Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Animal Health and Welfare

Quick start animex-ch Release 3.3

Data sheet of genetically modified lines or constrained mutants (**Form D**)

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

Introduction

The Data sheet of genetically modified lines or constrained mutants (**Form D**) can be used in two ways:
- After versioning, it can be attached to an announcement of constrained lines (Form M) and submitted to the canton
- it can be attached in the animal cards and submitted with the Form A

One of the most important elements of the new digital Form D is the versioning – as this Form can only be used after versioning. The versioning of Form D complies with the legal requirements which stipulate that the monitoring of constraint must be recorded and assessed in good time and documented. In practice, each version of Form D is an update of the Form and the (newly) entered data is "frozen in time" upon versioning.

Process Roadmap

Step 1
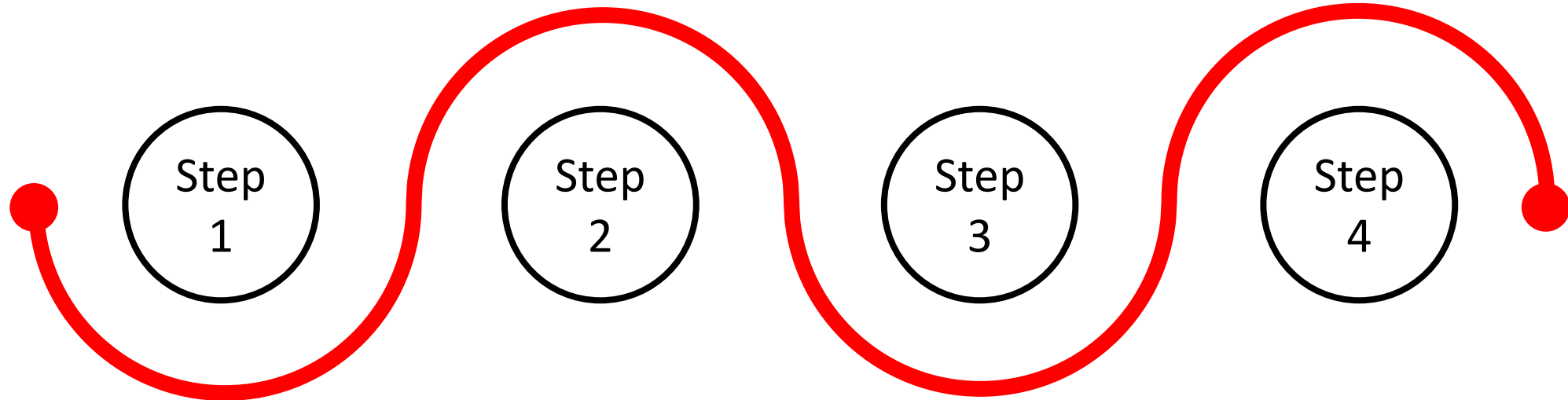
CREATE A FORM D

Create a new Form D – either as a new Form, or in tandem with a new Form A.
Can be created by following roles: IPI, SDI, RM, AWOI (Institute Users) ACT, IPF, SDF, HAF, AWOF (Facility Users)

Step 2

COMPLETE THE FORM

Enter the required details in the Form. Take special notice of mandatory fields.

Step 3

CREATE A VERSION

Create a version of the Form D. Separate versions should be created with each change or update. The versioning can be only performed by the HAF and AWOF roles.

Step 4

START USING THE FORM

After the Form D has been versioned it is ready for use and can be attached either to a Form A or a Form M.

Creation variables I

A data sheet of genetically modified lines or constrained mutants (**Form D**) can be generated and used by the facility and institute users only. There are two ways to create a new Form D:

① **②** Through the Datasheet search form – from the "Animal Experiments" or "Animal Facility" Tab → "Data sheet of genetically modified lines or constrained mutants" → "New data sheet (Form D)"
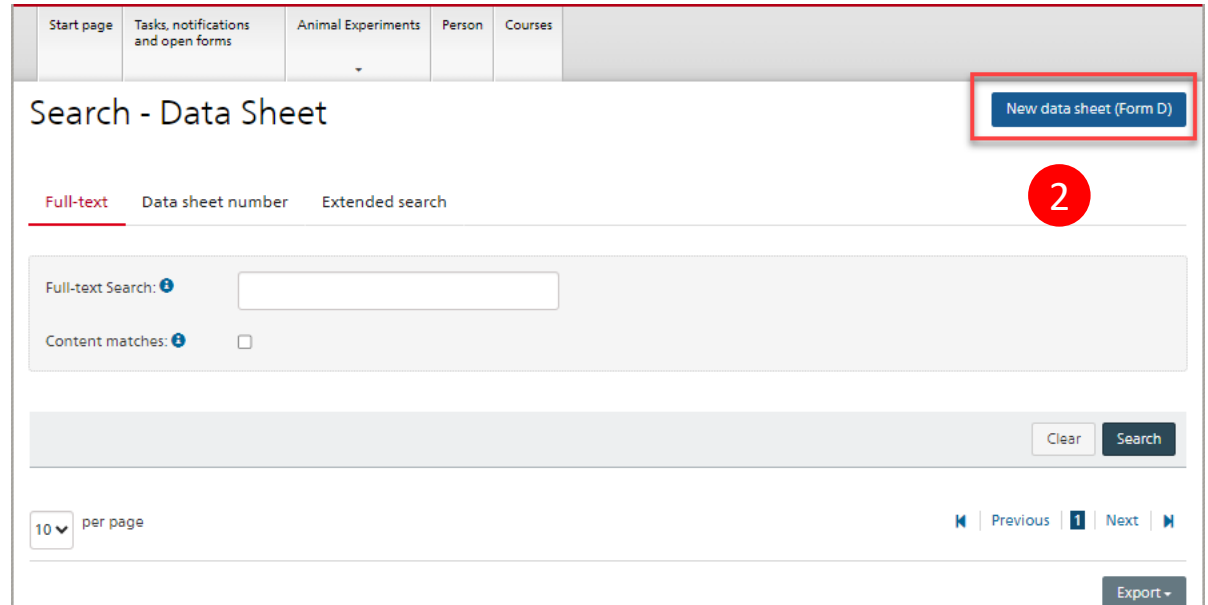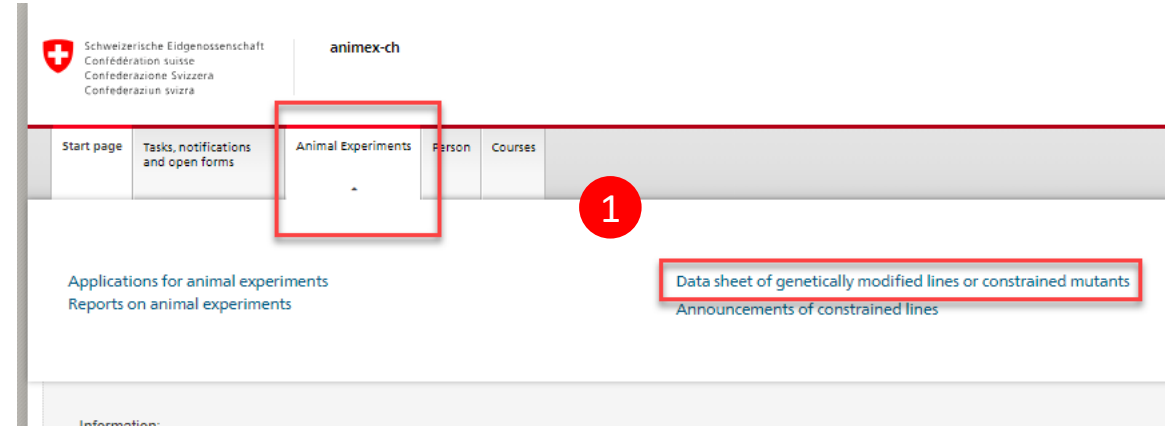
Creation variables II

A data sheet of genetically modified lines or constrained mutants (**Form D**) can be also be generated through the Form A:

Through an "Animal Card" of Form A by clicking "Create data sheet (form D)".

1

Clicking the button mentioned above will prompt a new page containing the start wizard (see next slide)

Start wizard for a facility user

Name of the animal facility:

① In order to create a form D your facility (Form H) needs to be in status «Approved». Mandatory selection of an approved animal facility where the user has viewing rights through a drop-down list.

Start wizard for an institute user

Creator institute / Name of the animal facility:

1 Mandatory selection of an institute. Selectable are institutes in which the logged in user has roles with his/her current login role

2 Mandatory selection of an approved animal facility, where the user's institute is listed as «Involved institute» in Form H.

Custom permissions for institutes

1 From the **left navigation menu** the user can open the pop-up «Custom permissions (Institute)»:

- **Form D** created by facility user: the chapter is only visible to HAF, AWOF
- **Form D** created by institute user: the chapter is only visible to AWOI, RM, SDI (**roles from the creating institute**), AWOF, HAF

2 Checkbox «Managed by RHAF/AWOF»:
If the Form D has been created by the Animal Facility the checkbox is default checked
If the Form D has been created by an institute the checkbox can be checked by AWOI, RM and SDI to enable facility users to manage the custom permissions of the Form D.

3 All involved institutes of Form H are listed (default: no access), RHAF and AWOF can give access for these institutes to Form D. The creator institute is default checked (non-editable)

The aim is to enable information exchange between institutes and to enable multiple institutes to use the same Form D and potentially Form M for commonly used mouse lines (i.e. commercially available mouse lines)
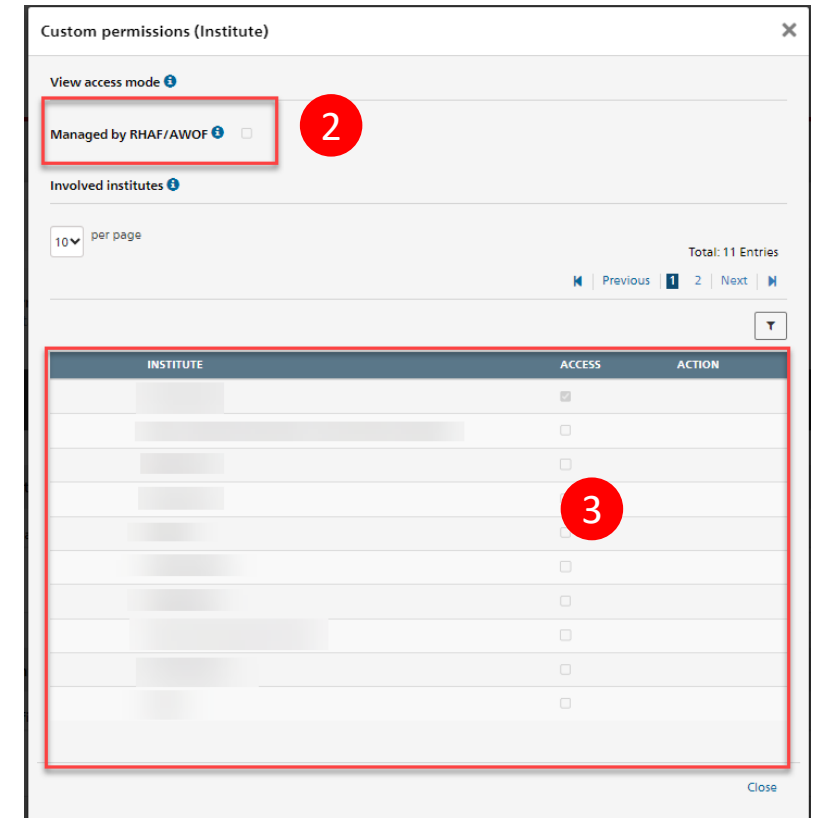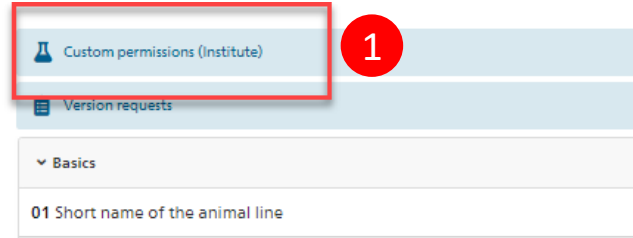
Basics (01 - 03)

01 Short name of the animal line
- mandatory field – can be an internal or commercial name (i.e. NSG mice)

02 Scientific notation of the animal line
- mandatory field – name needs to correspond international mouse nomenclature guidelines (http://www.informatics.jax.org/mgihome/nomen/).

03 Licensed animal facility
- non-editable fields – automatically filled out by the system. The information corresponds to the Form H with which the Form D is linked.

Basic scientific data (04 - 09)

In this chapter and all subchapters are editable and mandatory:

04 Animals
(1)
- **Animal species** (dropdown list with optional specification of the species in "Species specification" section)

05 Purpose
(2)
- **Purpose of the line** (mandatory free text field),
- **Database reference** (mandatory free text field),
- **Literature reference** (mandatory free text field),

Basic scientific data (04 - 09)

06 Production
- **Producer / Origin of the line** (mandatory free text field),
- **Spontaneous**
- **Method of production** (mandatory – if Spontaneous is chosen as NO),
- **Year of production** (mandatory free text field),

07 Number of generations
- **Number of generations** (mandatory selection from drop down list),
- **Status of breeding** (mandatory selection from drop down list),

Basic scientific data (04 - 09)

08 Genotype

(1)
- **Genotype list** - mandatory field – multiple separate genotypes must be added by clicking button "Add Genotype"

09 Hygiene status

(2)
- **SPF (Specific Pathogen Free) – when selected a free text box appears**
- **Other - when selected a free text box appears**

Summary of monitoring of genetically modified lines and constrained mutants (10 - 14)

In this chapter and all subchapters are editable and mandatory as following:

10 Status of monitoring of constraint
- Status of monitoring of constraint (mandatory)
- Amount of observations conducted (mandatory)
- Number of generations and animals observed (mandatory)

- **Please pay special attention to the tooltips (ⓘ) in this section of Form D as it defines the status of monitoring of constraint according to the relevant legislation.**

1

Summary of monitoring of genetically modified lines and constrained mutants ⓘ
10-14
13 ⚠

| 10 | Status of monitoring of constraint ⓘ |

Status of monitoring of constraint * ⓘ **1**
- ○ Completed / constraint definitely reported; decision of authority pending
- ○ Completed / strained line according to decision of authority
- ○ Completed / not strained
- ○ Still subject to clarification
- ○ Still subject to clarification / constraint provisionally reported

Amount of observations conducted * ⓘ

Number of generations and animals observed * ⓘ

Edit

Summary of monitoring of genetically modified lines and constrained mutants (10 - 14)

11 Phenotype
- Assessment (mandatory)
- Results of monitoring of constraint in comparison to wild type
  - Mortality rate (mandatory)
  - Reproduction rate (mandatory)
  - Behavior (mandatory)
  - Feeding behavior, body weight (mandatory)
  - Clinical signs (mandatory)
  - Other (optional)
- Assessment of constraint
  - Phenotype-specific assessments (mandatory)

- **When clicked on "Different from wild type" or "Yes" for Clinical signs - mandatory free text boxes appears in which details and / or age of occurrence have to be provided.**

Summary of monitoring of genetically modified lines and constrained mutants (10 - 14)

12 Mitigation of constraint (mandatory free text field)

13 Criteria for withdrawal (mandatory free text field)

14 Degree of severity (mandatory free text field)

Please pay special attention to the tooltips (ⓘ) in this section of Form D – for example in regards to the mitigating measure; what is best and consistently used?

Data sheet revision history (15)

12 History (not editable by user)
- The system automatically creates new history entries, whenever a data sheet version is created or a user resets the Form D to the last version by using the "undo modifications" functionality.

Create a version

- **Creating a version of the Form D is a mandatory step allowing it to be attached to either a Form A or a Form M.**

- Only HAF / AWOF users have the ability to create a version directly.

- All other institute or facility users (i.e. AWOI, SDI, ACT), need to create a versioning request to the HAF and AWOF users, for their approval.

- Users must go to the **Version Requests** tab in the menu on the left to create a versioning request. This will prompt a pop-up (please see next slide).

- Only versioned Form D`s are searchable and can be attached to Form A

Create a version request (Institute Users)

- **1** After completing the free text field with their optional remarks (i.e. updates on the monitoring of constraints), the "Request new version" button needs to be pressed.

- **2** A new version request will be created which includes: a timestamp, the role of the user which created the request and the name of the user.

Approve or reject a version

- **Users with a HAF or AWOF role will receive a task in the "Tasks, notifications and open forms" tab.**

(1) • After assessing the request and the changes which were implemented in the Form D - to approve a version request – browse to the "Versioning" tab in the upper right menu and select "Create version"

(2) • A pop-up called "Create version" will appear. After filling in a mandatory comment related to the reason of versioning, press the "Create version" button to create a version.

(3) • To **reject a version** request - Users must go to the **Version Requests** tab in the menu on the left. This will prompt a pop-up which will include the mandatory remark from the user that requested the versioning. The version request can be rejected using the "**Reject request**" button.

- Users with **HAF** and **AWOF** roles can **create a new version of Form D without a previous request** by following steps 1 and 2.
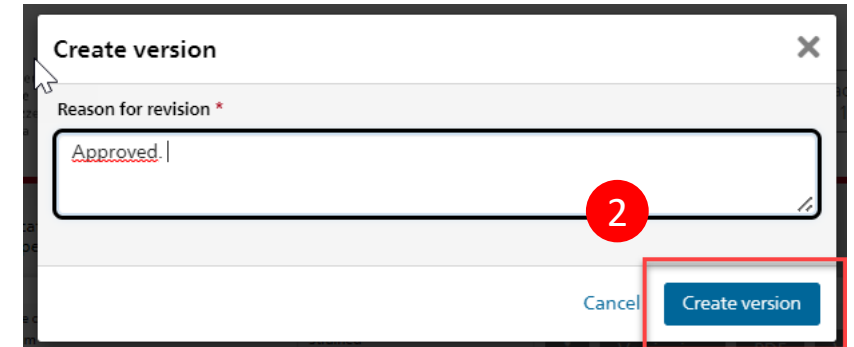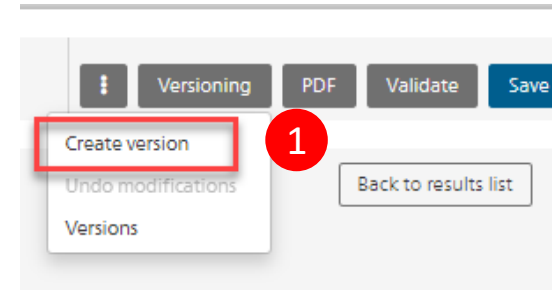
Updates on Form H

- **In case of any approved changes with Form H (supplementary applications or renewals), the Form D needs to be re-linked with the newly approved Form H.**

- Re-linking Form D is mandatory if this document still needs to be used. The necessity to re-link these two Forms is displayed as an alert in the header section of the Form D – "**Animal facility details updated. Please proceed to creating a new version**"

- A new version is created as described in the previous slide: **Versioning → Create version**

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Animal Health and Welfare

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