



Swiss Confederation

Information animal welfare

Application for the simplified license to create genetically modified animals (GMA) using recognized methods (Form G)

Explanatory notes to Form G

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1 Purpose and applicability

According to art. 142 para. 1 of the Animal Welfare Ordinance (SR 455.1) it requires a cantonal license to create genetically modified animals using recognized methods.

These explanations are directed to all license applicants and to the authorities responsible for animal experiments.

The purpose of these explanations is to facilitate the writing and evaluation of license applications and so reduce the number of further enquiries.

The explanations are to be taken as a reference text, should there be a lack of clarity when completing the individual sections.

The ordinance on the electronic information system for the administration of animal experiments (SR 455.61) regulates the operation of the application animex-ch.

2 Formal aspects of submitting an application

According to art. 9 and Annex 1 of the Animal Experimentation Ordinance (SR 455.163), it is defined which methods are considered recognized. Deviations that are part of the method of an animal experiment must be applied for within Form A and approved by the cantonal authority on a case-by-case basis.

Applications must be submitted online via the animex-ch information system using the form provided by the Federal Food Safety and Veterinary Office (FSVO).

The authorization procedure is based on art. 122 Animal Welfare Ordinance (SR 455.1). Accordingly, the license is issued in the name of the head of the animal facility (HAF). The authorization for an animal facility is thus a prerequisite and the duration of the authorization for recognized methods cannot be longer than that for the corresponding animal facility.

According to art. 114, para. 2 let. b Animal Welfare Ordinance the head of the animal facility is responsible in particular for the welfare of the animals in breeding and trade.

Further instructions from the cantonal authorities, e.g. with regard to language or whether documents (e.g. scientific literature, publications) should be attached, must be considered.

3 Explanations to the individual sections

These explanations provide information about the purpose of each entry, what content is expected and what should be paid attention to.

Heading:	Application number
CONTENT	Not to be filled in by the applicant, as the numbering is done by the system (national number) and the authorities (cantonal number).
PURPOSE OF ENTRY	Unambiguous identification of the application.

BASICS

Section 01 Approved animal facility

CONTENT	<ul style="list-style-type: none"> • License number of the animal facility: <ul style="list-style-type: none"> ○ National number: National (generated by animex-ch) license number of animal facility. ○ Cantonal number: Number of the animal facility assigned by the cantonal authority. • Address of the animal facility <ul style="list-style-type: none"> ○ Name. Name of the approved animal facility applying for a simplified license to create genetically modified animals (GMA) using recognized methods. The license can only be issued in the name of the head of an approved animal facility. If the name of the animal facility cannot be selected in the pulldown list, the animal facility must be created in the system via the master data management process and approved by the cantonal veterinary office. ○ Street ○ Postal Code ○ Town • Head of animal facility (HAF): Contact details of the person responsible for the animal facility. • Animal Welfare Officer (AWOF): Name of the person with the function of the animal welfare officer in the animal facility. • Study director (SDF). Name of the person responsible for implementing methods to create genetically modified animals.
PURPOSE OF ENTRY	For communication with the authorities.

Section 02 Address of the cantonal authority

CONTENT	Postal address of the responsible cantonal authority (cantonal veterinary service)
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- **Name**
- **Street**
- **Postal Code**
- **Town**

Section 03

Application type

CONTENT

Assignment of one of the three application types: [N]= New application; [R]= **Renewal application**; [S]= **Supplementary**.

Changes to the duration or species used in a current license must be applied for to the authority as part of a supplementary application using form G.

One of the following three application types are displayed:

- **[N] New application:** applying for the simplified license to create genetically modified animals for the first time using recognized methods. There is no formal connection with a previous simplified license.
- **[R] Renewal application:** Application for a renewal of a simplified license to create genetically modified animals after expiry of the existing license. It is mandatory to indicate the number of the basic authorization. It can be created starting with 6 months before the expiration of the "parent" license or when the parent has expired.
- **[S] Supplementary application:** Application for amendments to the valid simplified license to create genetically modified animals. It is mandatory to indicate the number of the basic license.

PURPOSE OF ENTRY

Assign the application to an "application family".

Section 04

Purpose of creating genetically modified animals

CONTENT

Purpose of creating genetically modified animals with a simplified license according to art. 142 Animal Welfare Ordinance (SR 455.1) and art. 9 Animal Experimentation Ordinance (SR 455.163).

Purpose of production

Indication of the purpose to create genetically modified animals according to art. 9 of the Gene Technology Act (SR 814.91) and art. 138 para. 2 of the Animal Welfare Ordinance (SR 455.1). In animals the dignity of a living being must not be violated by modification of the genetic material by gene technology (art. 8 of the Gene Technology Act (SR 814.91)).

- **Science:** Genetically modified vertebrates may only be produced for research with a view to increase fundamental knowledge, for the benefit of human or animal health, or in connection with the preservation and improvement of ecological living conditions (e.g. not for research to breed faster horses or "fantasy mutations" such as luminous fish).
- **Therapy:** Genetically modified vertebrates may be produced only for therapy of humans or animals.
- **Diagnostics:** Genetically modified vertebrates may only be produced

for diagnostics to protect the health of humans and animals (but not diagnostics in sports).

Section 05

Statement of correctness

CONTENT

Confirmation statement that relates to the person responsible for the submission of the application.

Name und role

Name and role of the person submitting the request to the cantonal authority. The name is inserted by the system when the application is submitted.

Statement of correctness

By submitting to the cantonal authority, the head of the facility (or animal welfare officer) confirms that the information provided in the application form is complete and correct.

Time stamp of submission to the canton

Time stamp of the date when the application was submitted to the canton.

PURPOSE OF ENTRY

Replaces signature in the electronic dossier.

PERSONNEL

Section 06

Personnel list

CONTENT

List of persons involved to create genetically modified animals using recognized methods.

Name

Name of the person (HAF, SDF, IPF) authorized to use recognized methods for creating genetically modified animals according to Annex 1 of the Animal Experimentation Ordinance (SR 455.163).

Only involved persons IPF who have been previously added to the personnel register in animex-ch directory can be added. HAF and SDF will be transferred from Section 01.

The named persons must prove that they meet the requirements for education and training (art. 115, 132, 134, 190, 195 of the Animal Welfare Ordinance (SR 455.1)).

Role

The function of the person in the performance of the approved methods for creating genetically modified animals must be stated: head of animal facility (HAF), study director (SDF) or involved person (IPF) person.

Responsibility

Area of responsibility of this person shall be indicated.

PURPOSE OF ENTRY

To assess the level of training and qualification of persons using simplified methods for creating GMA and to provide information for queries of a technical nature.

ANIMALS

CONTENT

Information according to art. 28 let. f and g of the Animal Experimentation Ordinance (SR 455.163) on animals genetically modified by recognized methods.

Section 07

Species list and method

CONTENT

List of all animal species in which the recognized methods for the production of genetic modified animals (GMA) are to be used.

- **Animal species**

Create a list of all animal species where you want to generate GMA using recognized methods. Only one animal species can be selected per animal card.

- **Recognized method**

Indicate the recognized method used according to Annex 1 let. d. of the Animal Experimentation Ordinance (SR 455.163) for the generation of GMA. Only one selection can be made.

Modification of genetic material for the purposes of inheritance is the only recognized method for producing genetically modified animals according to Annex 1 let. d. of the Animal Experiment Ordinance. Contrarily, the use of viral vectors, which do not result in modifications of germ cells or lead to transgenic animals, must continue to be applied for as an animal experiment.

- **Capacity and animal trade**

Capacity to produce GMA and extent of trade with these animals.

A corresponding document can be uploaded or a corresponding description can be entered into the text field.

- **Procedure**

Description of the procedures according to sequence, manipulations, anesthesia, analgesia, place of performance (art. 128, 135 Animal Welfare Ordinance (SR 455.1)).

If possible, attach working instructions (SOP) and references to literature or databases.

A corresponding document can be uploaded or a corresponding description can be entered in the text field.

- **Record of constraint**

Information on the performance of the constraint assessment of the genetically modified animals produced, according to art. 124 Animal Welfare Ordinance (SR 455.1) as well as art.12-16 and 19-21 Animal Experimentation Ordinance (SR 455.163).

Documentation of assessment of constraint enclosed: If possible, documentation of assessment of constraint should be enclosed with the application.

A corresponding document can be uploaded or a corresponding description can be entered into the text field.

- **Capacities for genotyping and marking**

Description of available capacities for genotyping and marking.

A corresponding document can be uploaded or a corresponding description can be entered into the text field.

- **Are the animals marked at the same time during genotyping?**

The information is to be given by means of a yes/no selection.