



# Information Animal Welfare

## Explanatory notes to the Announcement of constrained lines (Form M)

V1.3 20.11.2023

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## 1. Purpose and scope

These explanatory notes are addressed to institutes, animal facilities and the competent cantonal authorities.

In order to identify constrained lines and to take appropriate measures against the constraint, a constraint monitoring must be carried out in accordance with Article 124 TSchV.

If constrained animal lines are bred in a laboratory animal facility or if new constraints are detected in existing animal lines, these must be reported to the cantonal authority, regardless of whether they are genetically modified, spontaneously mutated or chemically/physically induced lines (Art. 12 TSchG, Art. 126 TSchV). The Form M in combination with the Form D for genetically modified lines or constrained mutants are used for this purpose.

## 2. Requirements and creation of a Form M

To generate the Form M in animex-ch, you must:

- Have access to an approved laboratory animal facility in animex-ch (i.e. you need to have a valid Form H).
- Or have access to an institute that is confirmed as a participating institute in a Form H. At the same time, the access of your institute to the attached Form D must be confirmed in the Custom permissions (see Quickstarts).
- You need to have at least one of the following roles associated with that Form H:
  - IPI, SDI, RM, AWOI (Institute Users) – or associated ASI roles.
  - ACT, IPF, SDF, HAF, AWOI (Facility Users).
- Have access to a corresponding data sheet (Form D) which has at least one version.
- In the case of a Common A/M process (explained below): have access to an open Form A (draft or returned for rewrite).

## 3. Stand-alone vs. Common A/M Process

There are two ways to create a Form M: either by choosing the stand-alone workflow or by using the Common A/M process.

- Stand-alone: regular workflow of the form. Once the application is approved (for definitive announcements) or returned as accepted (for provisional announcements), it can be submitted as an attachment of a Form A.
- Common A/M: Form A and Form M have a common workflow and are linked together. There is a separate status for form M with the workflow Common A/M, namely the status SIGNED\_DEF. Once a Form M has Signed and Definitive status, it can be attached to the corresponding Form A and both forms can then be submitted together to the canton.

## 4. Explanations of the individual chapters

### Header:

CONTENT

### Form M

License Family which includes the national number and cantonal number (i.e. N-12345-ZH000/2023)

Short name of the animal line: Information is retrieved from Section 04

Type: Information is retrieved from Section 03

Stand-alone / Common A/M

PURPOSE OF ENTRY

Unique identification of Form M

ADDITIONAL INFORMATION

All elements from the Header are filled in by the system automatically. The cantonal number is assigned by the canton.

## BASICS

### Section 01:

CONTENT

#### Licensed animal facility

Information on the laboratory animal facility, the identification of the animal line and the persons responsible for the line.

License numbers of animal facility

- National number: National license number (generated by the system) of the laboratory animal facility, license as per Art. 122 Animal Welfare Ordinance (SR 455.1).
- Cantonal number: Cantonal number of the laboratory animal facility.

Address of the animal facility

- Name, street, postal code, town: Prefilled according to the facility selected in the wizard. If the name of the facility cannot be selected in the pull-down list, the laboratory animal facility must be created in the system by the cantonal veterinary office via the master data administration process and in the follow-up approved by the cantonal veterinary office.

Involved animal facility unit(s)

- Optional selection of units of the facility: Name, Address

Head of Animal Facility

- Name, E-Mail, Tel. No, Street, Postal Code, Town.

PURPOSE OF ENTRY

Details of the owner of Form M

ADDITIONAL INFORMATION

The information in this section is taken from Form D. For involved animal facility unit(s): if the laboratory animal facility consists of different units, the unit housing the animals for which the notification is being made should be indicated here.

### Section 02:

CONTENT

#### Address of the cantonal authority

The cantonal veterinary office will be prefilled by the system.

- Name
- Street
- Postal code
- Town

### Section 03:

CONTENT

#### Announcement type

Will be prefilled according to the selection in the wizard

- New announcement
- Supplementary announcement

### Section 04:

CONTENT

#### Short name of the animal line

Name assigned by the producer of the animal line / animal facility (laboratory-internal name). Prefilled from the associated data sheet (Form D).

PURPOSE OF ENTRY	The use of a short name serves to link a short name with the scientific name and to simplify the identification and use of the animal line.
ADDITIONAL INFORMATION	Information according to Annex 2 of the Animal Experimentation Ordinance (SR 455.163)
<b>Section 05:</b>	<b>Scientific notation of the animal line</b>
CONTENT	Prefilled from the associated data sheet (Form D). Correct name of the animal line according to international nomenclature for clear identification. Prefilled from associated data sheet. For international nomenclature rules, see: <a href="http://www.informatics.jax.org/mgihome/nomen/">http://www.informatics.jax.org/mgihome/nomen/</a>
PURPOSE OF ENTRY	Clear identification of the animal line
<b>Section 06:</b>	<b>Related data sheet of genetically modified lines or constrained mutants</b>
CONTENT	<p>Specification of the associated data sheet (Form D). The data sheet is a compulsory annex to the announcement.</p> <ul style="list-style-type: none"> <li>• National number of data sheet - Prefilled national number from the associated data sheet for genetically modified lines or strained mutants.</li> <li>• Note: Basic scientific data (Form D chapter 04-09) and mitigation of constrained (Form D section 12) can be viewed via the Form D tab.</li> <li>• Connect to last version {Ver_num}: The button is visible and click-able only when the Form M is editable and there is a newer version of the associated data sheet.</li> </ul>
PURPOSE OF ENTRY	In the data sheet information on scientific identification and the constraint monitoring is summarized for reporting. The data sheet must be enclosed with the announcement and updated continually.
<b>Section 07:</b>	<b>Owner of the line</b>
CONTENT	<p>The indication of the owner of the line is optional. If no person is selected no confirmation in Section 15 is required.</p> <ul style="list-style-type: none"> <li>• Name and role</li> <li>• E-mail</li> <li>• Tel. No</li> </ul> <p>Institute or Facility</p> <ul style="list-style-type: none"> <li>• Name</li> <li>• Street</li> <li>• Postal Code</li> <li>• Town</li> </ul> <p>Name of the person who owns the local colony of the line:</p> <p>The following details can be selected if the Form M is created by the laboratory animal facility:</p> <ul style="list-style-type: none"> <li>• SDI and RM of institutes specified in the user-defined authorizations of the associated data sheet (see Quickstart).</li> <li>• SDF and HAF of the associated laboratory animal facility.</li> </ul> <p>If the form M is created by the institute:</p> <ul style="list-style-type: none"> <li>• SDI and RM of the institute creating the Form M.</li> <li>• SDF and HAF of the associated laboratory animal facility.</li> </ul>
PURPOSE OF ENTRY	Indication of the person (owner of the line) who is involved from the institute side in the observation of the line and in the associated announcements of constraint. According to Art. 114 Para 2 Animal Welfare Ordinance (SR 455.1) the head of the animal facility is responsible for compliance with animal welfare regulations and the announcement of constrained lines in his facility.

## ANNOUNCEMENT OF CONSTRAINED ANIMALS

### Section 08:

CONTENT

#### Purpose of announcement

Announcement according to Article 124 Animal Welfare Ordinance (SR 455.1) of constraints observed in genetically modified animals (GMA) or mutants. In the Animal Experimentation Ordinance (SR 455.163) differing information is requested depending on whether it is a provisional announcement for small rodents (Article 17), a definitive announcement for small rodents (Article 18) or an announcement for strained fish lines (Article 22).

In each case, the data sheet for GMA or strained mutants (Form D) Article 23 Animal Experiments Ordinance (SR 455.163) must be enclosed. Section is prefilled according to selection in wizard

PURPOSE OF ENTRY

Requirements according to Articles 17, 18 and 22 Animal Experimentation Ordinance (SR 455.163).

### Section 09:

CONTENT

#### 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. Mandatory indication for a provisional announcement: At least the rich text editor has to be filled-in or a document to be uploaded in the section header.

PURPOSE OF ENTRY

According to Article 124 Animal Welfare Ordinance (455.1) and Article 17 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION

This field is only relevant for the provisional notification. On the basis of the constraints already identified during constraint monitoring, it should be stated how often and with regard to which additional parameters the animals will be additionally checked in the future.

### Section 10:

CONTENT

#### Specific observation plan

This field is only for the definitive announcement relevant and editable. Need to include an indication of the specific observation plan. Mandatory indication for a definitive announcement: At least the rich text editor has to be filled-in or a document to be uploaded in the section header.

PURPOSE OF ENTRY

Requirements according to Article 124 Animal Welfare Ordinance (455.1).

ADDITIONAL INFORMATION

A specific observation plan must be described. This description must take into account the expected development of the phenotype in relation to age and must define which characteristics or clinical symptoms are to be monitored and with which frequency.

### Section 11:

CONTENT

#### Breeding

Prerequisite information for the rationale and weighing of interests (section 12-14). Editable and mandatory for definitive announcements only.

Information in accordance with Article 18 (rodents), resp. Article 22 (fish), Animal Experimentation Ordinance (TVV) on:

- the intended scope of breeding;
- the planned number of animals for use in animal experiments;
- the desired gain in knowledge and potential benefits.

PURPOSE OF ENTRY

According to Article 127 Animal Welfare Ordinance (SR455.1) and Articles 18 and 22 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION

The extent of breeding to be carried out with this line must be stated. Specifically, state how many animals are to be bred under this announcement, and how many animals are to be bred for which animal experiments. For example, in the case of constrained lines, where the constraint cannot be completely eliminated even by strain-reducing measures, an animal experiment licence must be obtained before breeding can commence, in accordance with

Art. 136 (SR455.1). Highly constrained lines should not be assessed by the Commission only after 100 animals have been bred (weighing of interests), but breeding restrictions should be imposed at an early stage if necessary (Art. 127 TSchV, Art. 18 TVV).

## RATIONALE AND WEIGHING OF INTERESTS

### Section 12:

#### Suitability

CONTENT

Rationale for selecting the animal line in order to clarify the research question

PURPOSE OF ENTRY

Prerequisite for harm-benefit analysis (weighing of interests). If the suitability of the proposed methods in order to achieve the intended aim is not established, the method must not be carried out.

ADDITIONAL INFORMATION

It must be shown why this line is suitable to contribute to clarification in a specific research question. The advantages and benefits of the line in relation to its use in a specific research area must be presented

### Section 13:

#### Necessity (3R)

CONTENT

Rationale that the 3R (replace, reduce, refine) criteria are met. To be explained is also, why a method that does not require animals does not exist (Replace), why the breeding cannot be carried out with fewer animals (Reduce), and how all possibilities to reduce the strain on the animals are exploited (Refine).

PURPOSE OF ENTRY

Prerequisite for harm-benefit analysis (weighing of interests). The necessity of the method is established if the intended aim cannot be achieved by a method that does not require animals or that entails no strain for the animal or less strain than the proposed methods. If the necessity is not established, the breeding must not be carried out.

ADDITIONAL INFORMATION

With regard to 3R principles, reasons must be given as to why the breeding detailed in Section 11 is required. Finally, it must be explained which measures will be taken in terms of refinement (strain-reducing measures, termination criteria, etc.).

### Section 14:

#### Weighing of interests

CONTENT

The overall strain and the interests must be weighed against each other. To assess is the anticipated information or benefit in relation to the pain, suffering, harm, injury or anxiety caused to the animals and injury to the dignity of the animal in other respects.

Information in accordance with Article 18 (rodents), resp. Article 22 (Fish), Animal Experimentation Ordinance (SR 455.1) on

- the weighing of the observed constraint for the animals (chapter 11 and 14 data sheet (Form D))

*versus*

- the potential benefit for research, therapy or diagnostics and the likelihood of this benefit being realized (chapter 11, Breeding and use in animal experiments).

PURPOSE OF ENTRY

Assessment of the application with regard to the balance between expected gains in knowledge or other results (interests) and the pain, suffering, harm, injury or anxiety inflicted (strain on the animals) in accordance with ethical considerations. (see art. 3 Animal Welfare Act (SR 455) and art. 127 Para 1 Animal Welfare Ordinance (SR455.1)).

ADDITIONAL INFORMATION

Genetic engineering interventions on vertebrates are permissible only if carried out for a purpose listed in Article 9 of the Genetic Engineering Act (GTG). However, it should be noted that interventions for these purposes are not automatically permitted. The application for such interventions must in any case be examined within the framework of a weighing of interests. Even if the desired goals or interests are assessed positively, this does not necessarily mean that they

always take precedence over the constraints caused by genetic modification of the animals. A comprehensive weighing of interests is necessary, especially in the context of producing genetically modified animals and conducting experiments with them. In particular, the purpose of the breeding must also be taken into account. For example, breeding a strained line can only be justified for the purpose of establishing a line and using it in animal experiments.

## CONFIRMATIONS

### Section 15:

#### Statement of responsibility by owner of the line

CONTENT

Confirmation statement referring to the responsibility of the owner of the animal line. Only applicable if “owner of the line” is selected in Section 07. In that case the information is prefilled by the system.

- Name and role
- Statement of responsibility by owner of the line: “The owner of the animal line is accountable that the information given on the strained line is complete and correct.”
- Timestamp of submission to the canton

PURPOSE OF ENTRY

Replaces signature in the electronic dossier.

### Section 16:

#### Statement of correctness by user of facility

CONTENT

Confirmation statement referring to the responsibility of person submitting the announcement.

- Name and role
- Statement of correctness by user of facility: “By submitting to the cantonal authority, the responsible person confirms that the information given in the application form is complete and correct.”
- Timestamp of the submission to the canton

PURPOSE OF ENTRY

Replaces signature in the electronic dossier. According to Article 114 Para 2 Animal Welfare Ordinance (SR 455.167), the head of the animal facility is responsible for compliance with animal welfare regulations and the reporting of constrained lines.

## **ABBREVIATIONS:**

1. IPI – Involved Person of Institute
2. SDI – Study Director of Institute
3. RM – Resource Manager
4. AWOI – Animal Welfare Officer of Institute
5. ACT – Animal Care Taker
6. IPF – Involved Person of Facility
7. SDF – Study Director of Facility
8. HAF – Head of Animal Facility
9. AWOF – Animal Welfare Officer of Facility