



Swiss Confederation

Information Animal Welfare

Licence application to perform animal experiments:

Explanatory notes to form A

V1.0

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V1.0

1 Purpose and applicability

Anyone wishing to conduct animal experiments must inform the cantonal authorities of this intention. Applications are to be submitted using the forms issued by the Federal Veterinary Office (cf. art. 18, para. 1 of the Animal Welfare Act (SR 455), art. 139 para. 1 of the Animal Welfare Ordinance (SR 455.1) and art. 30 of the Animal Experimentation Ordinance (SR 455.163).

These explanations are directed at all **licence applicants**, at the **authorities responsible** for licensing animal experiments and at the **members of the cantonal commissions** for animal experiments.

The **purpose of these explanations** is to facilitate the writing and evaluation of licence applications for animal experiments, and so reduce the number of further enquiries by the authorities.

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

The formulation of the various questions is not optimal for all areas. It is a compromise between questions specific to academic research and those specific to the development of chemical-pharmaceutical products. Therefore explanations and definitions are necessary. Certain sections are not essential for some of the applications and therefore either need not be completed or require only a brief entry.

2 Formal aspects of submitting an application

According to art. 139 para. 1 Animal Welfare Ordinance and article 30 Animal Experimentation Ordinance, applications have to be submitted according to the sample form of the Federal Veterinary Office.

Note:	On animex-ch, applications are to be completed online (art. 139 para. 1 Animal Welfare Ordinance).
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In those sections which have no meaning for a particular experiment, a remark such as "not relevant", "no stress", "not used", "no marking" or a dash (-) should be entered.

Further instructions from the cantonal authorities, e.g. with regard to language or whether pdf-files of scientific literature should be attached, must be considered.

3 Explanations relating to the individual sections

These explanations provide information about the **purpose** of each entry, what **content** is expected and what must be particularly attended 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

Information about attribution and framework of the application.

Section 01 **Address of the applicant**

CONTENT Postal address of the institute, laboratory or company, as well as the name, telephone number and e-mail address of the person with whom the authorities should communicate.

- **Company**
- **Institute**
- **Resource Manager.** Contact details of the Resource Manager (name, email, tel.no)
- **Study Director.** Contact details of the principal Study Director (name, email, tel. no)

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)

- **Name**
- **Street**
- **Postal Code**
- **Town**
- **Delegated application input.** Indicates whether an application for animal experiment is created in delegated mode in animex-ch for an institute or not.

Section 03: Intercantonal experiment?

CONTENT

Indicate whether parts of the experiment will be carried out in other cantons and, if so, in which canton(s). The application is to be submitted to the canton, where the experiments are mainly carried out.

Which parts of the experiment are to be carried out in which canton should be indicated under Section 10 (Location of the experiments).

Secondary cantons

Indicate all cantons in which parts of the requested experiment will be carried out.

Each canton in the list of secondary cantons will get a notification of the application by the system animex-ch and will be automatically prompted for its consent (by the primary canton). The license is coordinated and issued by the primary canton.

PURPOSE OF ENTRY

Indication of whether and, if applicable, in which other cantons parts of the experiment will be carried out.

Section 04 Title of application

CONTENT

The **aim of the experiment** and an **indication of the animal model/method** to be used should be identifiable from the title.

PURPOSE OF ENTRY

To permit a rapid search and easier processing by the authorities and the cantonal commissions. To indicate the aim of the experiment and the animal model/method.

Section 05 Title for the publication

CONTENT

Informative title drafted in advance by the Resource Manager/Study Director to be used for the publication according to art. 20 let. a Animal Welfare Act (SR 455) after the end of the experiment. This title may be revised on submission of the public report.

PURPOSE OF ENTRY

To indicate the title for publication according to art. 20 let. a Animal Welfare Act (SR 455).

Section 06 Application type

CONTENT

One of the following six application types are displayed:

- **[N] New application:** The first application to conduct an experiment

addressing a particular question/aim or applying a particular experimental method. No formal relationship exists with previous applications.

- **[R] Renewal application:** In the case of renewal applications, completion of section 21 is mandatory. Include rationale and necessity of renewal. Application to renew a licence for experiments with the same aim and the same or a slightly modified method, in order to continue the experiment after a licence has expired. Can be created starting with 6 months before the expiration of the “parent” licence or when the parent has expired.
- **[SC] Supplementary application:** Application to modify a currently valid licence in respect of the method (e.g. additional routes of administration for test substances) or the number of animals required, inclusion of other cantons, change of personnel (only if applied with other changes mentioned under SC) etc. within the accorded duration of the licence.
- **[SR] Personnel supplementary application for Resource Manager or Principal Study Director:** Indicate change of Resource Manager or Principal Study Director only.
- **[SP] Personnel supplementary application:** Indicate change of personnel information on Involved Persons (IPI) and Study Directors (SDI).
- **[SV] Supplementary application for extension of validity:** Indicate if the amendment concerns the duration of validity only. The maximum permitted licence period of 3 years can be extended by 10% in exceptional cases. Can be created starting with 3 months before the expiration of the “parent” licence.

If the aim of the experiment is to be changed, select "new application" and not "supplementary" or "renewal" application (Art. 141 para. 2 Animal Welfare Ordinance (SR 455.1)).

PURPOSE OF ENTRY

To assign the application to an "application family".

Section 07

Maximum prospective degree of severity

CONTENT

For details, see section 36. Indicate the maximum prospective degree of severity according to the details given under section 36.

PURPOSE OF ENTRY

Provides a quick insight into the extent of stress in the experiment.

Section 08

Duration of project and date of start

CONTENT

Details must be provided of the total period (e.g. 4 months or 2 years) during which the experiment or experiments are to be carried out (art. 141 para. 2 Animal Welfare Ordinance (SR 455.1)): the maximum period of licence is 3 years. The period may be indicated in years, months or days. At least one indication is mandatory. Further details, e.g. duration of experiment for individual animals or animal groups, must be given under sections 24 and 25.

Years, Months, Days. The period may be indicated in years, months or days. At least one indication is mandatory:

Years: "This field range is from 1 to 100 or empty = 0"

Months: "This field range is from 1 to 11 or empty = 0"

Days: "This field range is from 1 to 30 or empty = 0"

Date of proposed start. The information may be given if an experiment is to begin on a given date (e.g. only after 6 months). This entry is not mandatory.

If the start of a study ("Application valid from" date) is set in the future, e.g. 6 months after the decision, the application will be approved in the status "Approved on hold". The period defined by "Approved on hold" does therefore not necessarily correspond to the appeal period. The appeal period starts (in order to trigger the workflow within the system) with the date of decision and indicates the duration in which an appeal could be filed.

PURPOSE OF ENTRY

Serves to provide an overview of the period during which the project is to be carried out.

ANIMALS

Section 09

Animal list

CONTENT

Details of the animals used in the experiment: animal category, sex, number, origin.

PURPOSE OF ENTRY

Assessment of application according to art. 112, art. 118, art. 137 para. 4 let. A Animal Welfare Ordinance (SR 455.1) and art. 20 para. 2 Animal Welfare Act (SR 455).

Animal category

The category of the animals intended for the experiment must be specified.

In the case of constraint mutants (art. 2 para. 3 let. k Animal Welfare Ordinance (SR 455.1)), not only the species, but also the name of the strained line must be indicated.

In the case of invertebrates, indicate whether they are cephalopods or crustaceans (reptantia).

Larvae and fetuses (prenatal individuals) are to be considered as an animal category in their own right under the following conditions (art. 112 let. c and let. d Animal Welfare Ordinance (SR 455.1)):

- Fetuses (of mammals, birds or reptiles) that are included in the experiment during the last trimester of the development period before birth or hatching. If they are withdrawn from the experiment before birth or hatching, they represent an animal category in their own right (e.g.: mice fetus). If, in contrast, the experiment is continued after the age of birth or hatching, they conform to the normal (common) category of their species.
- Larval stages (of fish or amphibians) that are already ingesting food freely during the experiment. If they are withdrawn from the experiment before they reach adulthood, they represent a category in their own right (e.g: zebrafish larva). If, in contrast, the experiment is continued after adulthood, they conform to the normal (common) category of their species.

Sex

Regarding the sex of the animals, indicate whether an animal group is all male, all female or mixed-sex.

Use of genetically modified animals

For each animal category listed, state whether genetically modified animals are used.

Has this line been newly established in this facility especially for this experiment?

If the animals were produced by genetic modification (GMA) and bred specially for this experiment, this must be indicated.

Constrained line?

Confirm if the animals used for the experiment are bred in a constrained line. If the line has been evaluated, the decision of the head of animal facility HAF (in case of no constraint) or the cantonal authority will be recorded in the data sheet.

Data sheet information and related Forms

Select the related data sheet (Form D) or the announcement for strained lines (Form M with corresponding cantonal decision, if applicable) in the drop-down list or upload the corresponding information.

Note: The workflow for direct selection of Form D (or Form M) in drop-down list will be implemented in release 2 of animex-ch. Upload is the only option between release 1 and 2.

Previously approved

Displays the number of animals approved in the previous decision of the cantonal authority.

Requested number of animals

Indicate the number of animals newly requested for each category. The number also includes control animals and/or reserve animals.

In case of supplementary application, indicate the number of the animals requested additionally.

In case of demand for reduction of the number of animals asked for a category (e.g. if the category of the animals used will change), put in the respective negative number.

Total number of animals requested

Displays the number of animals to be used overall during the period of the licence.

In case of supplementary application, the new total number of animals is updated by the system.

Origin of the animals

The origin of the animals must be given. For each category, a choice must be

made between one of three categories of origin:

- a) **From previous experiment:** The animals are taken over from a previous experiment for the experiment applied for here. In addition, the licence number of the previous experiment must be given.

National or cantonal number of previous experiment. The national number of the licence for the previous experiment must be given. The cantonal number of the licence for the previous experiment may be indicated alternatively to the national number.

- b) **Approved animal facility (incl. own breeding):** The animals originate from an approved lab animal facility in Switzerland or from abroad. This indication of origin must also be given for own-bred animals, if approved by the authorities.

From Switzerland

Licensed animal facility according to art. 122 Animal Welfare Ordinance (SR 455.1).

National number and name of animal facility

If the animals originate from an approved animal facility in Switzerland, select the licence number (national number) in the drop-down list.

The name of the approved animal facility may be selected alternatively to licence number in the drop-down list.

If the name of the approved animal facility (in Switzerland) does not appear in the drop-down list, contact the cantonal veterinary service.

From abroad

Laboratory animal breeding facilities and suppliers abroad are regarded as recognised if they have a relevant licence as stipulated in the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (European Council Convention, art. 14 to 17).

The address of the laboratory animal breeding facility outside Switzerland must be given.

Name and address of animal facility

Name of the animal facility approved or licensed by the competent authority of the country of origin.

If the name of the animal facility does not appear in the drop-down list, enter name and full address information.

Indicate address of the approved animal facility.

- c) **Non-approved animal holding:** If the animals are from a non-approved animal holding (e.g. zoo, farm or companion animals), indicate name and address of the holding of origin in the popup field.

From Switzerland

Indicate the non-approved animal holding in Switzerland.

Name and address of animal holding

Indicate name and address (if available) of the non-approved animal holding.

If the name of the non-approved animal holding does not appear in the drop-down list, enter name and full address information.

From abroad

Indicate the non-approved animal holding outside of Switzerland.

Name and address of animal holding

Indicate name and address (if available) of the non-approved animal holding.

If the name of the non-approved animal holding does not appear in the drop-down list, enter name and full address information.

Other non-approved origin(s) of the animals

For any other origin (e.g. in the case of outdoor experiments), give a short indication of the origin/location and describe the situation in the field "Description of animal origin".

Description of animal origin

Describe origin precisely if animals do not come from an approved animal facility or non-approved animal holding.

Place where the animals are kept

CONTENT

The exact location of the place where the animals are kept must be given.

If the animals are not kept in an approved animal facility (e.g. in the case of zoo, farm, companion animals or outdoor experiments), activate radio button "Non-approved animal holding" and give details of the housing and care of the animals before, during, between and after individual experiments in the field "Description of animal holding".

The reasons for any deviations from the animal husbandry regulations in the Animal Welfare Ordinance (Animal Welfare Ordinance (SR 455.1)) should be given under Section 32.

A choice must be made between:

- a) **Approved animal facility.** If the animals are kept in an approved animal facility in Switzerland, give the national number and name of the approved animal facility.

National number / name of animal facility. If the animals are kept in an approved animal facility, select the licence number (national number) in the

drop-down list. The name of the approved animal facility may be selected alternatively to licence number in the drop-down list. If the name of the approved animal facility (in Switzerland) does not appear in drop-down list, contact the cantonal veterinary service.

Room numbers. Indicate exact identification of rooms where animals used in the experiment are kept.

- b) **Non-approved animal holding.** If the animals are kept in a non-approved animal holding (e.g. zoo, farm, companion animals or in the case of outdoor experiments), indicate name and address in the pop-up field and give details of their care and housing before, during, between and after individual experiments in the field "Description of animal holding".

From Switzerland / abroad

Indicate the non-approved animal holding in Switzerland or outside of Switzerland.

Name and address of non-approved animal holding.

Indicate name and address (if available) of the non-approved animal holding. If no definite location is known (e.g. wild animals or clinical study with animals of multiple origins), give short indication instead of name and add more distinctive information about the situation in "Description of animal holding".

Description of animal holding. Detailed information on animal housing and management if the animals are not kept in a licenced animal facility:

- available space and structuring of the housing unit
- cage type
- availability and use of exercise runs (duration, frequency)
- individual or group housing
- type of feeding and activities
- routine checks by animal care staff.

The reasons for any deviations from the animal facility requirements of the Animal Welfare Ordinance (SR 455.1) are to be given under Section 32.

Other non-approved place(s) of animal holding(s)

For any other place, give a short indication of the place/animal holding in the field "Description of animal holding".

PURPOSE OF ENTRY

Assessment of the application according to Art. 128 Animal Welfare Ordinance (SR 455.1) (requirements for installations) and Art. 119 Animal Welfare Ordinance (SR 455.1) (general and special animal husbandry regulations).

Section 10

Location of the experiments

CONTENT

Address of the institute/animal facility including the actual room number(s) where the experiment or parts of the experiment is/are carried out.

If parts of the experiment are carried out in different cantons, all locations should be indicated with the relevant details (address, room numbers).

Also indicate which specific parts of the experiment are to be carried out at which location.

PERSONNEL

Section 11

Personnel

CONTENT

List of persons carrying out measures and interventions as part of the experiment or directing the experiment.

Only persons who have previously been entered in the personnel register are eligible here. Their names appear in the drop-down list of the Name field for selection.

Persons directing or involved in the experiment must meet the further education and training requirements in art. 132 and 134 para. 1 Animal Welfare Ordinance (SR 455.1) and Chapter 3 of the Ordinance of the Federal Department of Home Affairs FDHA on further training in animal husbandry and handling of animals.

If more than one Study Director is involved, they must all be named and their areas of responsibility should be specified.

Name

Name of the person involved in the experiment. Only persons registered and accredited according to the personnel process are eligible here.

Role

The person's role must be stated, e.g. Study Director (SD), Involved Person (IP), Resource Manager (RM).

Area of responsibility

If more than one person has a study-directing role, their areas of responsibility should be specified.

PURPOSE OF ENTRY

Assessment of the qualifications of persons involved in the experiment (see art. 132 and 134 Animal Welfare Ordinance (SR 455.1)) and details for queries of a technical nature.

Section 12

Resource Manager

CONTENT

Indication of the person responsible for the field of animal experiments.

According to art. 130 Animal Welfare Ordinance (SR 455.1) the Resource Manager is responsible for:

- a. the allocation of personnel, infrastructure and other resources to the individual animal experiments;
- b. compliance with the regulations of animal welfare legislation and the conditions and requirements associated with the licence;
- c. the reports as defined in art. 145 para. 2 (Form AC);

- d. promotion of the education and training of personnel in the field of animal experiments.

Name

The Resource Manager mentioned here is responsible (see art. 129 para. 1 and art. 130 Animal Welfare Ordinance (SR 455.1)) that the persons named under Section 11 are familiar with the regulations of the Animal Welfare Act (SR 455) and ordinance (Animal Welfare Ordinance (SR 455.1)) in respect of animal experiments and that they meet the educational and training requirements (art. 130 let. d Animal Welfare Ordinance (SR 455.1))

Statement of Responsibility

The Resource Manager confirms that the persons named in the list of persons are familiar with the regulations of the Animal Welfare Act (SR 455) and Animal Welfare Ordinance (SR 455.1) applicable to animal experiments and that they satisfy the educational and further training requirements.

PURPOSE OF ENTRY

Replaces signature in the electronic dossier.

Section 13

Principal Study Director

CONTENT

Indication of the principal person responsible for the study.

If more than one person has a study-directing role, their areas of responsibility should be specified in Section 11, area of responsibility.

The principal Study Director according to art. 131 Animal Welfare Ordinance (SR 455.1)

- a. is responsible for the planning and proper conduct of the animal experiment in terms of scientific and animal welfare issues;
- b. is responsible for the allocation of work, for instruction of the persons conducting the experiment, for checks on the work, for the organisation of proper supervision of the laboratory animals and their monitoring in the experiment as well as the execution of the necessary documentation work;
- c. determines who is responsible for the animal husbandry for the duration of the experiment and arranges this in an agreement with the head of the animal facility.

Name

The Study Director mentioned here is held responsible according to art. 131 Animal Welfare Ordinance (SR 455.1) with regard to responsibilities in the experiment.

Statement of Responsibility

CONTENT

The Principal Study Director confirms his/her responsibility as stated in Article 131 Animal Welfare Ordinance (SR 455.1).

The responsibility of the Principal Study Director is stated explicitly on the application form as a reminder.

Deputy Study Director

Nominate the Deputy Study Director.

PURPOSE OF ENTRY

Replaces signature in the electronic dossier.

Section 14

Animal Welfare Officer

CONTENT

Indication of name and responsibility of the Animal Welfare Officer.

Name

The Animal Welfare Officer mentioned hereafter is according to art. 129 let. a Animal Welfare Ordinance (SR 455.1) responsible for the completeness of the application and completion of the information required to assess its indispensability.

Date and timestamp of submission

Date of submission of application to the cantonal authority.

Statement of completeness

CONTENT

The responsibility of the Animal Welfare Officer is stated explicitly on the application form as a reminder.

By submitting to the cantonal veterinary office, the Animal Welfare Officer confirms that the application has been completed in full and contains the information required to assess its indispensability (art. 129 let. a Animal Welfare Ordinance (SR 455.1)).

PURPOSE OF ENTRY

Replaces signature in the electronic dossier.

PURPOSE OF THE EXPERIMENT

CONTENT

In Sections 16-18, mark only one entry in each category and, where appropriate, enter a further mark in a sub-category.

Section 15

Field of study

CONTENT

The scientific discipline, in which the question will be processed, should be entered as the field of study.

The main field of study to which the experiment relates must be indicated. If there is any uncertainty regarding the field of study to which an experiment belongs, a decision must be made according to the principal objective of the experiment.

Section 16

Area of application

CONTENT

Indicate the biomedical area that is concerned with the question of the study.

The main area of application to which the experiment relates must be indicated. If there is any uncertainty regarding the category or sub-category to which an experiment belongs, a decision must be made according to the principal objective of the experiment. Only one main category and, in the case of safety testing, one sub-category must be ticked.

Description of categories is done according to the European Council Convention.

Biological (including medical) studies in the field of basic research

This category also includes studies in the fields of veterinary and dental medicine.

Studies of an applied nature are not to be included here.

Research, development and quality control (excluding safety testing) of products or devices for human and veterinary medicine

This category also includes studies in the fields of dental medicine and studies on the quality control of sera, vaccines and hormones. By contrast, toxicological studies for medicines are to be classified under "Safety tests for medicines" (see below).

Diagnosis of disease

This category includes all studies in animals in the field of human, dental and veterinary medical diagnostics.

Education and training

This includes experiments as part of the teaching curriculum at universities, in the education and training of surgeons and other doctors, as well as training of specialist personnel (laboratory personnel).

Protection of humans, animals and the environment through toxicological or other safety tests for substances

This includes all toxicity studies, including those for medicines and medical devices (see also toxicity guideline, FSVO no. 4.01).

Under this principal category, the field of application of the substance to be tested must also be given.

The following fields of application should be differentiated (sub-categories):

- **Pharmaceutical products and medical devices:** Includes substances and products as well as devices that are used predominantly in human (incl. dental) or veterinary medicine or are intended for such use.
- **Agriculture:** Agrochemicals include substances and products that are used predominantly in agriculture or are intended for such use.
- **Industry:** Industrial chemicals (includes substances and products that are used predominantly in industry or are intended for such use) as well as development substances that cannot (yet) be assigned to any of the other specific fields of use.
- **Private households:** Cleaning materials, detergents etc. Includes substances and products that are used predominantly in private households or are intended for such use.
- **Food additives:** Includes substances that are used predominantly as additives in foods or are intended for such use. Also to be included in this category are safety tests related to new manufacturing methods for foods or novel foods.
- **Environmental contaminants:** Includes the field of ecotoxicology, i.e. the investigation of possible or actual hazards of contaminants in the general environment, including radiation.
- **Other uses:** Includes all fields of application and risks that are not listed above, including experimental toxicology. It must also be indicated which use is concerned.

Other studies

This includes those studies that cannot be assigned to one of the above five main categories, for example applied research outside the field of drug development (feeding experiments or studies on nature conservation), as well as studies designed to check hygiene standards in animal breeding and housing facilities.

Please specify: Precise description of the association with other studies.

PURPOSE OF ENTRY

To compile annual statistics with target categories according to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (European Council Convention) and the Resolution of the ad hoc Committee of Experts on the Convention, dated 27 November 1992 (see art. 36 Animal Welfare Act (SR 455); art. 147 Animal Welfare Ordinance (SR 455.1)).

Section 17

Association with diseases or disorders

CONTENT

The planned experiment must be assigned to one of the main categories of diseases. If there is uncertainty about the main category to which an experiment belongs, the decision should be based on the main aim of the experiment. Only one main category or, in the case of human diseases, one sub-category may be ticked. Safety tests for medicinal products should be assigned to the disease as far as possible. If a medicinal product relates to more than one disease, select the category "Other diseases". Description of categories is done according to the European Council Convention.

Human diseases

- **Cancer (excluding carcinogenicity studies).** With the exception of carcinogenicity studies in the context of product safety.
- **Cardiovascular diseases**
- **Nervous and mental disorders**
- **Other human diseases.** Includes all diseases or disorders in humans not listed above. In addition, it must be indicated which other disease(s) or disorder(s) is or are involved. If there is an association with 2 or 3 of the above diseases at the same time, this category must be ticked as well.

Animal diseases

Includes all diseases or disorders in animals. In addition, it must be indicated which other disease(s) is or are involved.

No association with human or animal diseases

Examples are education and training or certain projects in the field of basic research.

PURPOSE OF ENTRY

To compile annual statistics with categories according to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (European Council Convention) and the Resolution of the ad hoc Committee of Experts on the Convention, dated 27 November 1992 (see Art. 36 Animal Welfare Act (SR 455); art. 147 Animal Welfare Ordinance (SR 455.1)). Registration of the number of animals used for human or veterinary medical purposes, especially with regard to three areas of human disease that are of particular public interest.

Section 18

Associated procedures required by law

CONTENT

Indication of the regulatory requirements (according to international or Swiss regulatory and marketing authorisation requirements) for the planned experiment.

Only one category may be ticked.

Concerns regulatory and marketing authorisation requirements for substances and products of all kinds and also other studies required by law, e.g. in the field of environmental protection. Description of categories is done according to the European Council Convention.

For Switzerland only

Covers projects required by Swiss regulation, including those necessitated by international obligations (e.g. European Pharmacopoeia). Not intended here: requirements due to the legislation on animal experimentation itself.

Indication of the guideline(s) or test method(s). Indicate the specific guidelines which cover the regulatory requirement.

For other countries only

Covers projects carried out especially to meet the requirements (mainly for marketing substances and products) of countries other than Switzerland (including the fulfilment of requirements stipulated by treaties to which Switzerland is not a party). In addition, it must be indicated which country/countries or which treaty (e.g. OECD, EC) is involved.

Indication of the guideline(s) or test method(s). Indicate the specific guidelines which cover the regulatory requirement.

Please specify countries.

For Switzerland and other countries

Covers projects that are carried out to meet the requirements of Switzerland and other countries. In addition it must be indicated which country / countries or which treaty is involved.

Indication of the guideline(s) or test method(s). Indicate the specific guidelines which cover the regulatory requirement.

Please specify countries.

No association with procedures required by law

No association with procedures of any kind, which are required by law, e.g. basic research, education and training.

PURPOSE OF ENTRY

To compile annual statistics with categories according to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (European Council Convention) and the Resolution of the ad hoc Committee of Experts on the Convention, dated 27 November 1992 (art. 36 Animal Welfare Act (SR 455); art. 147 Animal Welfare Ordinance (SR 455.1)).

Section 19

External expertise

CONTENT

Details on whether the project has been or is being appraised and, if so, by which institution/organisation. Indicate only independent appraisals, e.g. grant applications; indicate a corresponding number if available.

Expertise rendered by

Give the name of the appraising institution/organisation and the number/reference of the appraisal.

PURPOSE OF ENTRY

Presentation of any statements obtained on the scientific assessment of the project or validity of the method.

Section 20

Objective of the experiment and background

CONTENT

Give a brief description of the objective of the experiment (maximum one page):

- **Description of the aim**, general statement of the problem and presentation of the context/background. The description should be understandable by non-specialists. It should include a description of the general problem in the context of which the application should be considered.
- **Current state of research**: Presentation of what has not yet been sufficiently studied.
- **Anticipated knowledge to be gained** from the experiments (see weighing of interests, section 40). The question is which arguments lend weight to that gain. The anticipated gain in knowledge should be explained by stating a clearly formulated expectation. The gain in knowledge is further qualified by the embedding of the project in the scientific context. It must therefore be described in a comprehensible manner the project, i.e. the objective of the experiment, will fit into the existing state of knowledge and to what extent it will expand it.

An application may include only experiments or series of experiments with interconnected questions or clearly defined objectives (art. 141 para. 2 Animal Welfare Ordinance (SR 455.1)). If multiple objectives are pursued, multiple applications should be submitted.

PURPOSE OF ENTRY

To assess **compliance with the indispensability** (see section 38 to 40) of the experiment according to art. 17 Animal Welfare Act (SR 455); art. 137 and art. 138 Animal Welfare Ordinance (SR 455.1).

Section 21

Results of the previous application

CONTENT

Maximum one page must be completed in the case of renewal applications.

Brief summary of the results of the previous licensing procedure and rationale for renewal of the application, understandable by non-specialists.

Questions to be answered in this context include the following: What knowledge might be gained from the results? How many animals in what degree of severity were used? Did the statistics prove effective (e.g. with regard to the group size)? What will be adjusted in the continuation of the project?

Section 22

Hypothesis

CONTENT

Formulate the research question to be answered in the experiment or the hypothesis(es) to be tested (confirmatory study).

COURSE OF THE EXPERIMENT (METHOD I)

Section 23

Course of the experiments: Schematic representation

CONTENT

What happens to the animal in the experiments and when?

Description of the course of the experiment from a **temporal perspective**. Representation of the course of the experiment or individual steps and the staggering of experiments over time, e.g. flow chart, workflow diagram, table. If animals are used repeatedly within one or in independent experiments, the interval between the use in the experiments and the total duration should be indicated.

To include: animal model, animal groups, the overall duration of the experiment for each individual group.

The detailed description of procedures and their duration should be entered in Section 25; the rationale for the number of animals needed, etc. should be entered in Section 30.

PURPOSE OF ENTRY

Assessment of the method from a **temporal perspective**. It should be clear what happens to individual animals or animal groups during the experiment.

Section 24

Preparation of animals for the experiment

CONTENT

Description of

- screening examination (art. 135 para. 3 Animal Welfare Ordinance (SR 455.1));
- preparation (e.g. acclimatization, habituation, training) to the experimental conditions (art. 119 para. 1 Animal Welfare Ordinance (SR 455.1));
- method of marking or identification (art. 120 Animal Welfare Ordinance (SR 455.1), art. 5 Animal Experimentation Ordinance (SR 455.163)) and combination with the method of genotyping (art. 10 Animal Experimentation Ordinance (SR 455.163));
- nature of marking (justification for invasive marking methods).

An experiment begins with the receipt of the animals (from a breeding station, supplier, reserve supply or quarantine station) and their preparation for intervention or treatment.

PURPOSE OF ENTRY

Assessment of the preparation of animals for the experiment (art. 119 Animal Welfare Ordinance (SR 455.1)).

Section 25

Procedures / manipulations on the animal

CONTENT

Details of the various manipulations/interventions on the animals:

- surgical interventions: the type, location (e.g. organ or organ system) of the intervention, its course and duration should be given in full.
- blood withdrawal: volume, location, frequency.
- administration of substances: type, volume, location, frequency.
- inoculation: type and location; pathogen, infectious material, tumour cells, dose/amount, number of repetitions, etc.
- immunisation: type and location of intervention: type of immunogen or adjuvant, dose, number of boosters and intervals, antibody harvesting (volume, location, frequency of blood sampling).
- physical noxious agents (radiation, heat, cold): intensity, duration, frequency, organ systems affected.
- observation: type and frequency of sampling, reaction tests (e.g. labyrinth test).
- behavioural restrictions: type and duration of triggering (e.g. by social isolation, by neuroactive substances).

Interventions or manipulations on control animals should also be described.

Where appropriate, add standard operating procedures SOPs.

PURPOSE OF ENTRY Assessment of licence conditions (art. 140 Animal Welfare Ordinance (SR 455.1)) and prerequisite for assessing the **suitability** (section 38) of the method (art. 137 para. 3 Animal Welfare Ordinance (SR 455.1)).

Section 26 Anaesthesia and/or analgesia

CONTENT Indicate the medications to be used (where appropriate, the combination of agents, e.g. sedative), the dose and volume, the intended routes of administration and (e.g. inhalation, intravenous injection, indication of the vein) and consider the need of continuing administration.

In the case of anaesthesia, state the intended duration and whether the animals are to be euthanised under anaesthesia.

When administering analgesics, also indicate the frequency of treatment and the timespan over which treatment will be administered, the route of administration (local or systemic) and combinations with other measures (e.g. anti-inflammatory treatment, including dose indication).

Rationale of anaesthesia/analgesia

Reasons for selecting or for not using analgesics and anaesthesia should be stated. Other stress-reducing measures or reasons for not using them should be indicated under Section 35.

PURPOSE OF ENTRY Assessment of the application in accordance with the implementation provisions (art. 135 Animal Welfare Ordinance (SR 455.1)).

Section 27**Method of euthanasia**

CONTENT

Indicate the method of euthanasia, stating the substance used, the dose and route of administration, and the procedure to ensure the death of the animal.

PURPOSE OF ENTRY

Assessment of the application concerning the proper conduct of euthanasia (art. 135 Animal Welfare Ordinance (SR 455.1)).

EVALUATION OF THE EXPERIMENT (METHOD II)

Section 28

Recorded parameters

CONTENT

List of all parameters recorded in the experiment (including primary outcome parameters if appropriate) and indication of important associations with the main parameters.

Evaluations of test material after the death of the animals should also be described (histology, etc.).

Comment on parameter

Brief description of the parameter, importance, relation to research question.

Section 29

Experimental set-up and study design

CONTENT

Describe the experimental set-up and the study design (e.g. randomized block design, matched-pairs design, etc.).

Specific considerations to include for the **planning** of the study:

1. Allocation concealment / randomisation
2. Blinding
3. Sample size calculation (rationale see Section 30)
4. In- and exclusion criteria
5. Definition of outcome variables (e.g. in case of confirmatory studies, a priori definition of a primary outcome variable is important)
6. Statistical analysis plan (rationale see Section 30).

Indicate the number of animals per experiment, series and groups, the degree of severity per group and per animal line. Also to indicate are sex, genotype and age of animals.

Include a description of each group: e.g. dose, duration, control, randomisation, blinding and replication, if possible in table form.

PURPOSE OF ENTRY

Description of the study design and planning.

Section 30

Rationale for the numbers of animals

CONTENT

Indicate in summary the **reasons** for the planned numbers of animals per experiment/series of experiments per group, including the method used for statistical analysis (e.g. t-test, ANOVA, mixed-effects model, etc.). List the starting information used to estimate/calculate the numbers of animals. If possible, indicate the test parameters (statistical coefficients, level of significance, power).

What size of the measured effect is to be regarded as relevant? Other information, which may be important: handling of multiple or consecutive experiments, subgroup analysis and replication.

PURPOSE OF ENTRY

Rationale for the number of animals with respect to meeting the requirements according to art. 137 para. 4 regarding the smallest number of animals to be used and the appropriate statistical analysis applied.

Section 31 Expertise for statistical analysis

CONTENT

Indicate whether the experimental design and the planned statistical analysis have been verified by a person with expertise in biostatistics.

HANDLING OF ANIMALS

Section 32 Downgraded husbandry conditions

CONTENT	Details and reasons for any deviations from conditions in which animals are kept as defined in the animal protection ordinance (Animal Welfare Ordinance (SR 455.1)) (see chapter 2 section 1, chapters 2 and 4, art. 117 and 119 Animal Welfare Ordinance (SR 455.1)). Reasons should also be given for the withdrawal of food and water, long periods of immobilization, etc.
PURPOSE OF ENTRY	Assessment of the necessity of restricted housing (see art. 117 Animal Welfare Ordinance (SR 455.1)).

Section 33 Effects on the animals

CONTENT	<p>Assessment of all expected adverse effects of all manipulations and measures on the animals (take account of cumulative effects in the event of repeated procedures).</p> <p>Expected effects to be assessed in the application:</p> <ul style="list-style-type: none">• indicators of anxiety and other stress responses of the animals;• body weight changes and the course of growth; food and water intake;• pain and pain reactions;• exclusions and deaths;• further disturbances, e.g. in locomotion, posture. <p>The duration and frequency of the effects, their intensity and their course are all to be indicated.</p> <p>Following article 26 of the Animal Experimentation Ordinance (SR 455.163), to assess the acceptability of an experiment consideration shall also be given to further strain imposed on the animals through humiliation, through major interference in their appearance or their abilities or through excessive instrumentalisation. Indicate corresponding strain where appropriate, too.</p>
PURPOSE OF ENTRY	Assessment of adverse effects on the animals with regard to the importance of the experimental objective in relation to the resulting restrictions (see art. 19 para. 4 Animal Welfare Act (SR 455)).

Section 34 Monitoring of well-being

CONTENT	<p>To indicate:</p> <ul style="list-style-type: none">• criteria for intervention and termination (humane endpoints). Add a score sheet if appropriate.• the frequency of checks (who carries out checks, documentation and how often during which study phase?)
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PURPOSE OF ENTRY Assessment of the **monitoring** and **documentation** (see art. 135 and 144 Animal Welfare Ordinance (SR 455.1)).

Section 35: Refinement

CONTENT Details of mitigating measures or reasons for not using such measures **under the specific experimental conditions**, as well as criteria. Stress mitigating measures are all measures that help reduce the stress generated by the experiment.

Which measures are taken to reduce stress or minimize any harm imposed on the animals under the specific experimental conditions?

PURPOSE OF ENTRY Assessment concerning implementing rules according to art. 135, art. 137 para. 4 pro and 144 Animal Welfare Ordinance (SR 455.1).

Section 36: Distribution by degree of severity

CONTENT Indicate the maximum expected degree of severity for each animal category and group. The expected number of animals for each anticipated degree of severity should be given as a percentage. The classification of stress is based on art. 24 and art. 25 Animal Experimentation Ordinance (SR 455.163). The allocation is based on FSVO technical information no 1.04.

PURPOSE OF ENTRY Summary global evaluation of the expected maximum stress on the animals (art. 26 Animal Experimentation Ordinance (SR 455.163)).

Section 37: Use of the animals at the end of the experiment

CONTENT To be completed only if the animals are expected to survive the experiment.
If the animals will remain alive after the experiment and no longer be used for experimental purposes, their future use must be described using keywords.

PURPOSE OF ENTRY Assessment of the application concerning the implementing rules with regard to the further use of animals after an experiment (see art. 20 Animal Welfare Act (SR 455); art. 141 para. 4 Animal Welfare Ordinance (SR 455.1)).

RATIONALE AND WEIGHING OF INTERESTS

Details of the reasons and justifications for selecting the experimental method and animal category.

Section 38: Suitability

CONTENT

Rationale for selecting the experimental method in order to achieve the intended aim.

Reasons for selecting the animal model with regard to the experimental objective and depiction of scientific validity (i.e. construct validity, internal validity, and external validity) and reproducibility of the expected findings, if appropriate.

The peculiarities and/or advantages with regard to the experimental objective and stress arising for the animals must be shown. To indicate is the information on the relevance of the animal model and reproducibility of the measurements. To show is the extent to which it is possible to generalise or extrapolate to other study conditions, populations of animals or species, incl. humans.

For regulatory experiments (e.g. substance testing: test battery with in-vitro and in-vivo methods) indicate if an experiment is required by the authorities.

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 of the experiment is not established, the experiment must not be carried out.

Section 39: Necessity (3R)

CONTENT

Rationale that the **3R (replace, reduce, refine)** criteria are met:

Reasoning why the intended aim of the experiment **cannot be achieved by methods** that comply better **with all the 3R criteria**.

To be explained is also, why a method that does not require animals does not exist (**Replace**), why the experiment cannot be carried out with fewer animals (**Reduce**), and how all possibilities to reduce the strain on the animals are exploited (**Refine**).

The necessity of an experiment is established if the intended aim cannot be achieved by a method that does not require animals (**Replace**, e.g. cell cultures) or that entails no strain for the animal or less strain than the proposed methods. The question is therefore whether there is a suitable alternative to the proposed method.

The question of necessity also arises from the perspective of **Reduce** and of **Refine**.

PURPOSE OF ENTRY

Prerequisite for harm-benefit analysis (weighing of interests). The necessity of an experiment 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 experiment must not be carried out.

Section 40: 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. The presence of non-pathocentric types of strain does not change the severity classification of the experiment. However, it does lead to a higher overall assessment of the strain.

To be indicated and explained:

- On the **strain side**: which strain criteria are concerned in the experiment, and which is the resulting overall assessment for the strain side.
- On the **interests side**: the significance of the experiment with regard to the experimental objective.
- The applicant should set out arguments demonstrating that there is an **overriding interest** in his or her project and that the strain is therefore justified.

In the case of complex animal experiments, a weighing of interests must be carried out for each individual experiment.

Particular attention must be paid to the desired gain in knowledge according to sections 20 and the stresses on the animals according to sections 33 to 36. The importance of the experimental objective for humans and animals and the restrictions on the animals are to be weighted in accordance with ethical considerations.

For more details on the weighing of interests, see the document “Weighing of interests in animal experimentation” [[LINK www.blv.admin.ch](http://www.blv.admin.ch)].

PURPOSE OF ENTRY

Weighing of interests: 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 and 19 para. 4 Animal Welfare Act (SR 455)).

Note: The link to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes and the Resolution of the Ad Hoc Committee of Experts to the Convention of the 14th June 2010 can be found at <https://www.admin.ch/opc/de/classified-compilation/19860064/201006140000/0.457.pdf>