



E-submission Food Chain (ESFC) Platform

Applications for Emergency Authorisations of PPPs - Quick Reference Guide for Applicants

► 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 E-Submission Food Chain (ESFC) Platform.

► 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 submitted via the ESFC. The applications are made either by the Applicant (an industry or consultant user) or by the National Competent Authority (NCA) in a Member State (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 consultants 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 and submits an application on behalf of an applicant. Applicants should discuss with the National Competent Authority about what to do in such cases.

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

1. Applicants and their consultants (industry or consultant user profile)
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 authorisation of a plant protection product (PPP)

Access ESFC and select 'Create a new application' from the top right-hand side of the dashboard.

Select:

1. 'Pesticides' from the food domain list
2. 'Plant Protection Products'
3. 'Application for emergency authorisation'
4. Select the Member State to which the application is being submitted
5. Select the National Competent Authority (NCA) in the chosen Member State (in many cases there is only one option)

Select 'Start process' – an ESCF identifier number is given to the application.

The user completes the different fields within the dossier section indicated on the left-hand side: Administrative data, Product data, Classification and Labelling, GAP data and Consumer safety and justification.

- If multiple identical products are being authorised (products with the same Authorisation Holder) you can add multiple product trade names.
- The section for C&L, GAP and Consumer safety and justification must be fully completed.
- All mandatory fields (those marked with a red asterisk) need to be completed as a minimum but ideally all fields should be completed.
- To support your application, ensure that the fields within the consumer safety and justification tab are sufficiently completed, providing the required information in a clear and concise manner.
- In the MRL selection in the consumer safety section, 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.

Once all data has been completed and checked, click 'Submit'. The application is then submitted to the NCA in the Member State where authorisation is requested. Once submitted an application cannot be modified, however, it can be withdrawn by the applicant.

► Keep track of an application once it has been submitted

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 ESFC. Member States may ask applicants for additional information during their evaluation. Such requests should be handled outside of ESFC according to the procedures of the National Competent Authority.

Once the application has been completed the Member State will determine if an authorisation can be granted or not. If an authorisation can be granted, the Member State will complete certain information in EFSC and publish the final authorisation record in the EU Pesticides Database.

► Accessing ESFC for submitting applications for emergency authorisation of PPPs

Each organisation set up in SAAS (the user access authorisation system) has been allocated at least one lead user who can provide access to other users within their organisation. Accounts created previously for PPPAMS remain valid for ESFC. 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/esfc>

Need more help? A dedicated support desk service is also available to all users by contacting:

SANTE-E-SUBMISSION-FOOD-CHAIN@ec.europa.eu