Quick start animex-ch Release 3.3

Announcement of constrained lines (**Form M**)

For further information please consult the tooltip information within animex-ch and the explanatory notes (Form M)



Introduction

Form M has two announcement forms (Chapter 08): "provisional" and "definitive." Both can be submitted to the canton only with an attached versioned Form D. However, only the "definitive" ones can be approved by the canton in a similar fashion as with a Form A.

A "provisional" Form M, once marked as "Returned accepted" by the Canton, becomes non-editable and must be changed to a "definitive" when the constraint monitoring is finalized. To do so, a new version of Form D must be created with all necessary updates and attached to the "definitive" announcement for resubmission to the Canton for approval.

Both "provisional" and "definitive" forms can be **returned for revisions** and then resubmitted, similar to the process for Forms A, H, or G.

If a constraint is not confirmed after a provisional announcement or if the breeding is stopped, the announcement must be withdrawn. If a constraint is confirmed and the constraint monitoring is finalized, the provisional announcement needs to be submitted as a definitive announcement.

Note: only "definitive" (Signed) announcements can be used in the Common A/M Process.



Introduction II

To create a Form M, you must:

Have access to an authorized laboratory animal facility in animex-ch, i.e. a valid Form H must exist and you need at least one of the following roles associated with this Form H:

- IPI, SDI, RM, AWOI (institute roles)
- ACT, IPF, SDF, HAF, AWOF (roles at a laboratory animal facility)

Have access to a corresponding data sheet (Form D) with at least one version.

In the case of a Common A/M process: Have access to an open Form A (draft, return for rewrite).

As an institute role, you must have access to an institute that is confirmed as a participating institute in a Form H.



Introduction III

Form M can be used in two different processes: "standalone" or "common A/M".

Standalone process:

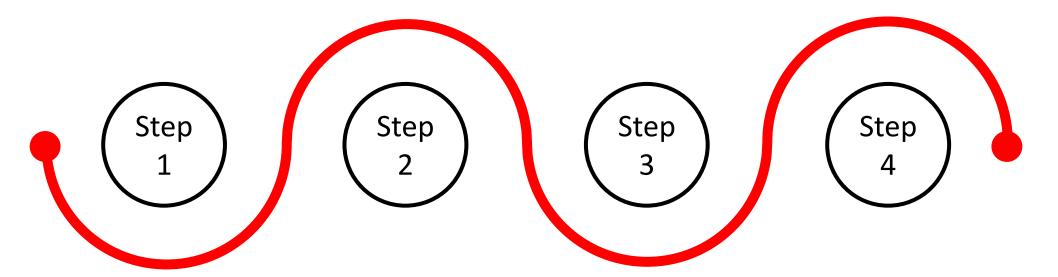
- Form M is linked to the versioned Form D and is accessible to multiple users in an institute or facility;
- Form M is submitted and approved in animex-ch independently of a Form A, but can be attached to any Form A after approval;
- The standalone process is especially suited to the approval of lines that potentially have a constraint but show no constraint under strain-reducing measures and can be used in various experiments;
- The Canton of the Animal Facility can be different than the Canton of Form A

Common A/M process:

- Form M is linked to the versioned Form D and Form A;
- In this case, the approval of a Form M in animex-ch is linked to the approval of a Form A. Forms M
 and A are submitted and approved in parallel in animex-ch;
- The common A/M process should be used notably where a line with a constraint is bred only for one specific experiment;
- The Canton of Form A needs to be the Canton of the Animal Facility



Process Roadmap – Standalone process



CREATE AND VERSION A FORM D

Create a Form D which needs to be versioned by the HAF role.

CREATE A FORM M

Create a new Form M
(Stand-alone process) –
this new Form M needs
to have an attached
versioned Form D. The
roles that can create a
Form M are: IPI, SDI,
RM, AWOI, ACT, IPF,
SDF, HAF, AWOF

SUBMIT THE FORM

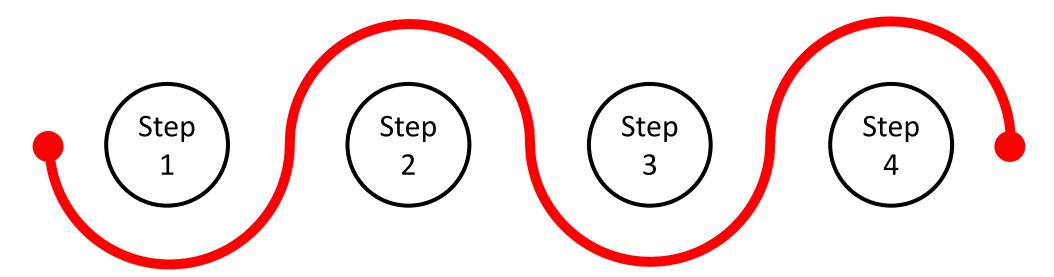
For institute roles: request a HAF review for the Form M. Confirm ownership. HAF or AWOF Roles can submit the Form M to the canton either as a provisional announcement or a definitive one. Provisional announcements can always be updated to definitive ones.

USE THE FORM IN A FORM A

After the Form M has been approved by the Canton it is ready for use and can be attached to a Form A.



Process Roadmap – Common A/M process:



CREATE AND VERSION A FORM D

Create a Form D which needs to be versioned by the HAF role.

CREATE A FORM M

Create a new Form M
(Common A/M process)

– this new Form M
needs to have an
attached versioned
Form D and an editable
Form A. The roles that
can create a Form M
are: IPI, SDI, RM,
AWOI, ACT, IPF, SDF,
HAF, AWOF

REQUEST SIGNATURE

For institute roles: request a HAF review for the Form M. Confirm ownership. HAF or AWOF Roles can sign only in definitive type of announcements.

USE THE FORM IN A FORM A

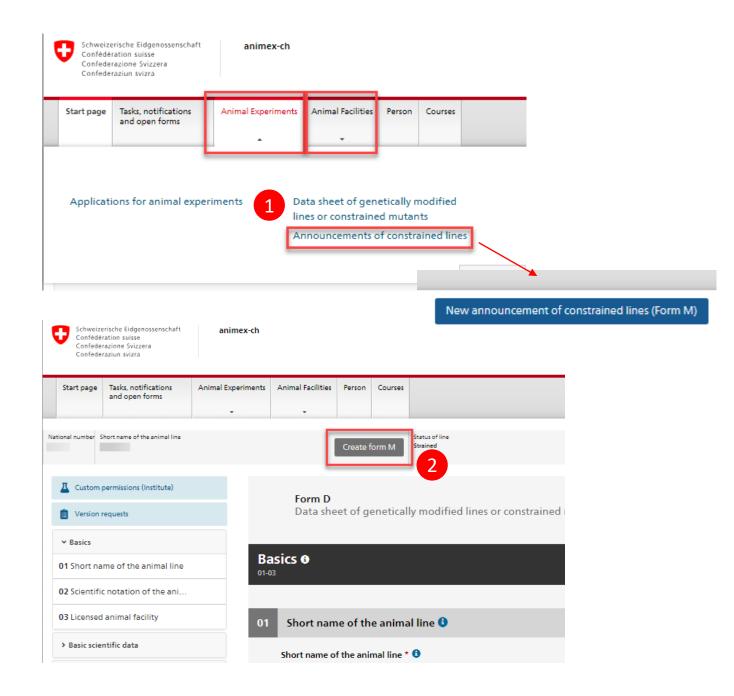
Once Form M has been signed by the HAF or AWOF role, it can be attached to a Form A and submitted together to the canton.



Start wizard

There are two ways to access the start wizard for a new Form M:

- Through the "Animal Experiments" (for institute users) or "Animal Facilities" (for facility users) Tab by clicking "Announcement of constrained lines" and then "New announcement of constrained lines (Form M)" in the constrained lines search page.
- Through a Form D, by clicking "Create form M" in the Header





Start wizard

Facility user:

Optional selection of an associated institute (names of the involved institutes of their facility)

Mandatory selection of a versioned Form D Mandatory selection of the purpose (provisional or definitive)

Institute user:

Mandatory selection of an associated institute (names of the institutes of the current user's logged-in unified-role), Form D and the purpose.

NOTE:

In order to select an institute, it must be active in the Form Ds custom permissions

The Institute users from the Institute which created the Form D will be able to edit Form M All enabled institutes from the Form Ds custom permission list will be able to view Form M (without editing rights)

New announcement of constrained lines (Form M)



Common A/M Process

When using the Common A/M Process, this option has to be selected from the radio button

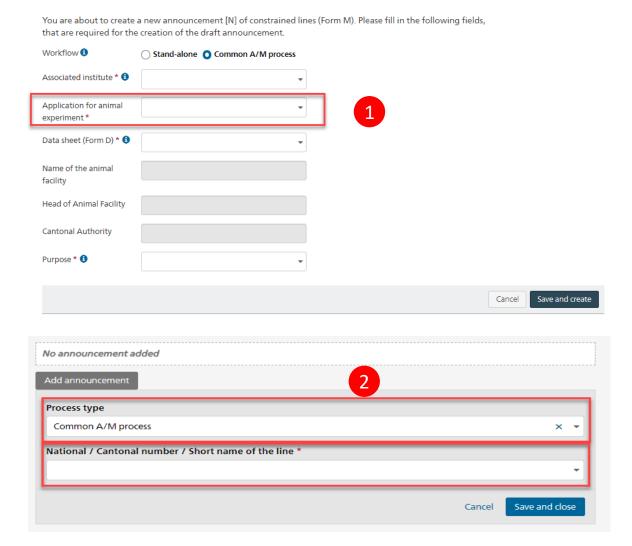
An additional dropdown list will appear – an editable Form A has to be chosen from this list.

The Form M (Common A/M Process) will be associated with the selected Form A

After creating and saving the new Form M, this can be added in the Form A via the animal card, by selecting "Announcements of constrained lines" → "Add announcement"

A pop-up appears in which the "Common A/M process" has to be selected. After this step, the previously created Form M becomes searchable in the dropdown list called "National / Cantonal number / Short name of the line"

New announcement of constrained lines (Form M)





Provisional announcement of constrained lines

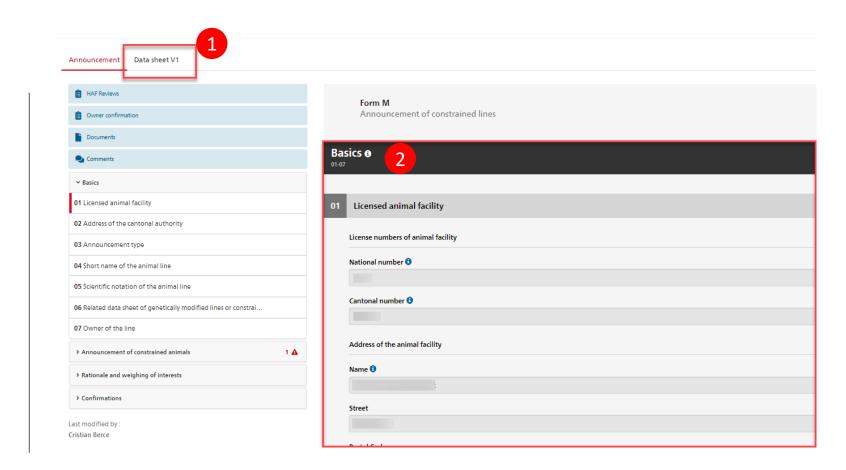


Basics 01 - 07

Switching between the editable Form M and the attached static version of the Form D is done through the tabs in the header

In the chapter «Basics» most fields are prefilled with the relevant information from Form D and non-editable except for:

- 01 Licensed animal facility: Involved animal facility unit(s)
- 07 Owner of the line





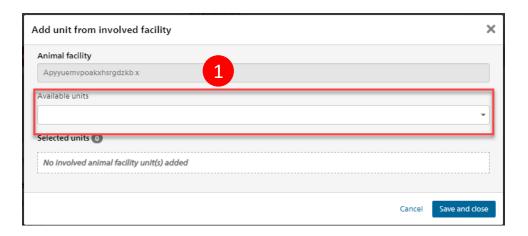
Basics 01 - 07

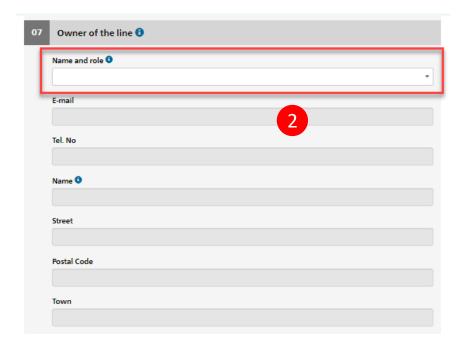
animal facility unit(s) - If the animal facility consists of different units, indicate here in which unit the animals are kept for which the notification is made. After clicking "Add Unit" a pop-up appears in which the available units from the involved facility can be selected through a drop down list.

01 Licensed animal facility: Involved

line can be selected from the drop-down list which is populated by the institute / facility users with the following roles: RM, SDI, SDF, HAF. The selection of the owner is important. Only persons having these kind of login roles can be selected as owner. These persons must have access to be able to answer an owner confirmation request

07 Owner of the line – The owner of the



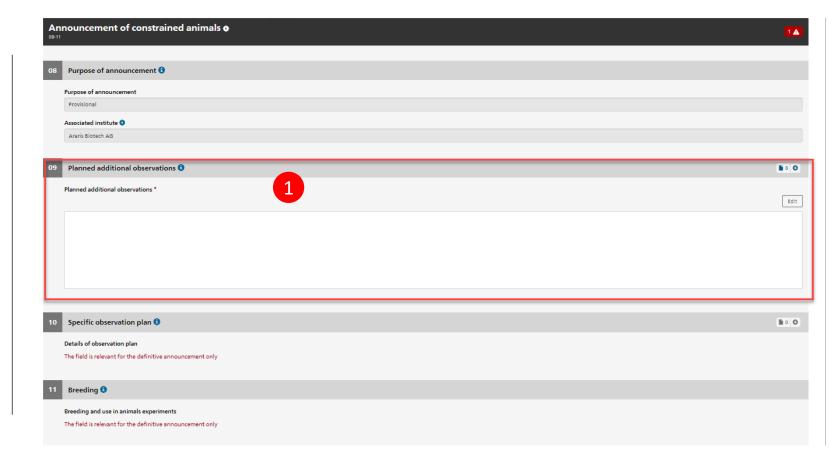




Announcement of constrained animals 08 - 11

For provisional announcements - in the chapter «Announcement of constrained animals», the only editable field is:

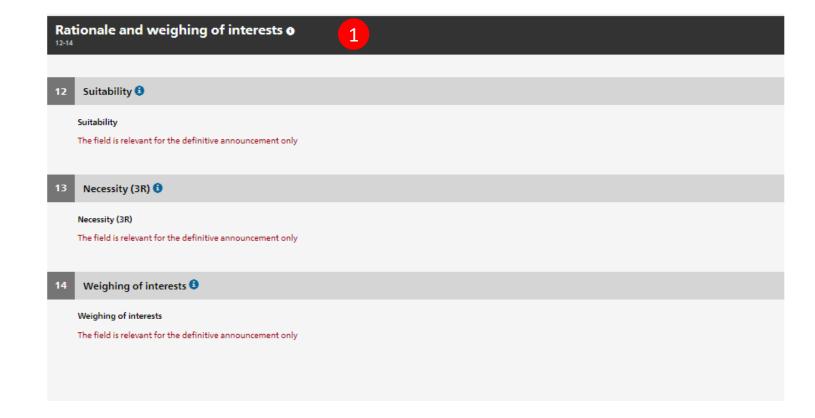
 09 Planned additional observations -Additional observations planned after submission of provisional announcement for small rodents (not yet listed in the data sheet), for continuing recording of constraint, have to be provided.





Rationale and weighing of interests 12 - 14

For provisional announcements – Chapters 12 to 14 are not editable.





Confirmations 15 - 16

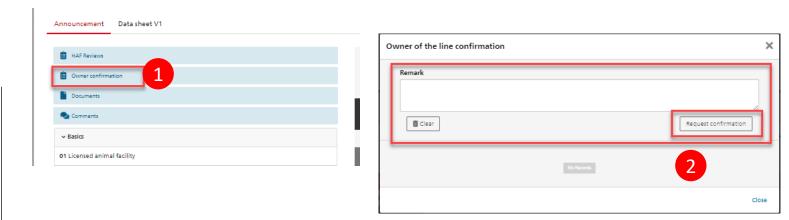
In the "Confirmations" section, all fields are automatically filled in when the notification is submitted to the canton.

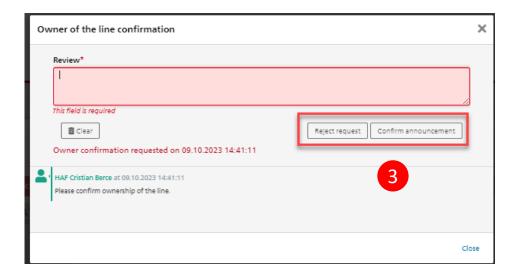
NOTE:

If no 'Owner of the line" is selected, the field remains empty. If an "Owner of the line" is selected, the owner needs to confirm the ownership of the line.

- Requesting an "Owner confirmation" can be done by the HAF and AWOF through the "Owner confirmation" button on the left menu. Selecting this option will prompt a popular window through which the
- prompt a pop-up window through which the confirmation can be requested.
- The owner of the line will receive a new Task called "Announcement awaiting owner confirmation" and can either confirm of reject the request with a mandatory text field.

The Owner or the ASI Roles of the Owner are the only roles which can confirm ownership. Form M can be submitted to the canton only after owner confirmation. After Owner confirmation request, owner cannot be modified anymore within the Form M (Field becomes grey and not editable).







Submitting the provisional announcement

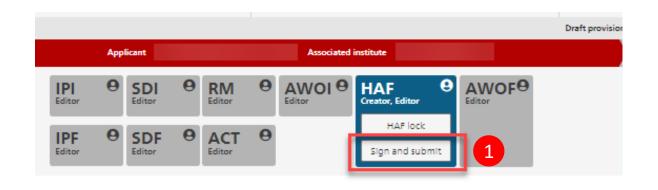
The provisional announcement can be submitted to the Canton by the HAF or AWOF roles.

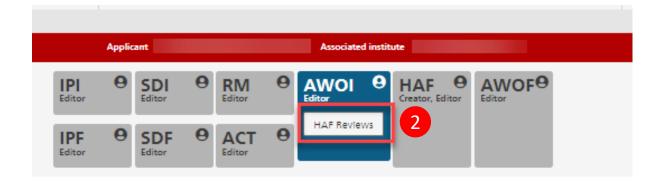
In case the Form is created by an institute role or a facility role different than HAF or AWOF, a HAF Review has to be requested through which the Form is forwarded to the HAF/AWOF. This can be done either to request a review or a submission of the Form

The HAF/AWOF can either enter a statement to answer the request (i.e. requesting more information about the animal line) and then return it for review or can directly submit the Form M to the canton. If the HAF/AWOF returns the document for review, the submitting role is notified.

It's only possible to have one open request at a time.

Once the Canton accepts the submission, the Form M is "Returned as accepted" and the HAF and AWOF roles are notified.





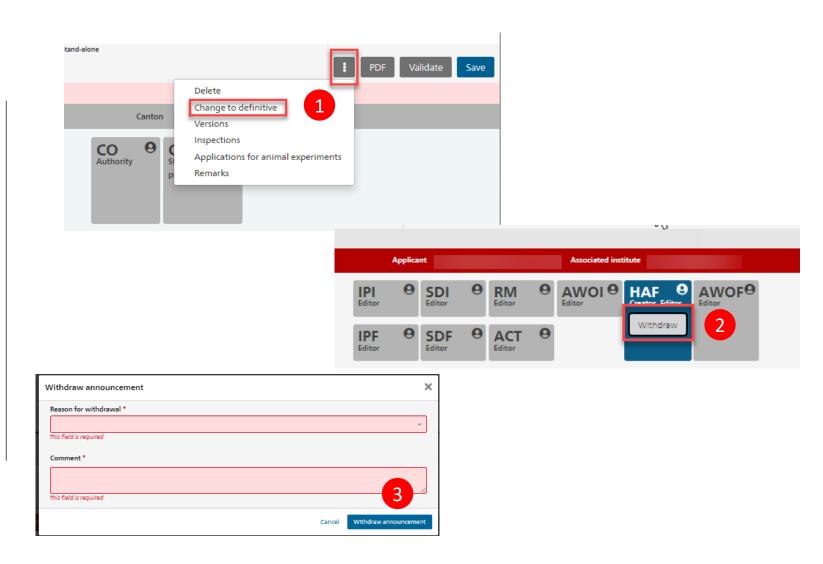


Definitive announcement of constrained lines



Changing to a definitive announcement or withdrawing announcement

- After the announcement has been "Returned as accepted" by the canton the Options button can be used to change any provisional announcement to a definitive announcement. In this case, Form D needs to be updated and versioned with the relevant information beforehand.
- If a constraint is not confirmed after a provisional announcement or if the breeding is stopped, the announcement must be withdrawn. This is done by the HAF or AWOF roles by clicking the button "Withdraw" in the Header, which prompts a popup window with a mandatory reason for withdrawal and comment.



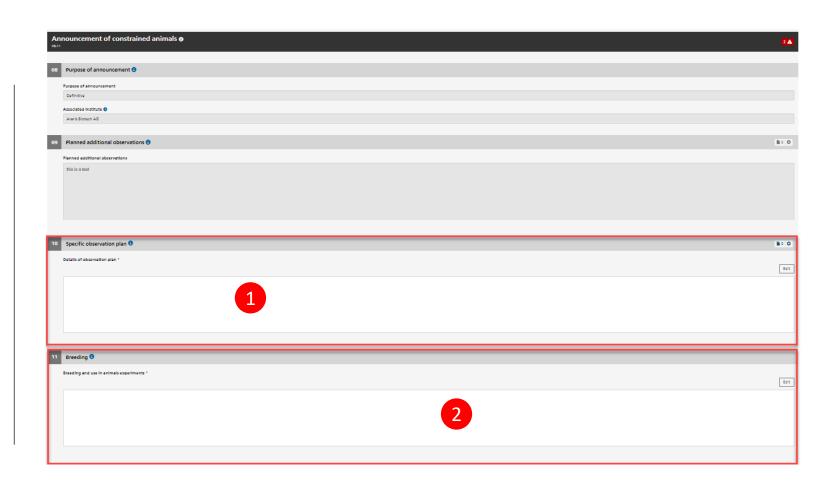


Announcement of constrained animals 08 - 11

When switching to a definitive announcement, in chapter «Announcement of constrained animals» the following fields become editable:

- 10 Specific observation plan
- 2 · 11 Breeding

Both fields are mandatory text fields for a definitive announcement.

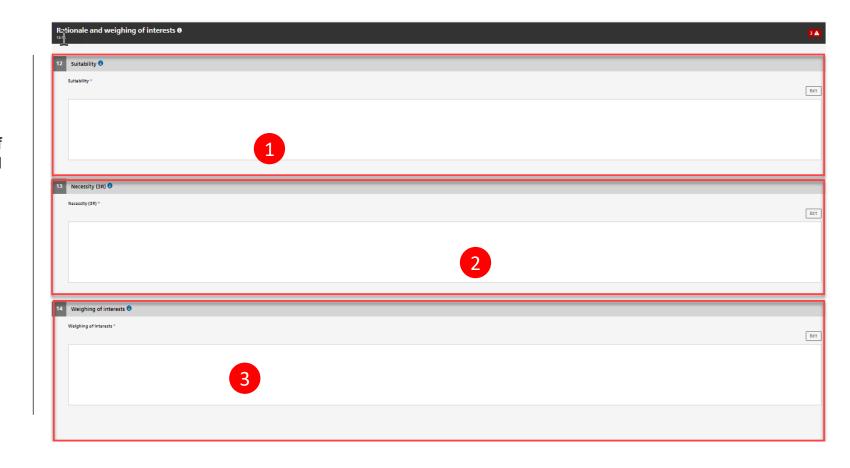




Rationale and weighing of interests 12 - 14

In the chapter «Rationale and weighing of interests» all fields become editable and mandatory:

- 12 Suitability
- 2 13 Necessity (3R)
- 14 Weighing of interests





Submitting the definitive announcement

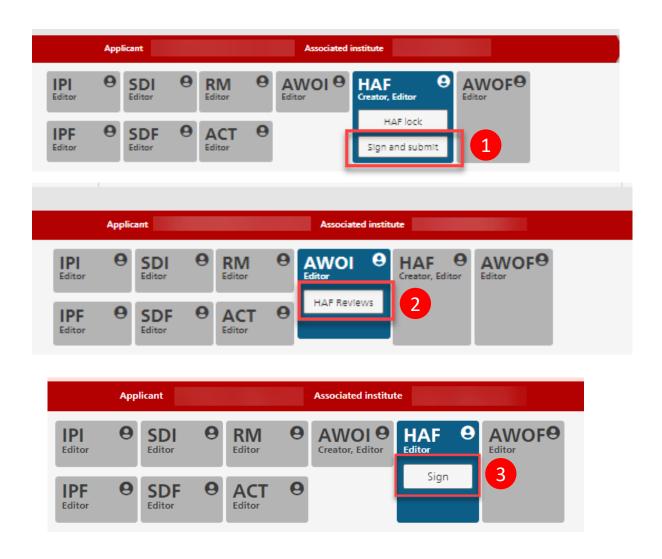
After completion of the aforementioned chapter, the definitive announcement can be submitted to the Canton by the HAF or AWOF roles.

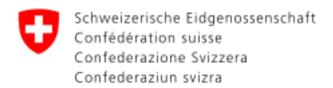
In case the Form is created by an institute role or a facility role different than HAF or AWOF, a HAF Review can be requested by the creator role. The HAF/AWOF can either return the Form M for review (if needed) or can directly submit the Form M to the canton.

It's only possible to have one open request at a time.

In case of using the Common A/M Process,

the "Sign and Submit" button is replaced by the "Sign" button. The HAF and AWOF roles can Sign the Form M. This will not submit the document to the canton but will enable its attachment to a Form A. In the Common A/M Process, Form A and M are then submitted together to the canton by the creator role.





For questions please use the following points of contact:

- Technical queries: Animex-ch application managers, FSVO, animex-ch@blv.admin.ch
- Subject-matter queries: Animal Experimentation division, FSVO, oberaufsicht-tv@blv.admin.ch