does not exist in the system already, just add it by filling in the form you can access next to the 'Authorisation Holder' field.
- Once you click 'save' you can check the classification and labelling information.
- Next, confirm the GAP table and select the appropriate field for each use in the 'Actions' tab - granted, not granted, suspended or withdrawn. Click 'save.'
- Confirm/update all the fields in the justification information section (in English) and then finally once you have checked and confirmed all tabs, click on the publish button to complete the authorisation. The authorisation will then be made public.

Benefits: Once complete the Commission and other National Competent Authorities can see all this information so there is no need to submit the notification form.

PPPAMS will send an email notification to all National Competent Authorities, EC and EFSA to inform them of the emergency authorisation. The notification will include a pdf attachment including details of the authorisation granted. This pdf can also be downloaded from within the system when you search and view an authorisation.

The PPPAMS will populate a public database on authorisations which will display key information on authorised PPPs in the EU.

▶ Reminder – Accessing PPPAMS

If you do no already have access to PPPAMS you can request access to the system by going to:

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

The lead user in your National Competent Authority will grant you access.

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

http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams/access_training/index_en.htm

Need more help?

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

SANTE-PPPAMS@ec.europa.eu