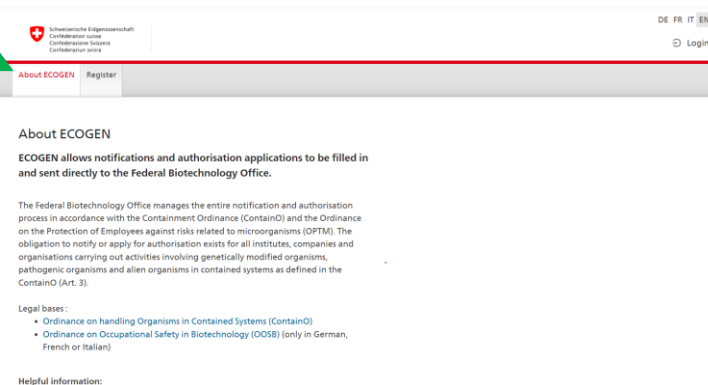


Ecogen user guide

www.ecogen.admin.ch

Take a look at Ecogen homepage
too. You'll find useful information
and contact details.



The screenshot shows the top part of the Ecogen website. At the top left is the Swiss flag logo and the text 'Schweizerische Eidgenossenschaft', 'Confédération suisse', 'Confederazione Svizzera', and 'Confederaziun svizra'. To the right is the text 'Département fédéral de l'environnement, des transports, de l'énergie et de la communication DETEC', 'Office fédéral de l'environnement OFEV', and 'Division Sols et biotechnologie'. In the top right corner, there are language options 'DE FR IT EN' and a 'Login' button. Below the header is a navigation bar with 'About ECOGEN' and 'Register' links. The main content area starts with the heading 'About ECOGEN' followed by the text: 'ECOGEN allows notifications and authorisation applications to be filled in and sent directly to the Federal Biotechnology Office.' Below this is a paragraph explaining the process: 'The Federal Biotechnology Office manages the entire notification and authorisation process in accordance with the Containment Ordinance (ContainO) and the Ordinance on the Protection of Employees against risks related to microorganisms (OPTM). The obligation to notify or apply for authorisation exists for all institutes, companies and organisations carrying out activities involving genetically modified organisms, pathogenic organisms and alien organisms in contained systems as defined in the ContainO (Art. 3).' This is followed by 'Legal bases:' and a list: '• Ordinance on handling Organisms in Contained Systems (ContainO)', '• Ordinance on Occupational Safety in Biotechnology (OOSB) (only in German, French or Italian)'. Finally, there is a section for 'Helpful information:'.

January 2024



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First login to Ecogen

1. Go to www.ecogen.admin.ch and click on login.

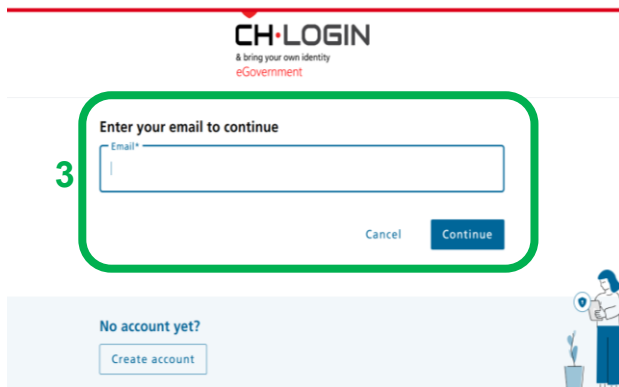


About ECOGEN

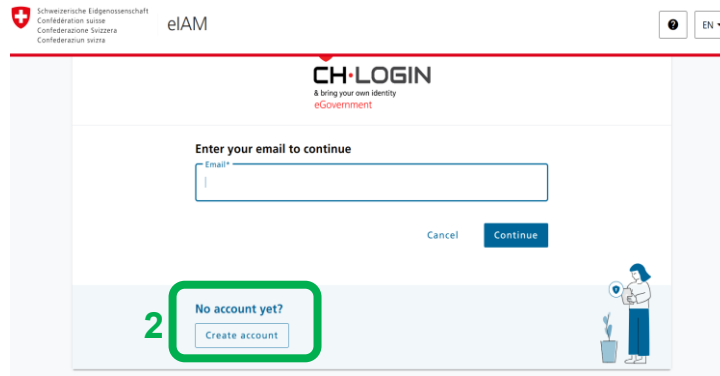
ECOGEN allows notifications and authorisation applications to be filled in and sent directly to the Federal Biotechnology Office.

The Federal Biotechnology Office manages the entire notification and authorisation process in accordance with the Containment Ordinance (ContainO) and the Ordinance on the Protection of Employees against risks related to microorganisms (OPTM). The obligation to notify or apply for authorisation exists

3. Go back to www.ecogen.admin.ch, click on login (1.) and use your CH-login credentials to log in.



2. Click on «create account» and follow the instructions to create your CH-login.





Register a new organisation on Ecogen

Log in to Ecogen and register a new organisation via the platform. Your request will be processed within a few days by the Federal Coordination Centre for Biotechnology (KBB).

The screenshot displays the Ecogen portal interface. At the top left, the Swiss flag logo is visible next to the text 'Schweizerische Eidgenossenschaft', 'Confédération suisse', 'Confederazione Svizzera', and 'Confederaziun svizra'. The page title is 'Portal | Internal'. In the top right corner, there are language options 'DE FR IT EN', a message notification 'Message 99+', the user name 'Boris', and a 'Log out' link.

The main navigation bar includes 'Dashboard' (highlighted with a red box), 'Dossiers', 'Organisations', and 'Organisms'. Below this, a 'Worklist' section contains a link 'Request portal access' (highlighted with a green box).

Two forms are visible:

- Request for user access:** A form for requesting employee or admin privileges for an existing organisation. It includes a 'Request' dropdown menu and three input fields: 'Organisation', 'My role in the organisation' (with a dropdown menu showing 'Employee without administrator rights'), and 'My email address in the organisation' (with the value 'boris@example.ch'). A 'Send' button is at the bottom.
- Registration of new organisation:** A form for registering a new organisation for the ECOGEN portal. It includes a 'Request' dropdown menu and three input fields: 'Name of organisation', 'My role in the organisation' (with a dropdown menu showing 'Location administrator'), and 'My email address in the organisation' (with the value 'boris@example.ch'). A 'Send' button is at the bottom.



Join an existing organisation

1. Log in to Ecogen and request access to the organisation of your choice.

Swiss Confederation | Portal | Internal

Dashboard | Dossiers | Organisations | Organisms

Worklist | Request portal access

Request for user access

Request employee or admin privileges for an existing organisation.

Request

* Organisation:

* My role in the organisation: Employee without administrator rights

* My email address in the organisation: boris@example.ch

Type in the name and select the organisation from the drop-down list.

2. The location administrator of your organisation must process your request using its own account on Ecogen.

Dashboard | Dossiers | Organisations | Organisms

Worklist | Request portal access

Create new application

Worklist

Draft 38 | Query 2

Number	Title	Organisation	Status
A230017-00	New notification SOP user	_Roman Test	Active
A210083-02	Abbrechen und Weiterfahren	Gymnasium Appenzell	Active

User access requests

Request date	Organisation	Requester
08.05.2023	_Roman Test	Boris Example

Click on the request to accept or reject it



Joining several organisations

1. Using the CH-Login you created to log in to Ecogen, you can request to access more than one organisation following the instructions on [«Join an existing notification»](#).
2. In any organisation where the location administrator has granted you access, your «user» email address will always remain the same as the address of your CH-login. You can however modify the «person» email address to match your address in the organisation.

Organisations Organisms Archiving Reports Master data

← _Roman Test active Edit

Persons Locations Dossiers

Show inactive: Role: All

Search

Person	Role	User	Telephone number	Status	Actions
Test, Dummy test.dummy@romantest.ch	Administrator (Loc. ad.)	dummy-user-1@iwf.io	The telephone number should not be empty.	active	Edit

+ New person C

The email address of the “person” on Ecogen can be modified to match your address in the organisation.

The “user” address will always be the one linked to your CH-login in all the organisations you are registered with.

Click on the menu and select “edit” to modify a person’s details.



Overview of the portal

1. **DASHBOARD:** Quick links to find your drafts, notifications in query and create a new notification

Number	Title	Organisation	Status	Responsible	CoA	Process step
A230017-00	New notification SOP user	_Roman Test	Active	Dummy Test	2	Query
A210083-02	Abbrechen und Weiterfahren	Gymnasium Appenzell	Active	sdf sdf	2	Query

2. **DOSSIERS:** List of notifications; you can filter them by process steps or search for one by its number in the search bar.

Number	Title	Responsible	Status	CoA	Process step
A230033-01	_AH Test Anederungskontrollen-Absturz	Hani56	Decision pending	3	Undergoing completeness check
A230033-00	_AH Test	Hani56	Decision pending	3	Undergoing consultation

3. **ORGANISATIONS:** manage the persons (email address, role (administrator or employee rights), etc.) and the locations in your organisation.

Person	Role	User	Telephone number	Status	Actions
Test, Dummy dummy-user-1@wlv.io	Administrator (Local)	dummy-user-1@wlv.io	The telephone number should not be empty.	Active	[Actions]

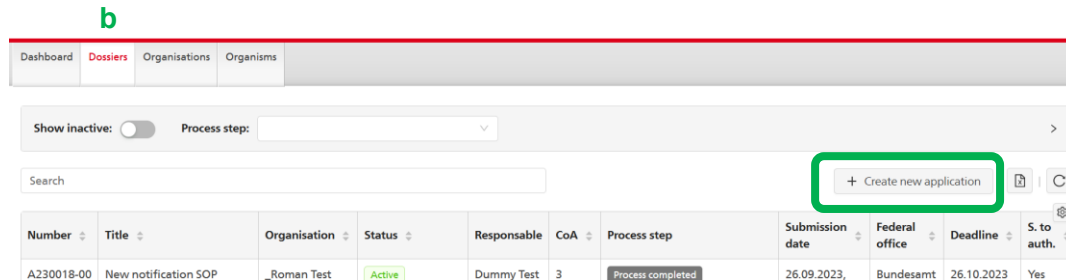
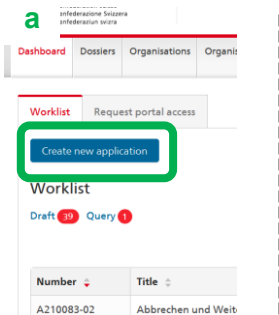
4. **ORGANISMS:** Lists of officially classified organisms with the most up-to-date risk group classification.

Name	Type	Family	Genus	Risk group	Alias of	Pathogenicity
Streptomyces avellaneus	Bacteria	Streptomyces		1		
Streptomyces aureoviticillatus	Bacteria	Streptomyces	Alphavirus	1		

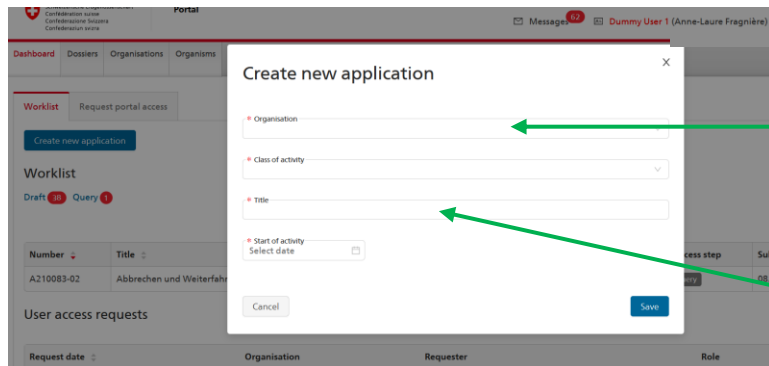


Create a new notification

1. Create a new notification from the «dashboard» tab (a) or from the «dossiers» tab (b).



2. Fill in the required field and press «save». A draft has been created.

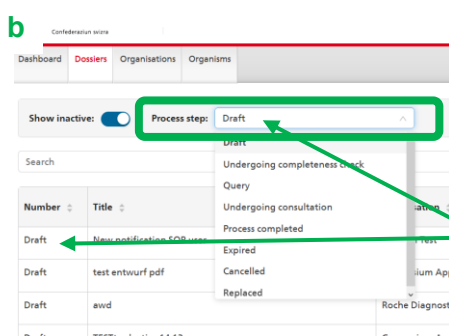
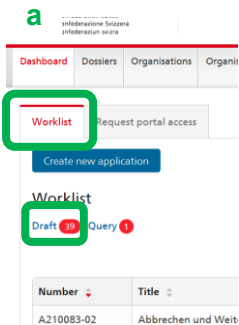


Type in the name and select the organisation from the drop down list.

Once saved, you cannot modify the title by yourself anymore.



Create a new notification



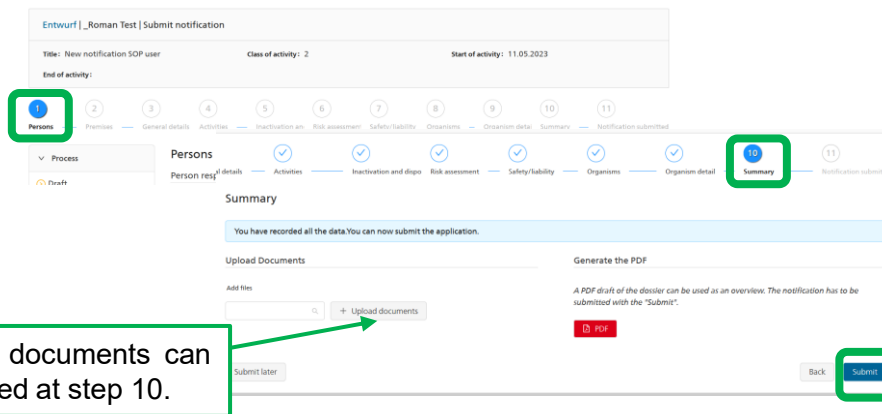
3. Find your new draft either from the «dashboard» tab (a) or from the «dossiers» tab (b).

Select the process step and click on the draft to open it.

4. Fill in all the steps of the form and click on submit.

Once submitted, a number is assigned to the notification (Axxxxxx-yy).

You can now find the notification easily by giving its number in the search bar under the tab «dossiers».



Additional documents can be uploaded at step 10.



Third party use (Step 2 – «Premises»)

If you are using a facility managed by another organisation, register this facility as a third-party use in your notification (step 2 of the form).

The screenshot shows a web form titled "Record third-party use". At the top left, there is a breadcrumb trail: "Entwurf | _Roman Test | Submit notification". Below this, the form has a header with "Title: New notification SOP user", "Class of activity: 2", and "Start of activity: 11.05.2023". A progress indicator shows five steps, with step 2, "Premises", highlighted in a green box. Below the progress indicator, there are tabs for "Persons" and "Process". The "Persons" tab is active, showing a "Person responsible" field. Below this, there is a "+ New value" button. A green arrow points from a callout box to this button. Below the button is a table with the following columns: "Location", "Type of installation", "Building", "Floor", "Room", "Max. safety level of installation", and "Actions". The "Location" column has a search icon and a dropdown arrow. A green arrow points from a callout box to this dropdown. The "Type of installation", "Building", "Floor", and "Room" columns have large empty text input boxes. A green arrow points from a callout box to these input boxes. The "Max. safety level of installation" column has a dropdown arrow. The "Actions" column has a trash icon. At the bottom of the form, there are three buttons: "Continue later", "Back", and "Next step".

1. Click «new value» to add a third party facility.

2. Type in the name and select the location from the drop-down list.

3. Fill in the rest of the boxes manually.



Register Organisms

Step 8 of the form «Organisms»: click on «new value» to register an organism.

Organisms

1. Type in the name and select the organism from the drop-down list. Select, if available, its officially classified version («officially classified» is indicated in brackets after the species name).

2. If the organism is not found using the search bar (see 1.), click [+] to register a new organism.

3. Select the answer:
No → you are using the natural organism.
GMO acquired → you are working with genetically modified organism but did not perform the genetic modification yourself, i.e. you received the organism already modified.
Yes → follow-up questions at the next step of the form will enable you to describe the specifics of the genetic modification (vectors, inserts).

⚠ How to register vectors (viral vector particles, plasmids, etc.) :

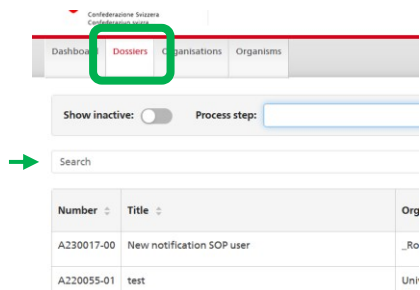
Vector characteristics are included as part of the information on the genetically modified organism.

1. Register the genetically modified organism.
2. Enter the vector characteristics in the organism details (next step of the form).
3. If the production of viral vector particles is the main aim of your activity, register the producer cell line as genetically modified in the organism list.

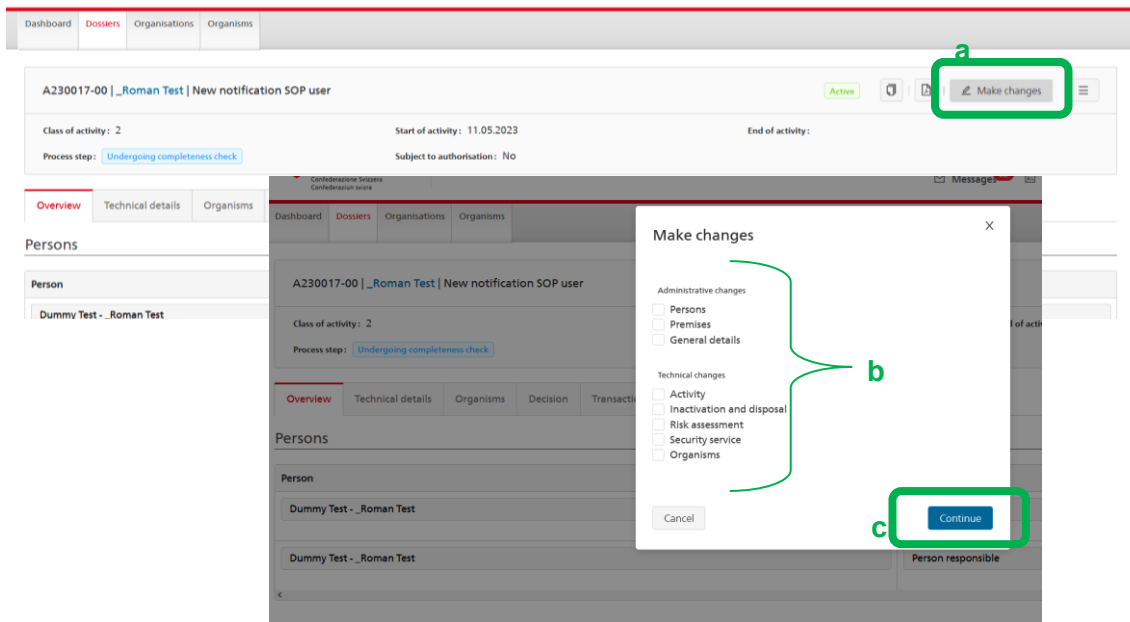


Modify an existing notification

1. Open the notification you want to modify (find it by its number in the search bar under the «dossiers» tab).



2. Click on «make changes» (a) and select the type of changes you want to make (b). Click «continue» (c) to open the form and modify your notification.





FAQ

What is an activity, a risk evaluation, etc.?

You find answers here: [FAQ-Topic Biotechnology](#)

What is a «transfer process»?

An notification not created or not yet modified on the new Ecogen platform might first need to be updated with the new Ecogen system before you can modify your notification. Follow the instruction of the platform to complete the «transfer process (just a few clicks).

Who can access the notifications of my organisation?

All members of your organisation.

Who can submit a notification on Ecogen?

You need to have administrator rights on Ecogen (see under tab «Organisation» then «Persons»: role = *administrator* or *employee* can be modified with the 3-layer menu at the end of the row).

Why registering the BSO and deputy BSO in the notification does not work?

Check the role of the BSO and deputy BSO in your organisation. They need admin rights. (see under tab «Organisation» then «Persons»: role = *administrator* or *employee* can be modified with the 3-layer menu on at the end of the row).

What is a location administrator (Loc. ad.) ?

The location administrator is one person per organisation with admin rights who has also permissions to grant access request to your organisation and is informed when your locations are mentioned as third-party use by another organisation. Location administrator is abbreviated in German “Sto.-V”, in French “Resp. site”, in Italian “esp. sede”.

Can I transfer a notification to another organisation?

Inform the KBB of the notification which should be transferred. A new draft will be created in the destination organisation (only persons and premises must be newly registered).

How to access my account settings?

Click on your name (up right corner) to access the settings.



FAQ

What do the process steps mean?

- *«Undergoing completeness check»*
Once submitted, the Federal Coordination Centre for Biotechnology (KBB) will first check the completeness of the notification.
- *«Query»*
If the notification is not complete, the KBB will send you the notification back in query on Ecogen and inform you with a personal email. Once you have corrected the notification and resubmit it, the notification is back «undergoing completeness check».
- *«Undergoing consultation»*
Once the notification is complete, the KBB forward the notification to the authorities.
- *«Process completed»*
The leading authority has issued a decision/autorisation.