



Swiss Confederation

# Information animal welfare

## Explanatory notes to reports on animal experiments (Form AC)

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## **1 Purpose and applicability**

It is the intention of the legislator to create transparency in the field of animal experimentation and thus to promote an objective discussion about it. In this respect the Federal Food Safety and Veterinary Office (FSVO) publishes annual statistics covering all animal experiments. It contains the necessary information to enable the assessment of the application of animal protection legislation (art. 36 Animal Protection Act; SR 455). International regulations and recommendations must be taken into account when designing and publishing the statistics (cf. art. 147 para. 2 Animal Welfare Ordinance; SR 455.1). This requires the collection of complete and reliable data on the number of animals used in animal experiments, their origin and intended use as well as the stress experienced as a result of the experiment, etc. For this purpose, the responsible persons conducting animal experiments must report the experimental activities annually (Form AC; cf. art. 145 para. 2 and 4 Animal Welfare Ordinance). In addition, the information contained in Form AC is part of the control of animal experiments performed.

The purpose of these explanations to Form AC is to facilitate the editing of the reports and thus to keep the number of queries small. They are to be understood as a reference work, in the event that ambiguities arise when filling out individual sections of the Form AC.

The explanations on Form AC are intended for all holders of a cantonal license to conduct animal experiments as well as for the licensing authorities.

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

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.

## **2 Legal basis and formal aspects of the reports**

According to art. 130 let. c Animal Welfare Ordinance (SR 455.1), the resource manager is responsible for reporting and, in accordance with art. 145 para. 2 Animal Welfare Ordinance, must report the following points to the cantonal authority via the animex-ch information system for each animal experiment:

- a. the completion of an experiment, the information on the experimental activity in the reporting year, the final information on the number of animals per species and the severity of strain, and confirmation of the accuracy of the information in accordance with art. 139 para. 1 let. a-c Animal Welfare Ordinance within two months after the completion of the experiment, but at the latest within two months of the expiry of the authorization.
- b. in the case of experiments extending over several years, by the end of February of each year, information on the experimental activity in the past calendar year.

The reports are to be recorded online in the animex-ch information system (art. 145 para. 2 Animal Welfare Ordinance). In justified cases, the cantonal authority may permit reports in paper form according to the form template of the FSVO (art. 145 para. 3 Animal Welfare Ordinance).

### 3 Explanations to the individual sections

The explanations to the individual sections provide information on the purpose for which a declaration is necessary, what content is expected and what special features must be taken into account. The explanatory examples for some sections clarify the expected content.

## Annual Report / Last Annual Report

The following information are required for the annual reports, including the last annual report:

<b>Heading:</b>	<b>Application number</b>
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

<b>Section 01</b>	<b>For the year {year}</b>
CONTENT	Identifies the reporting year.
PURPOSE OF ENTRY	Identification of the reporting year.

<b>Section 02</b>	<b>Intercantonal experiment</b>
CONTENT	Refers to intercantonal licenses. There is a separate tab for each canton and animal category.
PURPOSE OF ENTRY	Indication of whether parts of the experiment were conducted in other cantons, and if so, in which cantons.

### Section 03

#### Prospective degree of severity

CONTENT

Prospective maximum degree of severity as listed in the application.

### Section 04

#### Report type

CONTENT

Possible report types are: "Annual Report" and "Last Annual Report." The "Last Annual Report" type is generated when either the associated application has expired, the application has been terminated, or the application has been replaced by a renewal application. If an annual report has already been manually created for the reporting year, and any of the above three scenarios occur, the status will change from "Annual Report" to "Last Annual Report".

PURPOSE OF ENTRY

Assign the report to a "Report Family".

### Section 05

#### Resource Manager

CONTENT

Contact details of resource manager (name, e-mail, phone no.).

**Institute:** name and address of the institute.

Both are taken from the associated application.

The resource manager is responsible for submitting the reports on animal experiments to the cantonal authorities (art. 145 Animal Welfare Ordinance (SR 455.1)). The name is taken from the associated animal experiment license.

PURPOSE OF ENTRY

For communication with the authorities.

### Section 06

#### Address of the cantonal authority

CONTENT

Postal address of the competent cantonal authority (cantonal veterinary service).

- Name
- Street
- Postal code
- Town

**Delegated application input.** Indicates whether or not an application for an animal experiment was created in delegated mode by the cantonal authority for an institute.

## NUMBER OF ANIMALS USED IN THE CALENDAR YEAR

Record single or **repeated** uses of individual animals during the reporting year in the same experiment or in different experiments.

Repeated use is considered to be when, for scientific reasons, different individuals could just as well have been used. What is considered as repeated use is a technical decision and can be found in the application form A or in the animal experiment permit AB. In case of doubt, the cantonal authority must be contacted.

### Section 07

#### In {year} no animals were used

CONTENT

Select YES if you did not use any animals during the reporting year. The system will populate the numeric fields with 0 (zero) for all animal categories. The fields will remain viewable but are not editable.

PURPOSE OF ENTRY

Confirmation that no animal experiments were performed during the reporting year.

## ANIMAL CATEGORY

### Section 08

#### Animal category: {animal category}

CONTENT

List all animals used during the calendar year including eliminated or replaced animals.

If genetically modified animals only have been listed in Form A and within the experiment, wild types are identified in the category of genetically modified animals; these wild types must also be listed in the report. By adding another animal card in Form AC this can be performed. In this case the cantonal authority should be informed. It should be noted that Form A must always be complete with regard to the animal categories used and, if necessary, animal categories must be requested in a supplementary application, in order that Form A and Form AC are consistent regarding their animal cards and the used animals.

In the case of intercantonal experiments, a separate tab needs to be completed for each animal category and for each canton. In this case, each animal will be counted only once and reported in the canton where it was mainly used.

#### Source

Indication whether animal category was added in form A or was added in report

AC. Form A is usually the source. If, exceptionally, an animal category has to be added in the AC report, the canton should be contacted.

### **Number of approved animals**

Number of animals that have been approved according to the Form A application. This is entered by the system.

### **Amount of animals still available in year {year}**

Difference between the number of animals approved and the number of animals already used in previous years. This field is adjusted each time field #9 (9.2) is changed.

The calculated number only corresponds to reality if the numbers have been correctly recorded in the system in previous years. In any case, it is the responsibility of the resource manager to check how many uses of animals in animal experiments are possible on the basis of the animal experiment license, respectively to check the plausibility of the numbers given in animex-ch.

### **Number of animals exceeded**

Indication whether the authorized number of animals used has been exceeded.

The information is only visible for the canton and the FSVO for their control tasks. There will be a (non-blocking) warning to the canton if the numbers exceed the authorized number of animals used.

## **Section 09**

### CONTENT

### **Overall use of animals in year {year}**

Section 9 reports the total of all animals used.

The animals taken over from the previous year into the reporting year (9.1) and the animals newly used or used anew in the reporting year (9.2) are indicated.

The number of animals used more than once under this license number or additionally under a different license number in the reporting year should be entered in Section 9.4.

#### **9.1 Total number of animals taken over from the previous year under this national number (former Section 41)**

Number of animals already used in the same experiment in the previous year that are carried over into the new year (reporting year, since remained in the experiment over the turn of the year) under experimental conditions; the number is automatically taken over from section 12.2 of the previous year's report.

A use over the turn of the year is particular because it makes it part of two annual reports, even though it is only one use. As a consequence, this must be taken into account in the public report.

The numbers can only be processed by the institutes once the canton has returned the report to the institute. For a correction, the responsible cantonal authority must therefore be contacted.

#### **9.1.1 Number of animals in degree of severity 0 carried over from the previous year**

If this is the first report, "0" is automatically inserted.

#### **9.1.2 Number of animals in degree of severity 1 carried over from the previous year**

If this is the first report, "0" is automatically inserted.

#### **9.1.3 Number of animals in degree of severity 2 carried over from the previous year**

If this is the first report, "0" is automatically inserted.

#### **9.1.4 Number of animals in degree of severity 3 carried over from the previous year**

If this is the first report, "0" is automatically inserted.

### **9.2 Number of animals used newly or anew in the reporting year (former Section 42)**

Number of animals newly or repeatedly used in the experiment in the reporting year under this national number.

**Newly:** an animal has never been used in an experiment before.

**Anew:** an animal has already been used in an experiment before and subsequently has been used **repeatedly** in animal experiments.

Neither as "newly" nor "anew" counts the specific use of an animal over the turn of the year (this is counted under 9.1).

The corresponding uses of animals used **repeatedly** in the reporting year after they have already been used once under the same license number are counted repeatedly. In addition, they will also be added up accordingly under section 9.4.

In case of doubt, the cantonal authority decides whether an animal used in different phases of the experiment is to be counted once or several times.

### **9.3 Total number of animal uses (former Section 43)**

Total number of experimental animals used in the reporting year counted under this national number.

The total of animals used is equal to the sum of section 9.1 and section 9.2.

The total is not editable.

#### **9.4 Repeated use of animals in experiments (former Section 44)**

Multiple uses of animals during the reporting year in the same experiment or in different experiments are recorded if, for scientific reasons, different individuals could just as well have been used.

The total (9.4; not editable) of these multiple uses is calculated from 9.4.1 (Number of animals used repeatedly under this national number) and 9.4.2 (Number of animals taken over from another license).

The number of animals reported here is a partial amount of the total summed uses of animals in Section 9.3.

#### **PURPOSE OF ENTRY**

To record repeated use (9.4.1) and re-use (9.4.2) as defined in the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Council of Europe Convention), Resolution of the Ad Hoc Committee of Experts of the Convention of 27 November 1992.

##### **9.4.1 Number of animals used repeatedly under this national number**

Enter the number of animals that have been used under this license number (same national number) in different experimental units (=repeatedly) in the reporting year. If the animals are used more than once, the number of repeated uses must be added.

The animals taken over from the previous year under this license number are not to be counted under 9.4.1. These animals are indicated in field 9.1. After the end of these experiments, which have been processed over the turn of the year (9.1), the repeated uses in the follow-up must be counted accordingly here under 9.4.1.

##### **9.4.2 Number of animals used repeatedly taken over from another license**

Enter the number of uses of animals that have been used under this license number, which have already been used in a previous animal experiment under a different license number.

##### **National number of the licenses under which the animals were previously used.**

In case of re-use or multiple use of animals, indicate under which national number the animals were previously used, if applicable.

Can be modified by institute, canton (delegated mode) and FSVO.

#### **PURPOSE OF ENTRY**

To verify art. 135 para. 8 Animal Welfare Ordinance (SR 455.1), according to which animals may not be used more than once in severely stressful



experiments (DS3).

### **9.5 Number of new animals used in an animal experiment in the reporting year**

Shows the number of individual animals used in an animal experiment for the first time in the reporting year. The number of animals corresponds to the difference between Section 9.3 and Sections (9.1 + 9.4).

Number 9.3 contains the total number of animals used, number 9.1 contains the number of animals carried over from the previous year in the experiment, and number 9.4 shows the number of animals used repeatedly (number of multiple uses).

## **Section 10**

### **Origin of the animals used**

#### **CONTENT**

This refers to all the animals listed in Section 9.3.

The sum of numbers 10.1 + 10.2 + 10.3 + 10.4 must be equal to the sum of numbers 12.1 + 12.2 + 12.3.

#### **PURPOSE OF ENTRY**

To compile annual statistics relating to the origin of animals in accordance with the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Council of Europe Convention), Resolution of the Ad Hoc Committee of Experts of the Convention of 27 November 1992 (cf. art. 147 para. 2 Animal Welfare Ordinance (SR 455.1), art. 31 Animal Experimentation Ordinance (SR 455.163))

### **10.1 Number of animals taken over from previous year (section 9.1) or from an earlier animal experiment (section 9.4) (former Section 5.1)**

The total number of uses of animals taken over from the previous year (number 9.1) as well as of the animals that have already been used in another animal experiment (number 9.4) must be indicated.

The number of animals in Section 10.1 must be equal to or greater than the number of animals in Section 9.1.

### **10.2 Number of animals originating from approved animal facility in Switzerland (former Section 52)**

Indicate the number of animals used for the first time in an animal experiment and originating from the company's own approved animal facility or obtained from an animal facility in Switzerland approved according to Swiss animal protection law.

Relates to experimental animals according to the European Convention (SR 0.457, art. 21).

Other animal species originating from Switzerland but not from an approved

facility (farm animals, pets or wild animals according to art. 122 para. 8 Animal Welfare Ordinance (SR 455.1) are to be counted under section 10.4.

### **10.3 Animals from an animal facility or supplier abroad (former Section 53)**

Indicate the number of animals used for the first time in an animal experiment and obtained from a facility or supplier abroad.

Relates to experimental animals according to the European Convention (SR 0.457, art. 21).

**If animals are purchased from abroad, please indicate country of origin.**

The country of origin must be indicated.

Can be modified by institute, canton (delegated mode) and FSVO.

### **10.4 Number of animals of other origin (former Section 54)**

Indicate number of animals with origin other than

- from an unfinished or previous animal experiment (cf. Section 10.1)
- from an approved animal facility in Switzerland (cf. Section 10.2)
- from a recognized animal facility or supplier abroad (cf. Section 10.3).

This includes, for example, zoo animals and pets in clinical studies or studies on farm or wild animals, etc.

### **10.5 Define other origin**

Different categories of animals may be selected from a choice. If the selection is not applicable, an appropriate entry can be made under "Other".

Can be modified by institute, canton (delegated mode) and FSVO.

## **Section 11**

### **CONTENT**

## **Retrospective degree of severity**

Refers to all uses of experimental animals listed in Section 9.3.

The sum of Section 11.1 + 11.2 + 11.3 + 11.4 must equal the number of animals listed in Section 9.3.

The classification of strain is made in accordance with art. 26 of the Animal Experimentation Ordinance (SR 455.163): For the assessment of the stress of an experiment, art. 24 and 25 of the Animal Experimentation Ordinance as well as further strain imposed on the animals through due to humiliation, profound interference with their appearance or capabilities, or excessive instrumentalisation must be taken into account.

### **11.1 Number of experimental uses of animals in degree of severity 0 (former Section 61)**

Indication of the number of experimental uses of animals with no strain.

### **11.2 Number of experimental uses of animals in degree of severity 1 (former Section 62)**

Indication of the number of experimental uses of animals with mild strain.

### **11.3 Number of experimental uses of animals in degree of severity 2 (former Section 63).**

Indication of the number of experimental uses of animals with moderate strain.

### **11.4 Number of experimental uses of animals in degree of severity 3 (former Section 64).**

Indicate the number of experimental uses of animals with severe strain.

#### **PURPOSE OF ENTRY**

After completion of an animal experiment, the Federal Food Safety and Veterinary Office publishes the information on the severity of the stresses in the animal experiment (art. 20a<sup>1</sup> Animal Protection Act).

## **Section 12**

### **Elimination or further use of the animals**

#### **CONTENT**

Information on the further use of all animals used in animal experiments under this authorization number in the reporting year.

The sum of points 12.1 + 12.2 + 12.3 must equal the sum of points 10.1 + 10.2 + 10.3 + 10.4.

#### **12.1 Number of animals euthanized or perished (former Section 71)**

Enter the number of animals that were euthanized or died during or at the end of the experiment.

#### **12.2 Number of animals carried over to the (next) year for continuation of the experiment under this national number (former Section 72)**

Experimental animals that will continue to be used in the next year's experiment under this national license number beyond the end of the year. This number is carried forward into the next year's report (Section 9.1).

##### **12.2.1 Number of animals with degree of severity 0 carried over to the next year**

Indicate number of animals with degree of severity 0 to be carried over to next year under this national license number.

##### **12.2.2 Number of animals with degree of severity 1 carried over to the next year**

Indicate number of animals with degree of severity 1 to be carried over to next year under this national license number.

##### **12.2.3 Number of animals with degree of severity 2 carried over to the next**

## **year**

Indicate number of animals with degree of severity 2 to be carried over to next year under this national license number.

### **12.2.4 Number of animals with degree of severity 3 carried over to the next year**

Indicate number of animals with degree of severity 3 to be carried over to next year under this national license number.

### **12.3 Number of surviving animals at the end of the experiment (former Section 73)**

Indicate surviving animals at the end of the experiment which will be used in later experiments under a different national license number or which will be discarded as experiment animals.

### **12.4 Use of surviving animals after the end of the experiment**

#### **CONTENT**

To be completed only if an entry has been made in Section 12.3.

Can be modified by institute, canton (delegated mode) and FSVO.

Different categories of animals may be selected from a choice. If the selection is not applicable, an appropriate entry can be made under "Other".

Surviving animals may be used in other experiments under a different national license number or may be discarded as experimental animals and used elsewhere.

To verify art. 135, para. 8 Animal Welfare Ordinance (SR 455.1), according to which animals must not be used repeatedly in experiments involving high a level of stress (SG3). In the case of re-use or repeated use of animals, the experiments in which the animals were used must be known. This information is also necessary to ensure that animals used repeatedly in the same reporting year are only counted once.

#### **PURPOSE OF ENTRY**

To record repeated use (9.4.1) and re-use (9.4.2) as defined in the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Council of Europe Convention), Resolution of the Ad Hoc Committee of Experts of the Convention of 27 November 1992.

## ASSESSMENT OF THE EXPERIMENT

Information for the attention of the licensing authorities and cantonal animal experimentation commissions on the outcome of the experiments and on their continuation.

### **Section 13**      **Results achieved, in particular with regard to the purpose of the experiment and the knowledge gained**

**CONTENT**      Brief description of the results obtained in the reporting year with specific reference to the experimental purpose and knowledge gain (interpretation of results). For experiments that will be continued, the continuing objective must be indicated in the annual report.

**PURPOSE OF ENTRY**      Provides the authorities and the cantonal animal experimentation commissions with information on the outcome of the experiment and its continuation.

### **Section 14**      **For toxicological studies: number of substances tested, number of animals per substance**

**CONTENT**      Complete only if standard tests are conducted as part of the verification of the impact and non-toxicity of pharmaceutical preparations and toxicity tests of other substances and products.

Indicate the number of substances tested and the number of animals used per substance:

- summarized by substances for which the same number of animals was used.
- for deviations from the standard values: indicate the number of doses and the number of animals used in each group. Give reasons for the deviations.
- licenses with multiple standard protocols: Break down the numbers for each protocol.

### **Section 15**      **Suitability of method and 3R potential**

**CONTENT**      Describe the chosen method, species and number of animals (group sizes) retrospectively in terms of their suitability and necessity for achieving the experimental objective.

Indicate any difficulties and changes in the method, including agreements with the cantonal authority. State the reasons for the changes and explain the

expectations regarding the modified method. Describe the development of the new methods.

Estimate improvements and potential for 3Rs.

## Section 16

### Special events

CONTENT

Describe any unforeseen events that had an impact on the execution of the experiment. Examples may include: illness, accident, technical failure, or personnel problems.

List delayed start as well as abandonment of the experiment.

## Section 17

### Scheduled Reports and Publications

CONTENT

List any reports and/or publications that have already appeared or are planned. List, if possible authors, title, journal/location of publication, and source. If possible, attach a copy for the involved authorities.

## CONFIRMATIONS

## Section 18

### Confirmation Users of the Institute

CONTENT

The resource manager (Section 12 of the application) is the responsible licensee. He or she is according to art. 145 para. 2 Animal Welfare Ordinance in any case responsible for the timely reporting of the information on the experimental activity in the reporting year, the definite numbers per animal species and the corresponding degree of severity. In addition he or she is responsible for the confirmation of correctness of the information according to art. 139 para. 1<sup>bis</sup> let. a-c Animal Welfare Ordinance (SR 455.1).

A report can technically be submitted either by a resource manager or by the animal welfare officer. If applicable, the report may be submitted in delegated mode by the cantonal operator.

#### Name

Name of the person submitting the report to the cantonal authority.

The name is inserted by the system upon submission.

#### Statement of correctness

The person submitting the report to the cantonal veterinary service confirms that the information in the report is complete and has been checked for correctness

by the resource manager.

**Date: Time stamp of submission**

Date of submission to the cantonal authority.

PURPOSE OF ENTRY

Replaces the signature in the electronic dossier.

**Section 19**

**Confirmation of cantonal authority**

CONTENT

Confirmation by the enforcement authority that the completeness of the information provided in the report has been checked and that the content is plausible.

**Name**

Name of the person submitting the report to the Federal Office (FSVO). The name is inserted by the system upon submission.

**Statement of correctness**

By submitting to the Federal Office (FSVO), the responsible person confirms that the cantonal authority has checked the completeness of the information provided by the holder of the license and confirms its plausibility.

**Date: Time stamp of submission**

Date of submission to the Federal Office (FSVO).

PURPOSE OF ENTRY

Replaces the signature in the electronic dossier.

# **PUBLIC REPORT**

## **BASICS**

**Section 01**

**Summary**

CONTENT

Details of the associated form A.

- National number
- Cantonal number
- Title of the application

## Section 02

### Title of publication

CONTENT

Indication of the title of the request that will be published.

This title can be edited as soon as the public report is ready for editing.

## Section 03

### Field of study

CONTENT

Show the scientific field from the request for animal studies.

The scientific discipline on which the question is addressed shall be indicated as the field of study. The main field of study and the field of application of the experiment shall be indicated. If there is uncertainty as to which category or subcategory an experiment belongs to, a decision must be made according to the main objective of the experiment. Only one main category and, in the case of safety testing, one subcategory can be ticked. The description of the categories is based on the Council of Europe Convention.

Will be taken from Form A and cannot be edited.

PURPOSE OF ENTRY

Compilation of annual statistics, with target categories according to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Council of Europe Convention) and the Resolution of the Ad Hoc Committee of Experts of the Convention of 27 November 1992 (cf. art. 36 Animal Protection Act (SR 455); art. 147 Animal Welfare Ordinance (SR 455.1)).

## Section 04

### Area of application

CONTENT

Indication of the biomedical field concerned by the question of the study.

Taken from Form A and cannot be edited.



## ANIMALS

### Section 05

#### Total number of animal uses throughout the duration of the study

CONTENT

There is a summary table per animal category, showing each reporting year (under the same national number) and the number of animal uses. Specifically, it shows how many animals were carried over from the previous year (9.1), how many were used newly or anew (9.2), and the degree of severity of these animals used in the experiment (11.1-4).

The numbers in the "Published Total" row, which are used for publication, can be adjusted if indicated.

### Section 06

#### Note for researchers

CONTENT

The actual uses of animals under this license are listed in the table below. The actual number is calculated by subtracting the number of animals carried forward to the following year (recorded in Section 12.2) from the total animals used in each year and at all severity levels (recorded in Section 11).

## CONFIRMATIONS FOR PUBLICATION

### Section 07

#### Confirmation of the institute

CONTENT

According to art. 130 let. c Animal Welfare Ordinance (SR 455.1), the resource manager is responsible for reporting, in particular for the correct and complete verification of the data, which are transmitted to the canton and thus released for publication. In this sense, the responsible person of the institute (resource manager, animal welfare officer) must confirm that the data have been checked by the resource manager and can be released for publication.

#### Confirmation user:

"I confirm that the above data have been checked by the resource manager according to art. 145 para. 2 Animal Welfare Ordinance (SR 455.1) and can be released for publication in accordance with art. 20 let. a<sup>1</sup> Animal Protection Act (SR 455)."

If another institute user makes changes to the data, the checkbox is automatically cleared. This occurs if the report has not yet been submitted to the canton.

Once the checkbox has been activated, the name of the responsible institute

user and the time stamp of the confirmation will appear.

PURPOSE OF ENTRY

The execution of the legal obligation to report according to art. 145 Para. 2 Letter a Animal Welfare Ordinance is confirmed.

**Section 08**

**Confirmation cantonal authorities**

CONTENT

The primary canton provides confirmation that the data are plausible and can be published:

"From the cantonal operator's point of view, the data to be published are plausible".

As soon as the checkbox has been activated, the name of the responsible canton operator and the timestamp of the confirmation will appear.