



## Licence application to perform animal experiments: Explanatory notes to form A

---

Contents		Page
A.	Purpose and Applicability .....	2
B.	Formal Aspects of Submitting an Application.....	2
C.	Explanations relating to the individual sections.....	3
Heading:	Application number .....	3
Section 1:	Address of resource manager.....	3
Section 2:	Address of cantonal authority.....	3
Section 3:	Title of project.....	3
Section 31:	Field of study or area of application.....	3
Section 32:	Type of application .....	4
Section 33:	Animal species, number and origin of animals.....	4
Section 34.1:	Location of animals .....	6
Section 34.2:	Location of the experiments .....	6
Section 34.3:	Intercantonal experiment.....	6
Section 34.4:	Use of genetically modified animals .....	6
Section 35:	Maximum prospective degree of severity.....	6
Section 36:	Duration of project proposed start .....	7
Section 37:	List of persons / annex to form-A .....	7
Section 38:	Resource manager.....	7
Section 39:	Study direction.....	8
Section 4:	INFORMATION ON THE PURPOSE OF THE EXPERIMENT .....	8
Section 5:	INFORMATION ABOUT THE METHOD.....	12
Section 6:	INFORMATION ON THE REASON OF THE ANIMAL EXPERIMENT .....	19

## A. 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 (TSchG, SR 455), art. 139 para of the ordinance on the animal welfare (TSchV, SR 455.1) and art. 30 of the ordinance on animal experiments (TVV, 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 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. Knowledge of its content is not an absolute prerequisite for completing a licence application.

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.

These explanations only refer to Form A. Form C, intermediate and final reports, is dealt with in "Zwischen- und Abschlussberichte über Tierversuche: Erläuterungen zum Formular C" (FVO procedure no. 800.116-1.03), available also in French, but not in English.

## B. Formal Aspects of Submitting an Application

According to article 139, para 1 TSchV and article 30 TVV, applications have to be submitted according to the sample form of the Federal Veterinary Office.



**Note:** Once the information system e-tierversuche is operational, applications are to be completed online (art. 139 para 1 TSchV).

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.

The application must be completed in a legible font size (e.g. Arial 10 – 12).

The original of the application and, usually, 3 copies (including any additional sheets) are to be submitted to the cantonal licensing authority, which may advise the applicant to supply additional copies.

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

## C. 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. The explanatory **examples** for some sections illustrate the expected content. Stars (\*) indicate sections where an entry or description is unconditionally required.

### Heading: Application number

PURPOSE OF ENTRY Unambiguous **identification** of the application.

CONTENT NOT to be filled in by the applicant, as the numbering is done by the authorities.  
Application or project numbers used by an institute/laboratory for internal identification must be annotated "INTERNAL".

### Section 1: Address of resource manager

PURPOSE OF ENTRY For communication with the authorities.

CONTENT The **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.

### Section 2: Address of cantonal authority

CONTENT The postal address of the responsible cantonal authority (cantonal veterinary office).

### Section 3: Title of project

PURPOSE OF ENTRY To permit a rapid search and easier processing by the authorities and the cantonal commissions

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

EXAMPLE

- A test of the antibacterial action of drugs in mice with experimental Meningitis.
- Short title: Experimental Meningitis in mice.
- Production of polyclonal antibodies against enzymes influencing DNA-replication in hens.
- 

### Section 31: Field of study or area of application

PURPOSE OF ENTRY Notification of the authorities and the commissions with regard to the ruling on the application.

CONTENT The **speciality or field of application** to which the experiment is directly related

should be named. If indicated in substance, multiple nominations (speciality and field of applicability, multiple specialities, multiple fields of applicability) are possible in section 44.1.

EXAMPLE                   ▪ Education ▪ Immunology ▪ Neurology ▪ Paraclinic ▪ Pharmacology ▪ Animal Production ▪ Toxicology ▪ etc.

### Section 32:        **Type of application**

PURPOSE OF ENTRY        To assign this application to any documentation on the same method or aim of the same applicant that may already be available to the authorities from previous years.

CONTENT                    One of three possibilities is to be marked, namely:

- **New application:** The first application for conducting an experiment addressing a particular problem/aim or applying a particular experimental method. No formal relationship exists with previous applications.
- **Application for renewal:** Applications requesting the renewal of an expired licence for experiments with the same purpose and the same, or only slightly modified, method.
- **Supplementary application:** Application to modify a currently valid licence in respect of the method (e.g. additional routes of administration of the test substances) or the number of animals required, changes in the study directorship, etc. **within the accorded duration of the licence.** Changes to the text compared with the original version must be clearly marked.  
In the case of only isolated modification there is no need to complete a form - a written application by letter or e-mail is sufficient.
- **Application for extension:** Request for an extension of an existing licence to the maximum permitted licence period of 3 years (in exceptional cases +10%) In this case, a written application by letter or e-mail is sufficient.

The licence/decision number to which an application for renewal, a supplementary application or an application for an extension applies must be entered by the applicant.

When a new method is used, or if the aim of the experiment is changed, neither an application for renewal nor a supplementary application but a new one should be made (Art. 141 Abs. 2 TSchV).

### Section 33:        **Animal species, number and origin of animals**

PURPOSE OF ENTRY:        Assessment of application according to articles 112, 118, 137 para. 4 a TSchV and art. 20 para. 2 TSchG.

CONTENT:                    The **animal species** intended for the experiment must be specified. If several animal species are to be used, they should all be specified.  
In the case of pathological mutants (art. 2 para. 3 lit. k TSchV) not only the species, but also the strain or breed must be indicated. In the case of **dogs** the breed must

also be given and in the case of **invertebrates** the class.

**Larvae and embryos** are to be considered as an animal species in their own right under the following conditions (art. 112 lit. c and d TSchV):

- Embryos 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 a 'species' of their own (e.g: mice embryo). If in contrast the experiment is continued after the age of birth or hatching, they conform to the normal species.
- Larva stages that are already ingesting food freely during the experiment. If they are withdrawn from the experiment before they reach adulthood, they represent a 'species' of their own (e.g: zebrafish larva). If in contrast the experiment is continued after adulthood, they conform to the normal species.

Under **Total number per application** the number of animals to be used during the period of the licence overall must be indicated. The total number thus also includes the number of animals for additional groups and/or reserve animals.

The total number of animals must be given in every case. It forms the framework of an application and must not be exceeded. If necessary, a supplementary licence must be obtained. For one-off experiments the total number is derived from the number of experimental groups multiplied by the likely number of animals per group and the reserve animals. For standard experiments the total number (for a licence period of usually 3 years) is derived from the number of animals per standard test (= number of doses x number of animals per dose) multiplied by the number of tests carried out.

The **origin** of the animals must be given. For each species, a choice must be made between one of 3 categories of origin. Description of categories of origin:

- (a) **From a previous experiment:** Animals that are taken over from a previous experiment (using the same or a different method) for the experiment applied for here. In addition the **licence number** of the previous experiment must be given.
- (b) Licensed **laboratory animal husbandry** (art. 122 TSchV): animals that are obtained from a licensed laboratory animal housing facility. This also includes animals from the laboratory's own breeding husbandry if this is licensed by the authorities. The **licence number of the laboratory housing facility** must be given.

Laboratory animal housing facilities of breeders and dealers abroad are regarded as recognized if they have a licence to this effect relevant as stipulated in the European Council Convention (articles 14 to 17).

**Name and address of the supplier** must be given. If the animals are from the applicant's own breeding facility, this must also be indicated. If animals are obtained from several suppliers, all of them must be indicated, and it must be clearly visible which species is obtained from which supplier.

- (c) **Other origin:** this means that animals are to be used for the experiment that have neither been taken over from a previous experiment nor obtained from a licensed laboratory animal housing facility in Switzerland or a recognized laboratory animal breeder or dealer abroad. In addition, the origin of the animals must be given (e.g. a farm; wild catch; non-licensed laboratory animal facility; horse dealer; animals from a field study etc.).

**Name and address of the supplier** must be given. If animals are obtained from several suppliers, all of them must be indicated, and it must be clearly visible which species is obtained from which supplier.

Detailed information concerning **animal lines** and **strains** to be used are to be given in section 54.3.

Details about group sizes and number of experimental groups (including number of doses and number of animals per dose in the case of standard tests) must likewise be given under section 54.3.

The reasons for using the animal species proposed, for the number of animals and for any exemptions from the rules on origin must be indicated under 54.4.

### **Section 34.1: Location of animals**

PURPOSE OF ENTRY: Exact location of the animals (before, during and, if necessary, after the experiment).

CONTENT: Address of the animal husbandry including the actual room number  
Licence number of the animal husbandry.

EXAMPLE: 

- Animal husbandry of the Institute of Physiology, Sample Street 32, Room 206; H-02119/BE

### **Section 34.2: Location of the experiments**

PURPOSE OF ENTRY: Room or rooms in which the actual stages of the experiment are carried out.

CONTENT: Address of the institute/animal husbandry including the actual room number(s).

EXAMPLE: 

- Institute of Physiology, Sample Street 32, Laboratory number B115.

### **Section 34.3: Intercantonal experiment**

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

### **Section 34.4: Use of genetically modified animals**

PURPOSE OF ENTRY: Serves to provide a quick overview of whether genetically modified animals will be used in the experiment.

CONTENT: If so, the relevant data sheets for genetically modified lines and strained mutants must be enclosed. If there is a decision by the authorities on a strained line, the number of the decision must likewise be given.

### **Section 35: Maximum prospective degree of severity**

PURPOSE OF ENTRY: Serves to provide a quick insight into the scale of the stress in the experiment.

CONTENT: Information must be provided on the maximum severity expected for individual or all animals according to the details given under Section 56.4.

### **Section 36: Duration of project proposed start**

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

CONTENT: Under **Duration of project** 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 TSchV: maximum period of licence 3 years).

The **Date of proposed start** must be given, so that the authorities can estimate whether the start of the experiment is realistic in light of the approval procedure.

Further details, e.g. duration of experiment for individual animals or animal groups, must be given under Sections 51.1 and 54.2.

### **Section 37: List of persons / annex to form-A**

PURPOSE OF ENTRY: Assessment of the qualification of the persons involved in the experiment (see articles 132 and 134 TSchV) and also details for queries of a technical nature.

CONTENT: List of persons involved in the experiment. The details are given in the 'Annex to the licence application for animal experiments'. The following must be provided:

- **Surname, first name**
- **Function in experiment** (study director, deputy study director, person conducting the experiment)
- **Procedures in the animal** that are carried out by the person in the context of the experiment
- **Documentation of education and training** that are sent to the authorities.

### **Section 38: Resource manager**

PURPOSE OF ENTRY: Confirmation of the undersigned resource manager (see art. 129 para. 1 and 130 TSchV) that the persons named under Section 37 and in the annex are familiar with the regulations of the animal welfare act (TSchG) and (TSchV) ordinance in respect of animal experiments and that they meet the educational and training requirements (art. 130 d TSchV).

According to article 130 TSchV the undersigned 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 article 145 paragraph 2 (Form C);
- d. promotion of the education and training of personnel in the field of animal experiments.

CONTENT: **Name and signature, place and date.**

### **Section 39: Study direction**

PURPOSE OF ENTRY: Confirmation of the study director according to article 129 and 131 TSchV including deputization with regard to responsibilities in the experiment.

If several study directors are involved (e.g. in standard experiments), they must all be named.

The undersigned (principal) study director according to article 131 TSchV

- 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 organization 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 laboratory animal husbandry.

CONTENT: **Name and signature, place and date.**

### **Section 4: INFORMATION ON THE PURPOSE OF THE EXPERIMENT**

#### **Section 41: Association of research project with different target categories**

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 27th November 1992 (see art. 36 TSchG; art. 147 TSchV).

CONTENT: The applicant has to decide and indicate under which of the six main categories the planned experiment is to be classified. If there is any uncertainty as regards the category or sub-category to which an experiment belongs, a decision has to 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 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.
- **Discovery, development and quality control (excluding safety testing) of products or equipment in human or veterinary medicine.** This category also includes studies in the fields of dental medicine. The category likewise includes 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.** This includes all toxicity studies, including those for medicines and medical devices (see also toxicity guideline, FVO no. 800.116-4.01).

Under this principal category, the field of application of the substance to be tested must be given in addition. A distinction is to be made between the following fields of application (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 (includes 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).
- **Cosmetics or toiletry articles** (includes substances and products that are used predominantly as cosmetics or toiletry articles 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).
- **Possible environmental contaminants** (includes the field of ecotoxicology, i.e. the investigation of possible or actual hazards of contaminants in the general environment, including radiation. Ecotoxicity studies for substances in the above-mentioned categories (agrochemicals etc.) are to be included here).
- **Other uses** (includes all fields of application and risk that are not listed above, including experimental toxicology. In addition, it must also be indicated **which** other use is concerned).
- **Other studies.** This includes those studies that cannot be assigned to 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 laboratory animal breeding and housing facilities.

## **Section 42: Association of the project with various diseases or disorders**

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<sup>th</sup> November 1992 (see art. 36 TSchG; art. 147 TSchV). 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.

CONTENT:

The applicant must decide and indicate in which of the main categories the planned experiment belongs. If you are unsure in which main category an experiment belongs, the decision must be based on the principal objective of the experiment. Only one main category or, in the case of human diseases, one sub-category may be ticked. Description of categories according to the European Council Convention:

- **Diseases in humans:**
  - **Cancer** (with the exception of carcinogenicity studies in the context of product safety).
  - **Cardiovascular diseases.**
  - **Nervous and mental disorders.**
  - **Other 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 between 2 or 3 of the above diseases at the same time, this category must be ticked as well).
- **Diseases in animals** (includes all diseases or disorders in animals). In addition it must be indicated **which** other disease(s) is or are involved.
- **No association with diseases** (and mental disorders in humans and animals, e.g. education and training, safety tests for chemicals, certain projects in the field of basic research).

**Safety tests for medicines** must be classified as far as possible according to indication. If an application concerns several areas, then the category "other diseases" must be selected.

**Section 43: Association of the project with procedures required by law**

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<sup>th</sup> November 1992 (see art. 36 TSchG; art. 147 TSchV). Concerns regulatory and marketing authorization requirements for substances and products of all kinds and also other studies required by law, e.g. in the field of environmental protection.

CONTENT:

The applicant must decide and indicate in which of the four categories the planned experiment belongs. Only one category may be ticked. Description of categories according to the European Council Convention:

- **For Switzerland only:** covers projects required by Switzerland, including those necessitated by international obligations (e.g. European Pharmacopoeia).

Not intended here: the requirements due to the legislation on animal experimentation itself.

- **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.
- **For both:** 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.

If the project falls under one of the above three categories, **guidelines or test methods** to be used must be indicated in full. If rarely applied guidelines or test methods are to be used, a copy must be enclosed with the application.

- **No association** (with methods required by law of any kind, e.g. basic research, education and training).

#### **Section 44.1: General description of the aim of the experiment state of knowledge presentation of what is not sufficiently known**

PURPOSE OF ENTRY To assess the admissibility of the experiment according to art. 17 TSchG; art. 137 and 138 TSchV.

CONTENT A description of the **general problem** to which the application is related. What **importance** is attached to the objective of the experiment?  
Circumscription of the necessary information for different categories of experimental aims:

- For **basic research studies** a complete description is needed (e.g. summary of the project submitted to the National Fund). The present state of knowledge in the field concerned must be presented, showing what is not yet sufficiently known and is therefore to be investigated in the project.
- For experiments **testing the activity of substances** or their innocuity the general problem has to be addressed. Explanations must be provided to justify testing of **substance combinations** (product, commodity).  
For experiments in the **development and testing of medicinal and non-medicinal products** it must be shown why knowledge of the effect to be investigated here is crucial for the further development (e.g. criterion for selection or exclusion, characterization with regard to registration, as required by the authorities). For known commodities/products that are to be further investigated, the present state of knowledge on its **risk potential** must be presented.
- For experiments in the context of **production of biological substances, diagnostics** and **preservation or replication of live material** the general problem (e.g. the disease to be diagnosed, the tumour to be treated) as well as the need and importance of the substance, the diagnosis or the preservation of the material must be shown.
- For experiments carried out within the framework of **education and training**

the educational aim is to be stated and explanations must be provided to justify why this aim cannot be achieved without animal experiments.

An application for a licence to perform an experiment should in case only include experiments or series of experiments concerning a self-contained issue or with a clearly defined objective (art. 141 para.2 TSchV). However, if several objectives are pursued using differing methods, several applications have to be submitted.

## **Section 44.2: Actual question the experiment is designed to answer**

PURPOSE OF ENTRY To assess the admissibility of the experiment according to art. 17 TSchG; art. 137 and 138 TSchV..

CONTENT **Precise questions** to be answered by the experiments.

## **Section 5: INFORMATION ABOUT THE METHOD**

### **Section 51.1: Overview of the project**

PURPOSE OF ENTRY Overview enabling the judgment of the method. **It should be clear what happens to each animal or animal-group throughout the experiments.**

CONTENT The method should be written as a clear overview. The course of the experiment and the individual steps, including the plans for biometric analysis (**experimental plan**, flow chart) should be identifiable. If relevant, a **designation of the animal model (name)** should be given. The detailed description of procedures, the duration of single phases per group of animals, the number of animals needed, etc. are to be entered in sections 54.1 to 54.4.

EXAMPLE 

- **Fixation methods for femur fractures:** The dogs are divided randomly into 3 groups. The health-status is checked and an X-ray picture of the right and left femur made. Daily one animal is operated (left femur, day 0 of the experiment). The animals are then held individually for 14 days (finally 2 animals together) and their general state assessed daily. At various time-intervals (3, 7, 14, 21 days, etc.) function-tests and X-ray examinations are carried out. Group 1 is sacrificed 28 days after the operation, followed by group 2 after 56 days and group 3 after 84 days. The femurs are then sectioned out for further examination. ▪

### **Section 51.2: Reason for selection of method showing its peculiarities / advantages**

PURPOSE OF ENTRY To assess the application for the suitability of the method (see art. 137 para. 3 TSchV).

CONTENT Why was this **particular method** or this model chosen?

The peculiarities and/or advantages with regard to the aim of the experiment and restrictions arising for the animals must be shown compared with other possible methods.

For experiments carried out in the context of **overall investigations** (e.g. substance testing: test battery with *in vitro* and *in vivo* methods) reference must be

made to the use of the other methods (e.g. prior screening *in vitro*).

It must be stated if an experiment is required by the authorities.

### **Section 51.3: Reason for selecting animal species and, where applicable, for using animals not bred for experimental purposes**

PURPOSE OF ENTRY To assess the application according to art. 20 para. 2 TSchG and 118 TSchV.

CONTENT Why aren't invertebrate animals used or **lower vertebrates**?  
Why are animals to be used that were not bred for experimental purposes?

### **Section 52: Preparation of animals for the experiment**

PURPOSE OF ENTRY Assessment of the preparation of the animals (art. 119 TSchV).

CONTENT **Screening examination** (art. 135 para. 3 TSchV), **Adaptation** or conditioning to the experimental conditions (art. 119 para. 1 TSchV); the nature and method of **marking** or **identification** (art. 120 TSchV, art. 5 TVV) and combination with the method of genotyping (art. 10 TVV); nature of tagging and review of the determination of origin of primates, cats and dogs; **pre-treatment**, withdrawal of feed or water.

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

EXAMPLE 

- Daily handling for 3 weeks
- Marking by means of microchip
- Running-wheel training for ca. 18 days
- Protein-enriched diet for 5 days
- Food withdrawal (drinking water available ad lib.) 24 h before intervention

### **Section 53.1: Anaesthesia and/or other means of controlling pain**

PURPOSE OF ENTRY Assessment of the measures taken to reduce pain and suffering (cf. art. 135 para. 5 TSchV).

CONTENT The **general anaesthetic** which is used (if relevant, the combination of agents, e.g. sedative) is to be noted, as well as the **dose**, the **route of administration** (e.g. inhalation, intravenous injection), the need for **further injections**, the intended **duration** of anaesthesia and also whether the animals are to be euthanized under anaesthesia.

When administering analgesics, the **analgesic** which is used (preparation) is to be noted, as well as the **dose**, the **route of administration**, the **frequency** of treatment and the **timespan** over which analgesic treatment will be made.

The use of **local anaesthetics** as well as other pain-reducing treatments (e.g. anti-inflammatory treatment) is to be noted.

If anaesthetics and other pain-reducing treatments are not used, the reasons for this are to be entered under section 53.2.

EXAMPLE                   ▪ Anaesthesia of rats with fentanyl (0.2 mL/kg bodyweight i.m.) and diazepam (2.5 mg/kg bodyweight i.p.). Duration of anaesthesia: approx. 30 min.   ▪

**Section 53.2: Reason for selection of anaesthesia or analgesia or, if applicable, reason not to use such measures**

PURPOSE OF ENTRY       Assessment of the application according to the rules of implementation (art. 135 TSchV).

CONTENT                   Reasons for selecting the specific pain-reducing measures.

Why might no **anaesthesia** be used to reduce discomfort?

For what reasons are no analgesics administered or no other pain-reducing measures taken?

**Section 54.1: Type of procedures/manipulations and parameters to be measured in the animal**

PURPOSE OF ENTRY       Assessment of the licence conditions (art. 140, TSchV) and the suitability of the method (cf. art. 137, para 3, TSchV) as well as the possibilities for reducing the stress on the animal.

CONTENT                   Summary of the required information for the various interventions/manipulations on the animal.

- With **surgical interventions**, the type and location (e.g. organ or organ-system) of the intervention, its course, its duration and the methodological differences between the various experimental groups is to be given in full.
- With **substance-administration** or application, there should be information about the method of administration, the location, the amount (weight, volume) and the frequency of administration or application.
- With **infections**, the infecting agent, the infected material or the tumour material should be noted. Further, the dose/amount of the noxious agent, the number of repetitions, and the method and location of injection/implantation are to be given, together with any other measures which are undertaken.
- With **immunization procedures**, the type of immunogen, the dose, the number of booster-treatments and the interval between, as well as the use and type of adjuvant should be given. It should also be noted at what intervals and how often blood is taken for the preparation of antibodies. The amount of blood taken and the method of taking it should be stated.
- With **physical interventions**, e.g. damaging radiation, heat, cold, mechanical force, etc., the intensity, the duration and the frequency of intervention are to be recorded. Also the main organ-systems affected should be noted.
- With **behavioural impairment**, the manner in which it is achieved (e.g. social isolation, neuroactive drug administration) should be given, as well as the nature of the impairment.

In addition to the information given about the treatment-groups, there should always be information about the interventions/manipulations sustained by the

**control-animals.**

If a substance is administered or an intervention made to produce standard pathological effects, this should be noted.

The justification for selecting the given method should be brought in section 54.4.

**Section 54.2: Duration of the series of experiments: total duration of experiment for each individual group or animal, incl. period during which the animal is exposed to substances or other noxae**

PURPOSE OF ENTRY: Assessment of the method with regard to time, particularly concerning the possibilities for reducing stress on the animals.

CONTENT: The **total duration of the experiment** for every single group or, where applicable, for every single animal and the **time** during which the animal is **exposed** to substances or other noxae (acute study phase) must be indicated if it can be usefully presented in a suitable tabular form.

The experiment starts with the housing of the animals for the experiment and their preparation for procedures or treatments. It ends with the euthanasia of the animals or, where applicable, with the conclusion of the last test and their complete restoration.

If the animals are to be used repeatedly, the interval between the individual experiments must be given.

EXAMPLES: 

- Less than one day for all animals with procedures lasting 2 to 4 minutes
- Group 1: 4 weeks, Group 2: 8 weeks with an acute phase of 3 to 5 days postoperatively
- Duration of experiment for all animals is 3 months with substance administration for 14 days, daily.

**Section 54.3: Number of animals per experiment/series of experiments: number of groups and number of animals per animal line, per group, sex of animals**

PURPOSE OF ENTRY: Assessment of the necessity of the requested number of animals (cf. art. 137, para 4 a, TSchV).

CONTENT: The **number of experimental groups** and the **number of animals/group** are to be given. All of the experimental independent variables, such as dose, duration, repetitions, controls, etc., are to be given, with this giving the total number of experimental groups.

**Additional groups** for a particular test (together with information about the instances when they will be employed) and/or the number of **reserve animals** (to replace any excluded animals) should be noted.

The animal lines or strains have to be indicated.

In addition to the above information, the total number of animals requested (where relevant also for 12 months) should be given in section 33.

Is it possible to obtain the desired information or knowledge with fewer animals through adept staggering of the individual parts of the experiment (art. 137 para. 4 lit.c TSchV)?.

The justification for the number of required animals is to be given in section 54.4.

EXAMPLE

- Unique experiment: 4 experimental groups (2 for method A, 2 for method B, one of each with a 1-week long experiment, and one of each with a 2-week long experiment), 4 animals/group and 2 reserve animals. ▪
- Experimental series: 5-6 experimental groups (3 doses of test-drug, 1 vehicle-control, 1 control, possibly 1 recovery group should the results of previous tests indicate the need), 6 animals/group. ▪

#### **Section 54.4: Reason for the planned numbers of animals per experiment/series of experiments (incl. statistical analysis of data)**

PURPOSE OF ENTRY

Assessment of the application according to art. 137 para. 4.

CONTENT

What method was used to calculate and define the proposed number of animals per experiment / series of experiments?

Formulate the main research hypothesis to be tested per experiment / series of experiments and any secondary hypotheses. What is the primary endpoint (primary target variable)? What secondary endpoints (secondary target variables) are there, if any?

What is the expected distribution of these variables? If normal distribution is to be expected (directly or after transformation): what is the scatter (variance, standard deviation)?

Design of the proposed tests for statistical analysis (one-sided, two-sided). What baseline result is to be expected (control group)?

What scale of effect is considered to be relevant (e.g. relevant difference in blood pressure between two groups)? What type I error probability ( $\alpha$  error) is used (p value) to assess whether a result is significant? What type II error probability ( $\beta$  error) is used or what power ( $1-\beta$ ) should be achieved?

The statistical approach to any subgroup analyses and the use of multiple testing must also be specified. What statistical approach will be taken when measuring an effect using different methods. Will p values be correspondingly corrected? If so, how? Were subgroup analyses and repeated testing been considered when calculating the number of animals needed?

#### **Section 55: Evaluation of the method**

PURPOSE OF ENTRY

Assessment of the suitability of the method (art. 137 para. 3 TSchV).

CONTENT

**The type and frequency of measurements during the course of the experiment** (e.g. clinical investigations), the planned tests of response (e.g. maze test), the acquisition of pathophysiological data (e.g. blood urea levels), etc. should be given.

The investigations carried out on experimental material after the death of the animals (histology, etc.) are also to be given.



### **Section 56.1: Expected effect on the health and well-being of the animals**

PURPOSE OF ENTRY: Assessment of the stress for the animals, to relate the importance of the experimental aim to the impositions on the animals (cf. art. 19, para 4, TSchG).

CONTENT: The expected effects on the well-being of the animals in terms of changes in the following parameters are to be given: **activity** of the animals; **bodyweight changes** and the course of growth; **food and water intake**; manifestations of pain and **pain reactions**; **exclusions** and deaths; disturbances, e.g. in locomotion; further behavioural changes, e.g. posture. The **duration** and **frequency** of the **effects**, their **intensity** and their **course** are all to be noted.

### **Section 56.2: Monitoring of well-being of the animals**

PURPOSE OF ENTRY: Assessment of the monitoring and documentation (cf. art. 135 para. 4 and 144 para.1 TSchV). (e.g. score sheet according to art. 144 para. 1 TSchV)

CONTENT: How often are the animal checked, by which person (study director himself, animal technician, laboratory technician, institute's veterinary practitioner)? What criteria are applied in the assessment? Do score sheets exist? Does the monitoring of the animals differ according to the study phase?  
In what form is the monitoring documented?

The study director is responsible for ensuring that the animals are adequately checked.

### **Section 56.3: Indications concerning stress-reducing measures and criteria for premature discontinuation of the experiment and criteria for renouncement to reuse animals**

PURPOSE OF ENTRY: Assessment of the implementation rules according to art. 135 para. 4 and 144 para.1 TSchV.

CONTENT: Definition of the **criteria** for **ending an experiment prematurely**.

What specific measures are taken to reduce any stress?

What criteria are applied when deciding whether a stressed animal may be used again in the experiment?

EXAMPLE: 

- Criteria for discontinuing an experiment: 1. Wound infection, 2. Technical fault in the implant, 3. Trauma around the wound, 4. Occurrence of general illness which requires systemic treatment. ▪

### **Section 56.4 Repartition of animals per severity degree**

PURPOSE OF ENTRY: Summary global evaluation of the animals' stress in the form of a numerical value for easier comparability (art. 30 j TVV).

CONTENT: In view of the overall restrictions to which animals may be subjected, a degree of severity (stress category) is to be defined according to the information "Einteilung von Tierversuchen nach Schweregraden vor Versuchsbeginn (Belastungskategorien)" (FVO procedure no. 800.116-1.04). Details should be given here as to the considerations or analogies to the examples in the information that served as a

basis for classification. In every case the **maximum expected degree of severity** is to be given. In addition, the animals may be approximately broken down according to the different degrees of severity expected.

More detailed information about the degree of severity (in terms of the number of animals experiencing the various degrees of severity) is to be provided in Form C (intermediate/final report) after completion of the experiment.

EXAMPLE                   ▪ Severity grade 3: 10% of animals; severity grade 2: 70%; remaining animals severity grade 0   ▪

**Section 57.1:**   **Indicate the name and/or the number of the husbandry licence**  
or if there is no lab animal husbandry licence indicate: housing and husbandry of animals before, during, between and after individual experiments.

PURPOSE OF ENTRY   Assessment of the application according to art. 128, TSchG (requirements for installations) and art. 119 TSchV (general and special animal husbandry regulations).

CONTENT               If the animals are housed in a **licensed animal husbandry**, this must be indicated and the licence number given.

In all other cases, details are to be given on  
- the available space and structuring of the installation  
- the availability and use of exercise runs (duration, frequency)  
- individual or group caging  
- type of feeding and activities.

If there is a **deviation from the animal husbandry regulations** (e.g. metabolism cages), the type, duration and the frequency of this deviation are to be given. When there is repetitive maintenance under deviant conditions, the intervals between, when the animals are maintained under legal conditions should be given. The reason for deviating from the legal requirements for husbandry are to be detailed in section 57.2.

**Section 57.2:**   **Reason for any deviations from conditions in which animals are kept as defined in the animal protection ordinance or with respect to the above-mentioned licence for laboratory animals husbandry**

PURPOSE OF ENTRY   Assessment of the application according to the need for restricted housing (cf. art. 117 TSchV).

CONTENT               Are **animal housing regulations** complied with?

If the binding animal housing regulations set forth in the animal welfare ordinance (cf. chapter 2 section 1, chapters 2 and 4, art. 117 and 119 TSchV) are not complied with during the experiment, the reasons for this must be explained.

Withdrawal of food, restraint and similar restrictions must also be explained.

**Section 58:**       **Fate of the animals: utilisation of the animals at the end of the (individual) experience;**

**repeated use in the same or another experiment);  
Method of euthanasia**

PURPOSE OF ENTRY Assessment of the application concerning the rules of implementation with regard to the euthanasia of (any suffering) animals and the re-use of animals after an experiment (cf. art. 20 TSchG, art. 135 TSchV).

CONTENT The **method of euthanasia**, stating the substance, dose and route of administration, where applicable (cf. "Richtlinien über das fachgerechte und tierschutzkonforme Töten von Versuchstieren", FVO procedure no. 800.116-1.03).  
**Repeated use** of animals in the same or a different experiment is to be noted.  
For animals that remain alive after the experiment and are no longer used for experimental purposes project, their **use** must be mentioned in abbreviated form.

**Section 6: INFORMATION ON THE REASON OF THE ANIMAL EXPERIMENT**

**Section 61: Other known methods which would allow comparable information to be obtained**

PURPOSE OF ENTRY Assessment of the application in terms of alternative methods (cf. art. 137, paragraphs 2 and 3, TSchV).

CONTENT Are **alternative methods** for the replacement, reduction or refinement of the experiment available?  
In vitro (replacement options) and in vivo methods (reduction or refinement options) from the **literature** or from **personal experience** are to be given and to be assessed.  
References to the literature should cite the **source**. The cantonal authority will inform the applicant whether copies of the publications should be included with the application.

**Section 62: Information on whether the project has been / is being appraised and, if so, by which institution/organization**

PURPOSE OF ENTRY Presentation of any statements obtained on the scientific assessment of the project.

CONTENT Name of institution/organization that is funding the project and has therefore assessed it. Possibly address of secretariat.

EXAMPLE ▪ National Science Foundation ▪ Private foundation, such as cancer league ▪

**Section 63: Assessment of the importance of the anticipated information or results in relation to the pain, suffering, injury or anxiety experienced by the animals and injury to the dignity of the animal**

PURPOSE OF ENTRY Assessment of the application in respect to the balance between the expected gain in knowledge or the results and the pain, suffering or injury inflicted on the animals

(cf. art. 3 and 19, para 4, TSchG, art.26 TVV).

CONTENT

The various aspects of the animal experiment are to be weighed against the interest of the animals. Particular attention must be given here to the desired gain in knowledge according to sections 44.1 and 44.2 and the stresses on the animals according to sections 56.1 – 56.4. The importance of the experimental aim for humans and animals and the restrictions on the animals are to be weighted according to ethical considerations.

Refer to: "Ethical Principles and Guidelines for scientific animal experiments" from the Swiss Academy of Medical Sciences and the Swiss Academy of Natural Sciences ([http://www.samw.ch/dms/de/Ethik/Tierethik/Tierethik\\_D\\_2006.pdf](http://www.samw.ch/dms/de/Ethik/Tierethik/Tierethik_D_2006.pdf))

---

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 27<sup>th</sup> November 1992 can be found at <http://www.bvet.admin.ch/themen/tierschutz/00777/index.html>.