



Schweizerische Eidgenossenschaft  
Confédération suisse  
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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

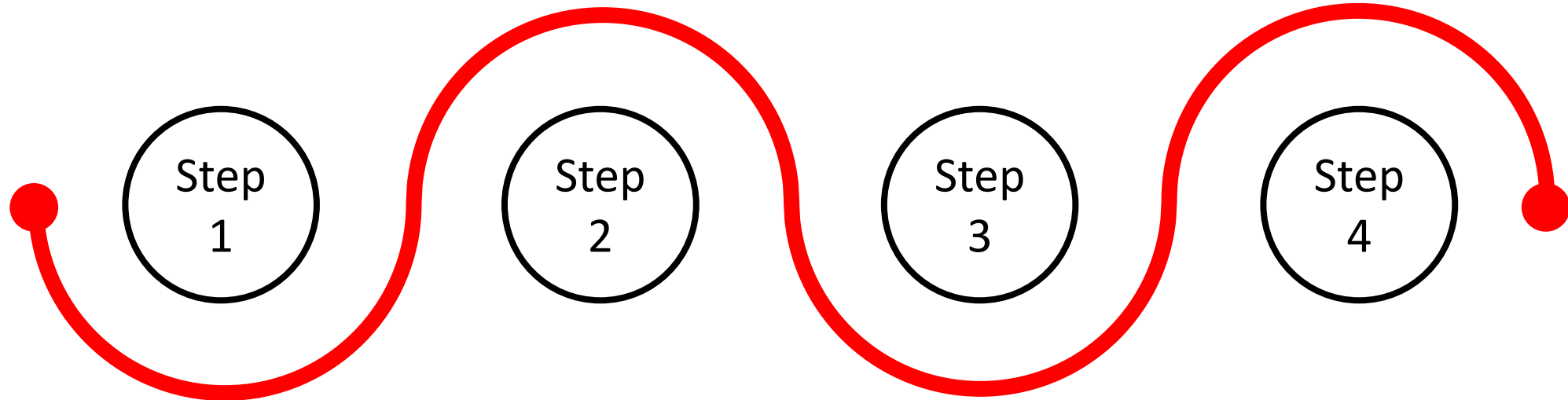
The Data sheet of genetically modified lines or constrained mutants (**Form D**) can be used in two ways:

- 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



## **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)

## **COMPLETE THE FORM**

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

## **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.

## **START USING THE FORM**

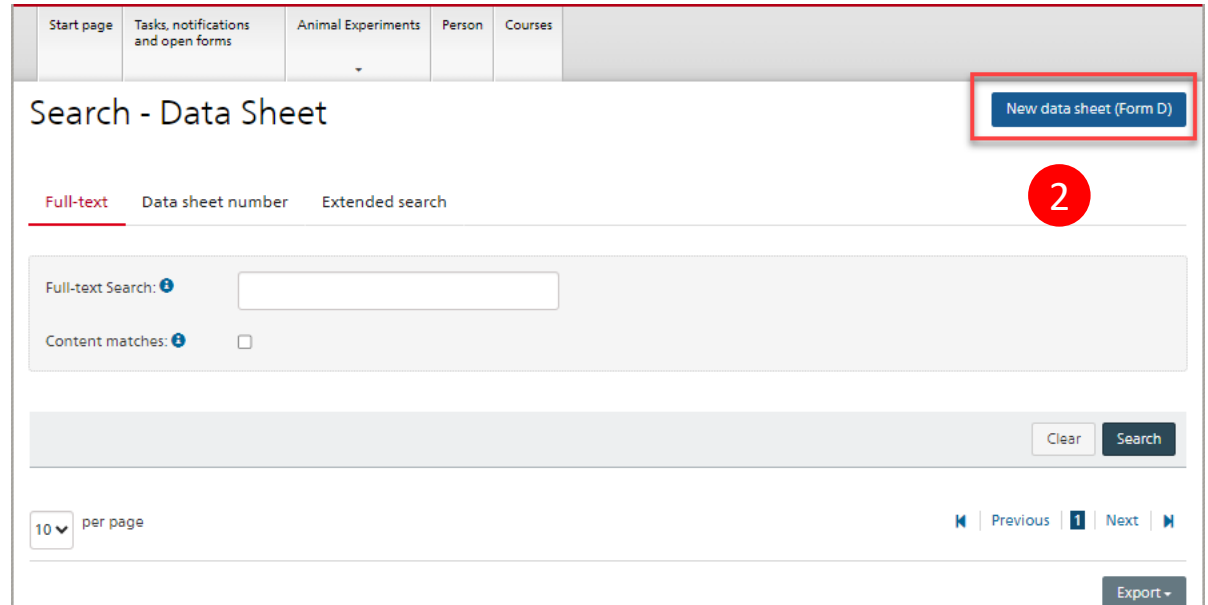
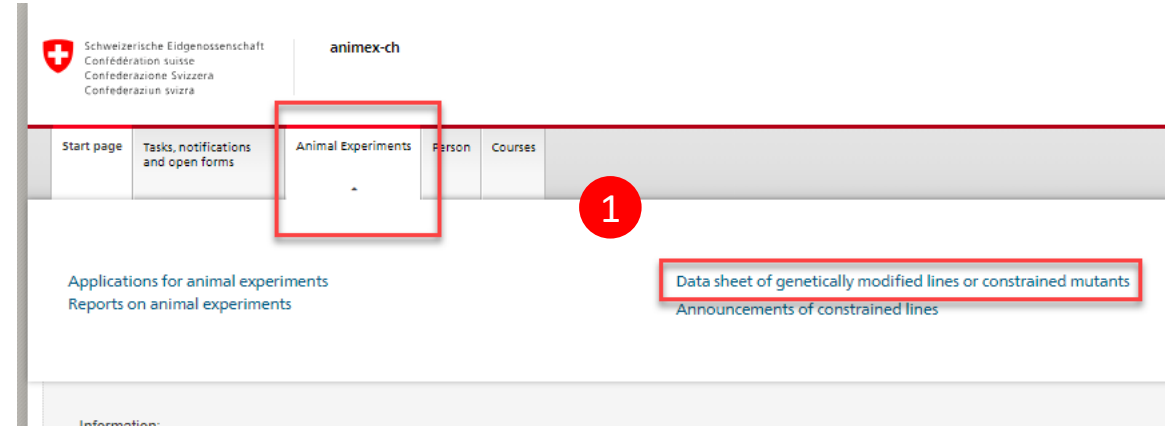
After the Form D has been versioned it is ready for use and can be attached either to a Form A or a Form M.



# 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 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)”
- 2





# 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)

The screenshot shows a web application interface with a sidebar on the left and a main content area on the right. The sidebar contains several cards: 'Animals' (09-10), 'Location' (10), and 'Personnel' (17-18). The main content area is a form titled 'Data sheet info and related forms'. It contains several sections with radio buttons and text input fields. The 'Create data sheet (form D)' button is highlighted with a red box and a red circle with the number 1. The form also includes a 'Cancel' button and a 'Save and close' button at the bottom right.



# Start wizard for a facility user

1

## Name of the animal facility:

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.

REF

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animex-ch

Animal Welfare Officer of Facility (AWOF)

Start page | Tasks, notifications and open forms | Animal Facilities | Person | Courses

## New data sheet of genetically modified lines or constrained mutants

You are about to create a new data sheet of genetically modified lines or constrained mutants (form D). Please fill in the following field(s).

Name of the animal facility \*

Head of Animal Facility

Cancel Save and create

Federal Food Safety and Veterinary Office

User Support Legal Framework Impressum Sitemap v3.3.0-519.1-RC.1 + 08f6857

2021 Access for All AA WCAG 2.0



# 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.

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DE FR IT EN

Animal Welfare Officer of Institute (AWOI)

Start page Tasks, notifications and open forms Animal Experiments Person Courses

### New data sheet of genetically modified lines or constrained mutants

You are about to create a new data sheet of genetically modified lines or constrained mutants (form D). Please fill in the following field(s).

Creator institute \*

Name of the animal facility \*

Head of Animal Facility

Cancel Save and create

Federal Food Safety and Veterinary Office

User Support Legal Framework Impressum Sitemap v3.3.0-519.1-RC.1 + 08f6857

2021 Access for All AA WCA 2.0



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

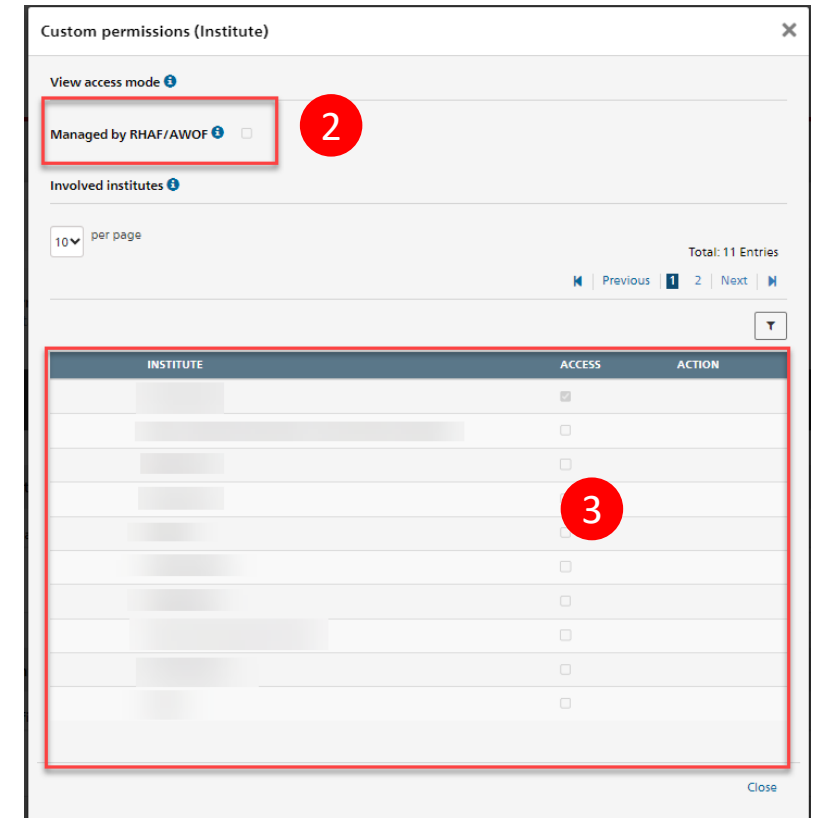
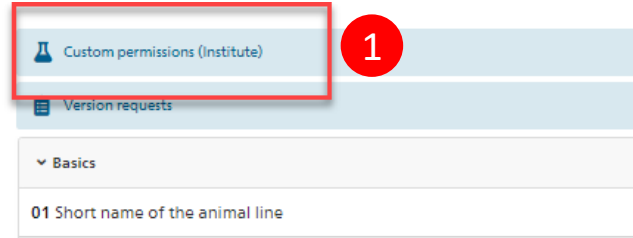
2

Checkbox «Managed by RHAF/AWOOF»:  
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 AWOOF 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)

1

## 01 Short name of the animal line

- mandatory field – can be an internal or commercial name (i.e. NSG mice)

2

## 02 Scientific notation of the animal line

- mandatory field – name needs to correspond international mouse nomenclature guidelines (<http://www.informatics.jax.org/mgihome/nomen/>).

3

## 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.

Form D  
Data sheet of genetically modified lines or constrained mutants Back to results list

**Basics** 01-03

01 Short name of the animal line ⓘ

Short name of the animal line \* ⓘ  
NSG 1

02 Scientific notation of the animal line ⓘ

Scientific notation of the animal line \* ⓘ  
NOD.Cg-Prkdcscid Il2rgtm1Wjl/SzJ 2

03 Licensed animal facility ⓘ 3

License numbers of animal facility

National number ⓘ

Cantonal number ⓘ

Address of the animal facility



# Basic scientific data (04 - 09)

In this chapter and all subchapters are editable and mandatory:

1

## 04 Animals

- **Animal species** (dropdown list with optional specification of the species in “Species specification” section)

2

## 05 Purpose

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

The screenshot shows a web form titled "Basic scientific data" with a sub-header "04-09" and a notification icon in the top right corner. The form is divided into two main sections:

- 04 Animals** (marked with a red circle containing the number 1):
  - Animal Species \***: A dropdown menu.
  - Species specification**: A text input field.
- 05 Purpose** (marked with a red circle containing the number 2):
  - Purpose of the line \***: A text input field.
  - Database reference \***: A text input field with a red border and the message "This field is required" below it.
  - Literature reference \***: A text input field with a red border and the message "This field is required" below it.



# Basic scientific data (04 - 09)

1

## 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),

2

## 07 Number of generations

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

The screenshot shows a web form with two sections. Section 06, titled 'Production', contains four fields: 'Producer / Origin of the line' (a text input field with a red border and 'This field is required' error message), 'Spontaneous' (radio buttons for 'Yes' and 'No', with 'No' selected), 'Method of production' (a dropdown menu), and 'Year of production' (a text input field with a red border and 'This field is required' error message). Section 07, titled 'Number of generations', contains two fields: 'Number of generations' (a dropdown menu with a red border and 'This field is required' error message) and 'Status of breeding' (a dropdown menu with a red border and 'This field is required' error message). Red circles with the numbers '1' and '2' are overlaid on the form, pointing to the 'Production' and 'Number of generations' sections respectively.



# Basic scientific data (04 - 09)

1

## 08 Genotype

- **Genotype list** - mandatory field – multiple separate genotypes must be added by clicking button “Add Genotype”

2

## 09 Hygiene status

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

08 Genotype \* ⓘ

Genotype list ⓘ

No genotype added

Add Genotype

09 Hygiene status ⓘ

Hygiene status \*

SPF (Specific Pathogen-Free)

Description

B i U A: [Rich text editor toolbar]

|type something

Characters : 0

Other



# 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)

1

- 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.

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.**

1

The screenshot shows a web form titled "11 Phenotype". It contains several sections for data entry:

- Assessment:** Radio buttons for "Internal", "External", and "Both".
- Results of monitoring of constraint in comparison to wild type:** A section header.
- Mortality rate:** Radio buttons for "Similar to wild type" and "Different from wild type". A red circle with the number "1" is placed next to the "Different from wild type" option. Below this is a text box labeled "Please, specify".
- Age of occurrence:** A text box.
- Reproduction rate:** Radio buttons for "Similar to wild type" and "Different from wild type". Below this is a text box labeled "Please, specify".
- Behavior:** Radio buttons for "Similar to wild type".



# 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?

The screenshot displays three sections of a form:

- Section 12: Mitigation of constraint ⓘ**  
Label: Mitigation of constraint \* ⓘ  
Field: A large empty text area for input.  
Action: Edit button
- Section 13: Criteria for withdrawal ⓘ**  
Label: Criteria for withdrawal \* ⓘ  
Field: A large empty text area for input.  
Action: Edit button
- Section 14: Degree of severity ⓘ**  
Label: Degree of severity \* ⓘ  
Field: Radio button options for 0, 1, 2, and 3.



# 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.

**Data sheet revision history** ⓘ

15-15

15	History ⓘ
----	-----------

No revision history added





# 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 / AWOOF 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 AWOOF 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

National number 1688 Short name of the animal line lorem ipsum Status of line Strained

Custom permissions (Institute)

Version requests 1

Basics

01 Short name of the animal line

02 Scientific notation of the animal line

03 Licensed animal facility

Basic scientific data

Summary of monitoring of genetically modified lines and constrained mutants

Data sheet revision history

Last modified by: Cristian Berce

Last modified on: 05.09.2023, 21:49 hour

Form D Data sheet of genetically modified lin

Basics 01-03

01 Short name of the animal line

Short name of the animal line \* lorem ipsum

02 Scientific notation of the animal line

Scientific notation of the animal line \*



# 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.

The screenshot shows a window titled "Version requests" with a close button (X) in the top right corner. Below the title bar is a text input field labeled "Remark" containing a single vertical bar character. Below the input field is a "Clear" button with a trash icon. To the right of the input field is a red circle with the number "1". Further to the right is a "Request new version" button, which is highlighted with a red rectangular box.

The screenshot shows the same "Version requests" window after the button is pressed. A red notification message "New version requested on 05.09.2023 21:54:47" is displayed at the top. Below it is a user notification for "AWOI Cristian Berce at 05.09.2023 21:54:47" with a green profile icon. The notification text reads: "Please approve this version. We have added the additional info. about the monitoring of constraints." A red circle with the number "2" is placed over the notification. A mouse cursor is visible over the text. At the bottom right of the window is a "Close" button.



# Approve or reject a version

- Users with a HAF or AWOOF 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”

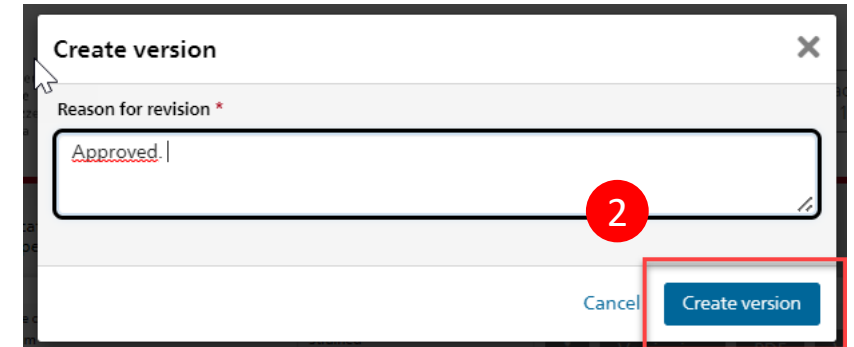
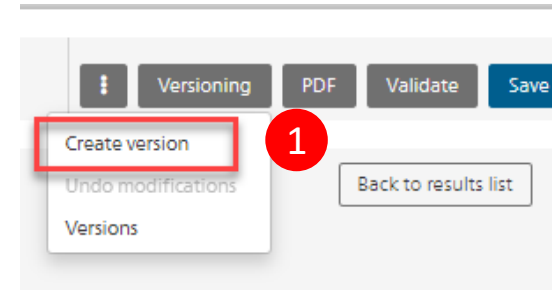
2

- 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 AWOOF roles can **create a new version of Form D without a previous request** by following steps 1 and 2.





# Updates on Form H

- 1 • 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.
- 2 • 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”
- 3 • A new version is created as described in the previous slide: **Versioning** → **Create version**

The screenshot displays the animex-ch web interface. At the top, the user is logged in as Cristian Berce. The main navigation bar includes links for Start page, Tasks, notifications and open forms, Animal Experiments, Animal Facilities, Person, and Courses. A warning alert (1) is visible: "Animal facility details updated. Please proceed to creating a new version". The "Versioning" button (2) is highlighted in the top right. Below the alert, the "Form D" section is shown, titled "Data sheet of genetically modified lines or constrained mutants". The "Basics" section is partially visible. A "Create version" dialog box (3) is open, with the "Reason for revision" field containing the text "Approved." and the "Create version" button highlighted.



For questions please use the following points of contact:

- **Technical queries:** Animex-ch application managers, FSVO, [animex-ch@blv.admin.ch](mailto:animex-ch@blv.admin.ch)
- **Subject-matter queries:** Animal Experimentation division, FSVO, [oberaufsicht-tv@blv.admin.ch](mailto:oberaufsicht-tv@blv.admin.ch)