

# 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



Emergency PPP v 1.0 February 2023

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# Welcome to the ESFC

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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.

# 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**.

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 One account, many EU services	ECA	S7 0 English (en)	EU Login One account, many EU services		ECAS7 D English (en)
		Create an account Login		Sign in to continue	9
	Create an account			Welcome back	
	It's transmitter under the state of the stat			Auriced Australiants and automatication and automat	
			About EU Login Cookies Privacy Statement	t Contact Help	Poweed by
About EU Login Cookies Privacy Statement Con	lact Help	Powered by	European Unión EU institutions	6.2.5 b-dikip   6 m	is Endersion
European Union EU institutions	8 2 5 b-dri3p   3 ms	Commission			

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.

	Applicant Tra Applicant Tra	aining - EN	Start new application	
	Create new ap	oplication	1 Food domain list Food domain list Decontamination Substances Extraction Solvents Food Contact Materials Food Contact Materials Food Inprovement Agents GMO Novel Foods Nutrition	~
\$ Applicant/Company name	Subject of the request	Action		
Column filter	Column filter			

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

rt new application		Start new application	
1 Pesticides	~	1 Pesticides	
2 Plant Protection Products	~	2 Plant Protection Products	
3 Application for emergency authorisation	~	3 Application for emergency authorisation	
4 Recipient Member State	~	4 Austria	
Austria Belgium Bulgaria Copratia Copratia Cacch Republic Dermark Estonia Finland France Gerece Hungary Leeland Iteland Italy Latvia Latvia		5 Bundesamt für Ernährungssicherheit           Start process   Once the application is created, the food domain, authorisation type and a cannot be changed. Please ensure that the selection you have made is co clicking 'Start process'.	application type rrect before

## **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.

European Commission	aas - Authorization System	Privacy Statement	Support	1	🖰 Logout	English (en)
European Commission > DG Health and Foo Home Request access User Data details	d Safety > Saas					
Select an application Select an application AAC - Administrative Assistance (no AAC - Food Fraud BP-Portal	x Food Fraud!)					
Cosmetic Products Notification Port Cosmetic Products Notification Port CPMS dyna_meetings ERN Service Directory	al SANTE (v3.2)	Top   n0046qc9 (n0046qc				
EU Common Catalogue Euceg reporting EUCoding European Reference Networks EUROPHYT Food System - CAP FOREMATIS						
FRUMATIS GM Consultations GMO web	•					

2. If you have no profile already set up, you are invited to click **Request profile**, and then select your organisation.

Ohary Statemet      Stapped     Sages - Authorization System	Phang Statement      Stagent      Sages - Authorization System
Europan ESFC	European Commission Description Description Description Description
Home	Home
Request access User Data details	Request access User Onto defails
ESPC v ESubmission Food Chain	The Commission shall process personal data information pursuant to Regulation 45/2001 EC on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
You don't have any User Profile for this Application. Please click here to request an access	New application access
	Select application     Select organisation     Select access profile     Gecap and Submission
	Application ESFC V
	Cancel Step 2 : solid an 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.

Select organisation Crganisation Crganisations			20 Select organisation	20 Create organisation	
Organisations					
25 v records per page			*Organisations		
		Search:		25 v records per page	Search:
(/				+ up / Applicant / Applicants-PEST	
Applicant		Details O		C. Eleonas	Details
	_	Details O			Details C
Ourse		Details O		Ο ΑΔΑΜΑ ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε. ΛΥΣΕΙΣ Γ	TA TH FEOPRIA Details
Services MS		Debit O		O ADAPTICA SAS	Details C
*Organisations CO				AEDES PROTECTA	Details C
0	25 v records per page	Search		0.42014.0.4	Datato A

4. Click Select an access profile.

2a Select organisation	2b Create organisation	
*Organisations		
	25 v records per page	Search: test
	- Back	
	O / Applicant / Applicants-PEST / TEST	Details 🕥
	<ul> <li>/ Applicant / Applicants-PEST / Test Organisation</li> </ul>	Details O
	Showing 1 to 2 of 2 entries	e 1 »
Organisation marked with	(ranuest submitted) can already be used to ranuest access	
organisation marked with	r (request submitted) can ancady be used to request access.	

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

New application a	access			New application	access		
Select application	Select organisation 1 Select ac	cess profile (6) Recap and Submission		1 Select application	2 Select organisation 3 Select access profil	e O Recap and Submission	
*Access Profile				Summary			
	Name	Status Description		Application	ESFC		
	Applicant			Organisation	Test Organisation		
	EFSA-read			Access Profile	Applicant		
	C EFSA-write						
	MS-read			Comments	Possible comment here		
	MS-write						
				Before submitting A request to get access to	o an application will be validated by the administrators. Ih	s is a manual process and can take a few days.	
				+ Step 3 : select an access	s protile	Cancel	Submit request acce
+- Step 2 : select an organisat	ion	Canoel	Step 4 : type a comment →				

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

Home				
Request access	User Data details			
ESFC	•	E-Submission Food Chain		
User Profiles				
25 v reco	ds per page		Search:	
Status 🔺	Organisation ≑		Access Profile *	
requested	/ Applicant / Applicants-PEST / Test Organisation		Applicant [requested]	
Showing 1 to 1 of	entries			« 1 »
Table legend Manage Manage	he user profiles you are Administrator of;   Delete; 📁 Reject rec	ason; * The search is not performed on this column.		

#### 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.eu

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

### **Create new organisation in SAAS**

If your organisation is not listed in SAAS, you can create a new one, or create suborganisations 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.

select application	2 Select organisation 3 Select access profile 4 R	ecap and Submission	
Select organisation	2b Create organisation		
Organisation d	letails		
	Create new Organisation		
Name			
Vebsite			
Gen. mail			
Gen. phone			
Sen. fax			
Address			
Zip code			
City			
Country	[No value selected]		
Parent Organisation			
	25 V records per page	Search:	
	and the second sec		

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.

Select application 2	Select organisation 3 Select access pr	ofile 4 Recap and Submission		
2a) Select organisation	2b Create organisation			
Organisation detai	s			
	Create new Organisation			
*Name	Test Chemic Org			
Website				
*Gen. mail	testchemic@org.com			
Gen. phone				
Gen. fax				
*Address	asdf			
*Zip code	asdf			
*City	adf			
*Country	Austria			
*Parent Organisation				
	25 v records per page		Search:	
Select your parent organisation from	🗲 up 🖉 / Applicant			
the folder list	→ Copen ○ Applicants-PEST			Details O
	Showing 1 to 1 of 1 entries			« 1 »

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.

New application	2 Select organisation 2 Select access profile  C Recap and Submission	Su You hav	ICCESS or request for the re been removed	e access was created successfully. This request has to be validated by an administrate d)	or before it is activated (Note: during saving some special characters may
Summary			ESFC	E-Submission Pood Cha	in .
Application	ESF-C testing	User	Profiles		
Access Profile	Applicant	25 State	v records	Organisation	Search:
Comments	Optional comment	requi	ested	/ testing (Organisation to be validated)	Applicant [requested] (Local Admin.)
		requi	ested ing 1 to 2 of 2 er	/ Applicant / Applicants-PEST / Test Organisation	Applicant (requested)
A request to get access t	o an application will be validated by the administrators, this is a manual process and can take a few days.	Tak	le lepind Manage the	user profiles you are Administrator of 👔 Delete: 🗰 Reject reasor: *The search is not perform	med on this column.
+- Step 3 : select an access	a profile Cancel	Submit request access			

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

-SUBMISSION Food Chai	in platform										Applicant Train	ning • cant
Dashboard											Create new app	olicat
My application list											4 APPLICATIONS	USTE
Application number	Question Number 🗘	Submission date	Authorisation type	٥	Application type \$	Current state	¢	Current phase	٥	Applicant/Company name	Subject of the request	A
ppp	Column filter	Column filter	Column filter		Column filter	Column filter		Column filter		Column filter	Column filter	
PPP-2023-71697			Plant Protection Products		Application for emergency authorisation	Draft		Process started		CHILD_BASF, Name	Default text	D
PPP-2023-69021		05/01/2023 10:07	Plant Protection Products		Application for emergency authorisation	Authorisation not granted		Process Finished		CHILD_BASF	asdf	
PPP-2023-69082		06/01/2023 09:47	Plant Protection Products		Application for emergency authorisation	Withdrawn		Process Finished		CHILD_BASF	ddd	
PPP-2023-71286		06/02/2023 09:54	Plant Protection Products		Application for emergency authorisation	Withdrawn		Process Finished		CHILD_BASE	XYZ trade name	

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 *a* 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.



My application lis							1 APPLICATION L
Application number	Authorisation type	Application type	Current state	Current phase	Owner(s)		
71697	Column filter	Column filter	Column filt	Column filter	Column filter		
PPP-2023-71697	Plant Protection	Application for	Draft	Process started	applicanttraining5@gmail.com	another-user@1.com	Add own



#### NOTE

The '**Unsubscribe**' option in the user drop-down list will remove your personal email address as a recipient of notification pings.

4	Applicant Training - Member states	EN				
	Support					
	Privacy statement					
	Unsubscribe					
Π.	Cookie details					
	Manage dossiers access					
	User profile information					



#### 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.

My application list			
Application number 🗘	Submission date	•	Authori
63331 <mark>X</mark>	Column filter		Colun
≪ ≫			

The status badges denote the current and next phase of the application. The dashboard timeline updates as the application proceeds through each phase.

sticides Application P-2023-69021 ritorisation not granted Process Finished	05/01/2023 Of Mis Authorisation not granted cannot be granted
sticides Application P-2023-69007 splcation Received Assessment in progress	27/12/2022 Application Received 20:41 Submitting draft
esticides Application PP-0000-229	Authorisation Cranted
Authorisation Granted Assessment done	27/12/2022 V Aution Station Granted
Authorisation Granter Assessment down esticides Application PP-0000-20 Authorisation Published Process Finished	27/12/2022 Authorisation Granted

# **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.

	E-SUBMISSION Food Chain platform			Applicant Training - P
*	÷ +			Submit
20	Pesticides Application PPP-2022-63331	Administrative Data		Dossier saved at 15:57:33
11 12	Draft With Applicant	Applicant Admin data •		
4	DOSSIER DATA	- Name		
0	Administrative Data	Applicant Name	Email	
	Product Data	Name	phoneyman@mail.com	
	Oleveites and Labelling	Phone number	Website	
	classification and Labelling	123456	xyz.com	
	GAP Data	Address	Post code	
	Consumer safety and justification	Address	12343	
	Documents		le la	
	MEMBER STATES / COMPETENT	Country		
	AUTHORITIES Belgium	Austria	- Clear	
	Federal Public Service of Health, Food Chain Safety and Environment (FPS • HFCSE)			
<u> </u>	AUTHORISATION TYPE Plant Protection Products			
1.26.0	Application for emergency authorisation			

Complete the Administrative Data and the sections that follow.

**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**

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'.

Pesticides Application 🏠	Product Data						Dossier saved at 09:24:31
Draft Process started	PPP Product						
DOSSIER DATA	Product trade name(s)* Enter the product trade name	here.					- +
Administrative Data							
Product Data	Copy existing product det	ails	1	1000 AL			
Classification and Labelling	Product company code *	Se	arch by company e	xisting product			Search
GAP Data	Function *		Organisation	Company	Formulation tuno	Eurotion	aubstance
Consumer safety and justification	Select a function		10	code	Politication type	Function	substance
Decumente		0	26037				
Documents	Active substance, Safener	0	26037	ddd	AL - Other liquids to applied undiluted	nematicide	(E)-2-Methyl-6-methylene-3,7- octadien-2-ol (isomyrcenol)
MEMBER STATES / COMPETENT AUTHORITIES	Select		1 .				Salact this product
Belgium -		1					Cancer and product

 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).

luct Data		Dossier saved at 16:14
PP Product		
roduct trade name(s)*		
Product trade name		- +
Copy existing product details		
Product company code	Formulation type * 🚱	

 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.

Function 😧					
attractant				-	Clear × +
Search for a function					× +
other					
attractant		Content of pure substance in product	Scale	Unit	
fungicide	- Clear	87	Enter a scale	g/kg	- Clear +
herbicide					
insecticide					
molluscicide					
nematicide					
plant growth regulator					

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).

(4Z	-9Z)-7,9-Dodecadien-1-	bl		IU/kg	n
(E)-	10-Dodecen-1-yl acetat	e		spores/ml	1
(E)-	11-Tetradecen-1-yl ace	ate		cfu/kg	
(E)- (m)	2-Methyl-6-methylene-2 /rcenol)	,7-octadien-1-ol		cfu/l	
(E) (iso	2-Methyl-6-methylene-3 myrcenol)	,7-octadien-2-ol		g/kg g/l	
(E)-	5-Decen-1-ol			granules/kg	
(E)-	5-Decen-1-yl acetate			granules/I	
ctive substance, Safer	er or Synergist	Content of pure substance	In product Scale	Unit	
Aminopyralid	- die:	ar 3	2	g/kg 🗸 C	lear 🗙
(E)-5-Decen-1-ol	- Cie	ır 1	2	g/kg -	lear 🗙
Select		Enter a content	Enter a cos	Select	ने जा

### **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.

 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 '+'.

lassification and Labelling	Dossier saved at 09:22:56
Classification	
No classification	
Classification*	
Flammable solid	- Clear - +
Search	- +
Flammable solid	
Flammable liquid	
Germ cell mutagenicity	
Hazardous for the ozone layer	
Hazardous to the aquatic environment	- Clear - +
Organic peroxide	
Oxidising gas	
Oxidising liquid	

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

GHS pictograms	
GHS pictograms	
Xn	<ul> <li>✓ Clear</li> <li>←</li> </ul>
Select a GHS pictograms	<b>-</b> +
	GHS01
	Xn Xn
	GHS03
	GHS04
	GHS05

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

Signal	
Signal	
Search	
warning	
danger	

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

Hazard stater	ment	
Hazard stateme	nt	
ppp_hazards.H	1332	- Clear +
Search		 - +
H332		
H334		
H335	ment	
H336	nt	

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.

Precautionary statement	
Precautionary statement	
Search	- +
P363	
P370	
P371	
P372	
P373	

6. Provide an additional statement if necessary.

Additional statement		
Additional statement		
Input free-text statement here		

### **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 ' $\checkmark$ ' arrow **minimises** the data fields for each use type. Click the ' $\blacksquare$ ' 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.

6000	Agricultur	e Plactice				
	Use No	Type of user	Crops	Growing crops	Pets / Harmful organisms	Action
~	1	Trained professional	Not provided	•	Not provided	
>	2	Trained professional	Not provided	·	Not provided	Clone
*	3	Trained professional	Not provided		Not provided	<b>I</b>

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

Type of use *		Type of user	Growing crops	*	
Select	Major 💽	Trained professional	Indoor (I)	- 0	lear 🗙 +
	Minor		Select	Glasshouse (G)	• × +
				Indoor (I)	
				Outdoor or field use (F)	

 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'.

			Name or EPPO Code *	n				Searc	
ood Ag	riculture Pract	ice			español čeština dansk			P .	
	Use No	Type of user			eesti ελληνικά English			Filter	
^	1	Trained profession	Eppo Code *	Name ¢	T	ype≎ La	nguage ¢	Preferred \$	Select
		/	STIBI	African lemon savory	P	FL en		false	
Туре	of use		PMNMI	annual polemonium	P	FL en		false	
Mir	nor		CIDGR	Bali lemon	P	FL en		false	
Cron	(s):*		GANMD	bumpy lemon	P	FL en		false	
	(6).	Select crop(s)	CIDLO	canton lemon	P	FL en		false	
			CYGFL	East Indian lemongrass	P	FL en		false	
									-

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

arch for an	EPPO Code						
me or EPPO Code *		Language		Ŷ	Search	Pets / Harmful organisms	Action
				Filter	_	Not provided	
Eppo Code *	Name \$	Type ≎	Language \$	Preferred \$	Select		
TIBCSE	17-year locust	GAI	en	false	0		
PRKAF	African locust bean	PFL	en	false		crops	
OCUMM	African migratory locust	GAI	en	false		(1)	Clear +
ROBKE	Allegheny moss locust	PFL	en	false			
ANCRMA	Arabian tree locust	GAI	en	false	0	(Harmful organism(s):*	
MENPME	Atlantic locust	GAI	en	false		Select pest(s) / Harmful organis	:m(s)
					-		

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

	Use No	Type of user	Crops		Growing crops	Pets / Harmful organisms	Action
^	1	Trained professional	• [ST • [CI • [G/ • [CI	'IBI] African lemon savory 🗃 DGR] Bali lemon 🗑 NMD] bumpy lemon 🍵 DLO] canton lemon 🍵	Indoor (I)	[PRKAF] African locust bean      [ROBKE] Allegheny moss locust	•
Туј	pe of use			Type of user		Growing crops	
N	Ainor		- Clear	Trained professional		Indoor (I)	Clear +

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.

	broadcast									
				- Clear +						
	Timing / Growth stage of crop and	d mission between *		And *						
	Timing Start	an dransing taken place at stage (0)		Select						
	Max No per use * 0^ P, V - Winte	r dormancy or resting period	No per crop / season		Min interval between applica	ations				
	1 - Beginning e	of seed inhibition								
	1^ P, V - Begin	ning of bud swelling								
	Max app rate per prod *		Scale		Unit					
tax app rate p	er prod		Scale	1	٥	Unit cfu/100 kg seed	- Cle			
Active substa	ance name	Max. application ra	te pe AS	Calculated	scale	Calculated unit				
Aminopyralid		0.27600002	-	37		granules/100_kg_seed				
(E)-5-Decen-1	I-ol	10.235001		26		g/100_kg_seed				
	(a) · · · · · · · · · · · · · · · · · · ·									
	Min water volume	Max water volume		Dependent on development stage crop	of 🗌 Yes PHI (days)	)				
	Seed treatment  Ves	Remarks								

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.

Aut	toSave 💽 Off		2~ (	(2 - ≠				GAR	_Templa	te_Do	wnlo	ad.xls	× -					₽ Searc	ih (Ali	(+Q)																
File Past	Home Cut Copy Format	Insert • t Painter	P Arial B	Page Layout I <u>U</u> → E	For 10 10	mulas Da	ata	Rev = =	iew E %	View	2 臣 Au	Deve Wrap Merg	loper Text je & Cente	Help	Sensi	tivity	General	69	8	9 8 F	GAP_D	sta_Dow	vnloa	datar •						) 54	arch (A	Vit+Q)				
F17 4 4 1	A B 1 2a	C D 3a 3b	С Е 4	fr C	6 H	I 7a 5 8 9 9 9	J I	K L Ba BB	n (days) 6 M	1 0 1	File Past	te	Home Cut Copy ~ Format Pai board	Insert inter	Pa Arial B I	ge Lay ∐	rout Fo 10 V E V Font	rmulas V A° A° V A	Data A"	Re = = = =	view	View View View Align	w 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Developer Wrap Text Merge & Ce	H	ielp - rs	Sens Sens	sitivity sitivity	General R ~ % Nu	9 mber	*88 -	-	Condit Formatt	iional ting ~	Format Table	as N
R Hee No	Type of user	Crop	Growing Crops	Pest/harmful organism EPPO c	Method / Kind	Timing / Growth stage of crop 8	Mare Mr. Olive	Max No / cron or season	Min. interval between applicatio	Man and the selfer level and		A 1 2a	B		3a		D 3b	E	4	F 5a	ganism EPPO code	3 н	6	I J 7a 7b variable of crop & season	K 8a	or season gg	tween application (days) 😠 🛛	n rate per prod	P.Q.R.S 10b uoseasoud bet crob/seasou	T 12a (eu/) %	D 12b (L/ha)	> 12c > 12c	W 13	g of seeds per ha) 14 ×	Y 16	Z 17
												2 2 1 trai	ned profes	sional	Type of user D 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	BI / GR E IMD E	African lemo Bali lemon bumpy lemo canton lemo	e Indoor (I) in in	Growing Crops	PRKAF	IIA	rican lo legheny	Wethod / Kind	bean ss locust	Max. No. / Use	Max. No. / crop	Min. interval bet	Max. application	Max. total rate p	Min water v olum	Max water volun	oN Dependent upon	(skapa) HHd	Seed density (k	Minor / Major us	Remarks
				s	ave t	his use		D	ownic	bad	GAF	P Ter	mplate		[	owr	nload G/	AP Data	-		Uple	oad (	GAI	P Data												

### **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.

Consumer safety		
MRL Values Table		
Default MRL of 0.01 mg/kg according to	rt 18(1)(b) Reg 396/2005	
/alue of tMRL *		
Value of tMRL		
/alidated analytical method *		
Validated analytical method		

1. **Consumer safety**: The Maximum Residue Level (MRL) Values Table is set to the default maximum level. However, if an **active substance**<sup>1</sup> 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.

<sup>&</sup>lt;sup>1</sup>See Active substances, safeners and synergists

Consumer safety and justification			Dossier saved at 13:45:36
Consumer safety			
MRL Values Table			
			Pesticide residues
EPPO Code for CROP	Product		Acetamiprid
Bali lemon	Select a product		N/A
canton lemon	Select a product	Ê	N/A
bumpy lemon	Select a product		N/A
African lemon savory	Select a product	Ê	N/A 🗆

a. Click the '<sup>a</sup>' 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**'.

Consumer safety and	justific	cation				Dossier saved at 13:45:36
Consumer safety MRL Values Table	Choose	e a Food	l Product			
	Please of Alternatively	confirm a	value, or perform your	r OWN Search.		Pesticide residues
EPPO Code for	EPPO Cod	le	CIDGR			Acetamiprid
Bali lemon	ENG LATIN		Bali lemon None			N/A
canton lemon	Showing	382 results		Filter		N/A
bumpy lemon	Select	CODE \$	Proposed product category fro	om the EU pesticides database 0		N/A
African lemon savory	•	0100000	FRUITS, FRESH or FROZEN; TF	REE NUTS		N/A 🗆
,	0	0110010	Grapefruits			
	0	0110020	Dennan	Select	el	

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

sumer safety and justifica	tion		Dossi	er saved at 13
onsumer safety				
IRL Values Table				
			Pesticide residues	
EPPO Code for CROP	Product	t	Acetamiprid	
Bali lemon	Citrus fruits	8	Default MRL of 0.9 Reg. (EU) 2019/88	
canton lemon	Select a product		N/A	
bumpy lemon	Lemons	8	Default MRL of 0.9 🔲 Reg. (EU) 2019/88	
African lemon savory	Select a product		N/A	

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").

1005	еагооц	Product	
lease (	confirm a s	value, or perform your own search. ode represents a use for a mensedible use, select the option at the bottom of the list.	
EPPO Cod	le G	SANMD	
ENG	b	pumpy lemon	
LATIN	Ν	None	
Showing	382 results	Filter	
Select	CODE \$	Proposed product category from the EU pesticides database	\$
۲		Not Applicable - nor-settible con	
0	0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0	0110000	Citrus fruits	
1.00	0110010	Grapefruits	
0			

- 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.

Justification	
Type of danger *	
Type of danger	h
Size and effect of danger *	
Size and effect of danger	1
Absence of any other reasonable means *	
Absence of any other reasonable means	11
Rationale *	
Rationale	11
Mitigation measures *	
Mitigation measures	1
Applications in progress *	
Applications in progress	11
Research activities *	
Research activities	1

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.

bocuments		
Documents		
non confidential.pdf	o	Remove
Research summary - justification section.pdf	0	Remove
Other - Function information.pdf	0	Remove
Choose file	Browse	Remove

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

≡ *	E-SUBMISSION Food Chain platform	Dossier PPP-2022-64946: Draft	Ē	
<b>≗</b> ∾ ≜	Pesticides Application PPP-2022-64946	Control Contro	Dossie	er saved at 10:20:05
<b>ଡ</b> ଏ	DOSSIER DATA Administrative Data	Comments Provide message here  [AN Comments] [AN Commen	rmful organisms IDIQU] acorn cup gall hipid 👕 ALSBA] acorn barnacle	Action
	Product Data Classification and Labelling	Complete action Close	ELSLA] acom moth 🍵	
	GAP Data	g cr Minor • Clear Trained professional Indoor (i)	) - Clear	

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.

	Withdraw	Dashboard								Create new op	plication
Doesier Overview		My application list									
		Application number0	Question Number 0	Submission date	Authorisation type 0	Application type 3	Ourrent state 0	Current phase 0	Applicant/Company name	Subject of the request	Action
08/02/2023 O Auro Application Received		\$1697	Column filter	Column filter	Dolumn filter	Column filter	Column filter	Column filter	Column filter	Column filter	
Submitted version		PPP-2023-71697		08/02/2023 14:33	Plant Protection Products	Application for emergency authorisation	Application Received	Assessment in progress	CHILD_BASE, Name	Default text	

# **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.

