FSVO Ordinance on Laboratory Animal Husbandry, the Production of Genetically Modified Animals and Methods of Animal Experimentation

(Animal Experimentation Ordinance)

of 12 April 2010 (Status as of 1 February 2025)

The Federal Food Safety and Veterinary Office (FSVO)[1],

on the basis of Articles 124 paragraph 2, 136 paragraph 2, 142 paragraph 4 and 209 paragraph 1 of the Animal Welfare Ordinance of 23 April 2008[2] (AniWO),

ordains:

Section 1 Scope

Art. 1

This Ordinance contains regulations on:

a. the husbandry of laboratory animals;

b. the production, breeding and husbandry of genetically modified laboratory animals and mutants that have a clinical pathological phenotype;

c. the registration and documentation of strain and reporting procedures;

d. the definition of the degrees of severity;

e. intercantonal animal experiments;

f. applications and reports concerning laboratory animal facilities and animal experiments.

RU **2010** 1479

1 The name of this administrative unit was modified on 1 Jan. 2014 pursuant to Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This change has been made throughout the text.

2 SR **455.1**

Section 2 Husbandry of Laboratory Animals

Art. 2 Monitoring of laboratory animals
(Art. 121 AniWO)

1 Technical installations such as ventilation and automatic drinking systems shall be fitted with an alarm device if the failure or a malfunction of these systems can cause harm to the animals.

2 The condition of the animals' housing environment, especially bedding, feed and water, and also the well-being of the animals shall be checked daily.

3 The well-being of small rodents must be checked when they are transferred to clean cages. The animals must also be visually inspected at least three times a week. At weekends, the condition of the housing environment and the well-being of the animals need not be checked if it can be shown that the animals are not adversely affected by this procedure.

4 Small rodents are the animals listed in Annex 3 Table 1 AniWO.

5 If an animal shows signs of any strain, this should be indicated on the enclosure or cage.

6 The frequency of checks as specified in paragraphs 2 and 3 shall be increased in accordance with the strain observed.

7 A record shall be kept of the checks.

Art. 3 Individual housing of incompatible animals
(Art. 119 para. 2 AniWO)

A record shall be kept of the beginning and end of individual housing for incompatible animals and of special events arising during such housing.

Art. 4 Run for dogs
(Art. 71 para. 2 AniWO)

The run for dogs may be in an outdoor enclosure.

Art. 5 Marking of small rodents
(Art. 120 AniWO)

1 Invasive methods such as tattoos, microchips, ear notches or amputation of toe tips may be used for marking small rodents intended for breeding.

2 For marking small rodents not intended for breeding, the use of invasive methods must be justified in the context of the specific experiment.

3 Marking with ear tags is not permitted.

4 If marking is indispensable for genotyping, the marking and biopsy must be combined.

Art. 6 Measures and procedures in animal rooms
(Art. 135 para. 9 AniWO)

The following measures and procedures may be performed in rooms where animals are kept:

a. marking procedures;

b. administration of substances or food, such as brief injections or gavage;

c. taking of samples such as blood, hair, urine and saliva.

Art. 7 Documentation
(Art. 114 AniWO)

[1] The allocation and instruction of personnel taking care of laboratory animals must be recorded in a comprehensible manner.

[2] In the animal rooms, it must be clearly indicated who is responsible for compliance with animal welfare regulations for each animal.

[3] Personnel must have access at all times to the documentation on strain and on the criteria for euthanasia.

Art. 8 Qualification of animal caretakers
(Art. 116 AniWO)

At least one third of personnel in animal caretaker positions must hold a qualification as animal attendant as specified in Article 195 AniWO.

Section 3
Production, Breeding and Housing of Genetically Modified Laboratory Animals and Mutants that have a Clinical Pathological Phenotype

Art. 9 Approved methods for producing genetically modified animals
(Art. 142 para. 4 AniWO)

[1] The approved methods for producing genetically modified animals are listed in Annex 1.

[2] A method may be approved if it is in widespread practical use and best ensures the well-being of the animals compared with other methods. Both the implementation of the procedures and measures and the success rate and number of surplus animals must be taken into account.

[3] The approved methods shall be used in accordance with a standard protocol in a manner that best ensures the well-being of the animals.

[4] The laboratory animal facility shall keep a record of the success rate in the use of the approved methods for the attention of the cantonal authorities. If the success rate is unsatisfactory, the laboratory animal facility must take action to improve it.

Art. 10 Genotyping
(Art. 120 para. 1 and 123 AniWO)

1 The following methods and combinations thereof are approved for genotyping in production and breeding of genetically modified animals:

a. non-invasive methods such as the investigation of faeces or saliva;

b. methods combined with the marking of animals;

c. blood sampling.

2 Tail biopsies are only permitted in particular cases justified by the experiment in question. Not more than 5 mm of the tail may be removed.

3 In small rodents the following methods for combined genotyping and marking are permitted:

a.[3] amputation of the distal phalanx of a toe in the first nine days after birth; not more than two toe tips per animal may be amputated;

b. identification by means of ear perforation or notching after weaning.

Art. 11 Phenotyping
(Art. 124 AniWO)

In the production and breeding of animal lines or strains, the killing of animals for anatomical or pathological purposes and investigations such as behavioural studies with mild strain or blood sampling are permitted provided they serve to characterise the animal lines and strains. The studies shall be performed in a manner that best ensures the well-being of the animals.

Section 4
Record and Documentation of Strain and Reporting Procedures

Art. 12 Basic principles of recording strain in small rodents
(Art. 124 AniWO)

1 The recording of strain in small rodents must be documented. The following data must be entered:

a. results of inspections in accordance with Annex 4;

b. time and date of inspections and person carrying out inspections.

2 The frequency of inspections and the traits to be observed shall be constantly adjusted based on new findings from monitoring or from animal experiments.

3 Measures for reducing strain and criteria for euthanasia must be implemented immediately. The implementation must be documented.

3 Amended by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

Art. 13 Recording strain in small rodents
(Art. 124 AniWO)

[1] The head of the laboratory animal facility is responsible for recording strain. In particular, he or she shall ensure that:

a. the persons involved in monitoring genetically modified lines or lines that have a clinical pathological phenotype:
   1. have sufficient time to carry out and document the inspection in a manner that best ensures the welfare of the animals,
   2. maintain state-of-the-art knowledge in the field of recording strain,
   3. are immediately informed about new findings on clinical signs of strain in the lines to be assessed;
b. the basic principles stated in Article 12 are adhered to.

[2] The list of traits to be checked in accordance with Annex 4 shall be supplemented for each line with traits that can be expected or not excluded on the basis of the genetic modification.

[3] Strain records and reproduction and mortality data shall be constantly evaluated and compared with existing data on animals with the same genetic background.

Art. 14 Recording strain in new or insufficiently characterised lines of small rodents
(Art. 124 AniWO)

[1] New or insufficiently characterised lines of genetically modified small rodents shall be inspected for traits in accordance with Annex 4 while changing cages and observed at least once in between cage changes.

[2] Newborn animals shall be inspected for traits in accordance with Annex 4 within the first five days and thereafter checked and observed at intervals as defined in paragraph 1 until they are weaned.

[3] During the first three generations, all animals shall be checked and observed as stipulated in paragraphs 1 and 2.

[4] If a total of 100 animals from at least three generations have been checked and no signs of strain have been detected, the line is deemed to be free of clinical pathological phenotype.

Art. 15 Recording strain in small rodent lines likely to have a clinical pathological phenotype
(Art. 124 AniWO)

[1] A small rodent line is deemed likely to have a clinical pathological phenotype if:

a. evidence of genetically related strain is found in several animals; or
b. analysis of the data shows increased mortality or reproduction problems.

[2] In lines likely to have a clinical pathological phenotype, Article 14 applies to recording strain.

Art. 16 Recording strain in small rodent lines that have a clinical pathological phenotype
(Art. 124 AniWO)

In lines that have a clinical pathological phenotype, the scope of the inspections and the list of traits to be studied and documented shall be stipulated in the decision in accordance with Article 127 AniWO.

Art. 17 Provisional reporting of strain in small rodent lines
(Art. 126 and 145 para. 1 let. a AniWO)

1 If similar signs of strain are found in several animals of a new or insufficiently characterised line or of a line likely to have a clinical pathological phenotype, the head of the laboratory animal facility must report the strain observed to the cantonal authorities (provisional report).

2 The provisional report must contain the following information:

a. a precise description of the signs of strain observed in the summary of the strain record;

b. basic scientific data as specified in Annex 2;

c. planned additional observations;

d. planned or initiated measures to reduce strain and its expected impact;

e.[4] planned euthanasia criteria.

3 The provisional report must be submitted within two weeks of the strain being observed.

4 If strain is confirmed by additional recordings, the head of the laboratory animal facility must submit a definitive report in accordance with Article 18. If the initial strain is not confirmed, he or she must likewise report this to the authorities.

Art. 18 Definitive report of strain in small rodent lines
(Art. 126 and 145 para. 1 let. a AniWO)

1 The definitive report of strain in small rodent lines must be submitted at the latest when 100 animals have been checked in accordance with Article 14.

2 The definitive report must contain the following information:

a. basic scientific data as specified in Annex 2;

b. specific observation plan and results of strain recording, including degree of severity;

c. measures to be taken to reduce strain and its impact;

c[bis].[5] the euthanasia criteria to be applied;

4 Inserted by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).
5 Inserted by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

d. weighing the observed strain on the animals against the potential benefit for research, therapy or diagnostics and the likelihood of this benefit being realised;

e. intended scope of breeding and the number of animals to be used in animal experiments.

Art. 19 Recording strain in new or insufficiently characterised fish lines
(Art. 124 AniWO)

1 In the case of new or insufficiently characterised lines of genetically modified fish, the recording of strain includes:

a. observation of swimming behaviour and, if possible, swarm behaviour;

b. recording of reproduction performance;

c. check on general health;

d. test for clinical symptoms;

e. test for morphological changes.

2 The reproduction data shall be constantly evaluated and compared with existing data on animals with the same genetic background.

Art. 20 Recording strain in fish lines that probably have a clinical pathological phenotype
(Art. 124 AniWO)

1 A fish line is regarded as probably having a clinical pathological phenotype if:

a. evidence of genetically related strain is found in several animals; or

b. analysis of the data shows increased mortality or reproduction problems.

2 In fish lines that probably have a clinical pathological phenotype, Article 19 applies to recording strain.

Art. 21 Recording strain in fish lines that have a clinical pathological phenotype
(Art. 124 AniWO)

In fish lines that have a clinical pathological phenotype, the scope of the inspections and the list of traits to be studied and documented shall be stipulated in the decision in accordance with Article 127 AniWO.

Art. 22 Reporting procedure for genetically modified fish lines that have a clinical pathological phenotype
(Art. 126 and 145 para. 1 let. a AniWO)

The report of a genetically modified fish line that has a clinical pathological phenotype comprises the information defined in Article 126 paragraph 2 AniWO including the weighing of strain against benefits as specified in Article 18 paragraph 2 letter d of this Ordinance.

Art. 23 Data sheet for genetically modified lines and mutants that have a clinical pathological phenotype
(Art. 124 AniWO)

1 In the case of genetically modified lines and mutants that have a clinical pathological phenotype, the most important information shall be entered in a summarising document (data sheet). The data sheet contains the following information:

a. the basic scientific data in accordance with Annex 2;

b. a summary of strain recording in accordance with Annex 3;

c. where applicable, the decision on lines that have a clinical pathological phenotype (Art. 127 AniWO).

2 The data sheet shall be submitted to the cantonal authorities at the latest when an application for animal experiments using the line or mutant in question is submitted for approval or when a report is submitted concerning this line or these mutants.

3 It serves as a communication in accordance with Article 13 of the Containment Ordinance of 25 August 1999[6] when genetically modified animals are moved from one enclosed system to another. When a new line that is not yet sufficiently characterised or a line that probably has a clinical pathological phenotype is passed on, all data available up to this time shall be provided with the animals.

Section 5 Definition of the Degree of Severity of Strain

Art. 24 Categories of strain resulting from experimental procedures or measures
(Art. 136 para. 2 AniWO)

The following four categories are used for strain on animals resulting from procedures or measures in the context of animal experiments:

a. *Severity grade 0 – no strain:* Procedures and actions performed on animals for experimental purposes that do not inflict pain, suffering or harm on the animals, engender fear or impair their general well-being;

b. *Severity grade 1 – mild strain:* Procedures and actions performed on animals for experimental purposes that cause short-term mild pain or harm or a mild impairment of general well-being;

c. *Severity grade 2 – moderate strain:* Procedures and actions performed on animals for experimental purposes that cause short-term moderate or medium to long-term mild pain, suffering or harm, short-term moderate fear or short to medium-term severe impairment of general well-being;

d. *Severity grade 3 – severe strain:* Procedures and actions performed on animals for experimental purposes that cause medium to long-term moderate pain or

6 [AS **1999** 2783, **2003** 4793 No I 3, **2006** 4705 No II 82, **2007** 4477 No IV 35, **2008** 4377 Annex 5 No 6. AS **2012** 2777 Art. 33 No 1]. See now: the O of 9 May 2012 (SR **814.912**).

severe pain, medium to long-term moderate harm or severe harm, long-term severe fear or a severe impairment of general well-being.

Art. 25 Categories of strain due to genetic modifications
(Art. 136 para. 2 AniWO)

The following four categories are used for strain on animals resulting from genetic modifications:

a. *Severity grade 0 – no strain:* Genetic modifications that do not inflict pain, suffering or harm on the animals, engender fear or impair their general well-being;

b. *Severity grade 1 – mild strain:* Genetic modifications that cause mild pain or harm or a mild impairment of general well-being;

c. *Severity grade 2 – moderate strain:* Genetic modifications that cause moderate pain, suffering or harm, fear or impairment of general well-being;

d. *Severity grade 3 – severe strain:* Genetic modifications that cause severe pain, long-term suffering, severe harm, severe fear or a severe impairment of general well-being.

Art. 26 Strain to be considered for assessing the acceptability of an experiment
(Art. 136 para. 2 AniWO)

To assess the acceptability of an experiment, consideration shall be given to the strain defined in Articles 24 and 25 and also to further strain imposed on the animals through debasement, through radical intervention in their appearance or their capabilities or through excessive instrumentalisation.

Section 6 Intercantonal Animal Experiments

Art. 27[7]
(Art. 145 para. 2 and 4 AniWO)

1 In the case of intercantonal animal experiments (Art. 139 para. 5 AniWO), the numbers of animals must be reported to the primary canton. They must be broken down according to canton.

2 If animals change location during the experiment, they shall only be registered in the canton where the experiment mainly took place.

3 The primary canton shall check the report and send the animal numbers for all participant cantons to the FSVO in accordance with Article 145 paragraph 4 AniWO.

7 Amended by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

Section 7
Applications and Reports concerning Laboratory Animal Facilities and Animal Experiments

Art. 28 Content of applications for approval of a laboratory animal facility
(Art. 122 AniWO)

Applications for the approval of laboratory animal facilities must contain the following information:

a. a statement of the purpose of the laboratory animal facility;

b. animal species housed in the facility and capacity of the facility for each species;

c. number and size of rooms, such as animal stalls, laboratory, rooms for procedures and support rooms, as well as air conditioning and lighting;

d. housing installations, hygiene standards and access arrangements, as well as cleaning standards;

e. monitoring standards for feeding, the cages and the animal stalls;

f. details on the origin, genetic modification, marking and husbandry of the animals;

g. details on the method of production, breeding and husbandry of genetically modified animals or lines that have a clinical pathological phenotype;

h. health monitoring;

i. disposal of animal cadavers;

j. emergency concept;

k. name of the head of the facility and his or her deputy;

l. number and qualification of personnel;

m. description of animal inventory control, including the documentation of recording of strain where applicable.

Art. 29 Content of reports on laboratory animal facilities
(Art. 145 para. 1 let. b AniWO)

[1] Reports on laboratory animal facilities must contain the following information:

a. number of animals born in the facility, counted at the time of weaning;

b. number of animals imported from abroad.

[2] The numbers of animals shall be itemised by animal species.

[3] Lines that have a clinical pathological phenotype shall be reported individually. Their designation must match that in the data sheet.

[4] In the case of lines free of clinical pathological phenotype, the following may be summarised per species:

a. genetically modified lines;

b. non-genetically modified lines.

Art. 29[8] Content of reports on laboratory animal facilities
(Art. 145 para. 1 let. b and 1[bis] AniWO)

[1] Reports on laboratory animal facilities for each calendar year must contain the following information:

a. the number of animals born in the facility;

b. the number of imported animals;

c. the number of animals that have not been used in an animal experiment and:
   1. have been supplied to third parties, or
   2. have been killed or have died.

[2] The numbers of animals shall be itemised by animal species.

[3] The numbers of animals shall be specified as follows:

a. numbers in accordance with paragraph 1 letter a:
   1. for mice and rats: from day 9 after birth,
   2. for fish and amphibians: from the free-feeding stage,
   3. for birds: from the date of hatching;

b. numbers in accordance with paragraph 1 letter b:
   1. for imported eggs and larvae of fish and amphibians: from the free-feeding stage,
   2. for bird eggs: from the date of hatching;

c. numbers in accordance with paragraph 1 letter c:
   1. for fish and amphibians: from the free-feeding stage,
   2. for birds: from the date of hatching,
   3. for all animals other than those in numbers 1 and 2: from birth.

[4] Lines that have a clinical pathological phenotype shall be reported individually. Their designation must match that in the data sheet.

[5] In the case of lines free of clinical pathological phenotype, the following may be summarised per species:

a. genetically modified lines;

b. non-genetically modified lines.

Art. 30 Content of applications for the approval of animal experiments
(Art. 139 para. 1 AniWO)

Applications for the approval of animal experiments must contain the following information:

8 Amended by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

a. species, number, gender and origin of animals that are to be used;
b. information on the use of genetically modified animals or mutants that have a clinical pathological phenotype, including the data sheet in accordance with Article 23 of this Ordinance and, where applicable, the decision in accordance with Article 127 AniWO;
c. address of the laboratory animal facility;
d. rooms, infrastructure and location of experiment to be conducted;
e. names of the resource manager, study director, deputies and persons conducting the experiments;
f. number and qualification of personnel;
g. objective of experiment;
h. methodology, including timetable for different parts of experiment and times for interim analysis and, where necessary, interim reports;
i. total duration of experiment;
j. likely impact of strain on the condition of the animals, including degree of severity of strain for each part of the experiment or group;
k. monitoring of animals and criteria for euthanasia;
l. analysis of results;
m. justification for the experiment, the methodology, the strain on the animals and the number of animals;
n. weighing of strain on animals against benefits.

Art. 31 Content of reports on animal experiments
(Art. 145 para. 2 AniWO)

1 Reports on animal experiments must contain the following information:

a. species of the animals used and, where applicable, details of the genetically modified lines or lines with a clinical pathological phenotype to which they belong;
b. number of animals used per calendar year;
c. origin of animals;
d. strain on animals;
e. use of animals after the experiment;
f. results and assessment of the experiment.

2 The reports shall be written for animal experiments performed and not performed.

Section 8 Final Provisions[9]

Art. 31*a*[10] Transitional provision to the Amendment of 20 December 2024

In derogation from Article 29 paragraphs 1 and 3, the report on laboratory animal facilities relating to the calendar years up to 2025 must contain the following information:

a. the number of animals born in the facility, counted at the time of weaning;

b. the number of animals imported from abroad.

Art. 32 Commencement[11]

This Ordinance comes into force on 1 May 2010.

9 Amended by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

10 Inserted by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

11 Inserted by No I of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

Annex 1[12]
(Art. 9 para. 1)

Recognised methods for producing genetically modified animals

a. crossing of genetically modified lines;
b. pronuclear injection in mouse, rat, rabbit and guinea pig;
c. injection and aggregation of embryonic stem cells in mouse and rat;
d. use of viral vectors in mouse and rat;
e. intracytoplasmic sperm injection in mouse and rat;
f. injection into the cytoplasm or the yolk sac of early embryonic stages (1 to 16-cell stage) in zebrafish;
g. use of endonucleases.

12 Revised by No II of the FSVO O of 20 Dec. 2024, in force since 1 Feb. 2025 (AS **2025** 25).

Annex 2
(Art. 17 para. 2 let. b, 18 para. 2 let. a and 23 para. 1 let. a)

Basic scientific data

The following basic scientific data shall be provided on a breeding line:

a. animal species;

b. name of line;

c. type of genetic modification, database reference, literature, purpose of line;

d. producer, method of production, year of production, generation class, status of breed (discontinued, cryo-preserved);

e. genotype, genetic background, hygiene status.

Annex 3
(Art. 23 para. 1 let. b)

Summary of strain recording

The following information shall be provided on the procedure and results of recording strain:

a. scope of strain recording, results from mortality and reproduction data;

b. status of strain recording (under investigation, reported, completed);

c. description of the phenotype, assessment of the strain, degree of severity, expression of transgene (dominant/recessive, conditional, inducible);

d. specific needs, strain-reducing measures.

Annex 4
(Art. 12 para. 1 let. a, 13 para. 2 and 14 para. 1 and 2)

Strain recording in genetically modified small rodent lines and mutants that have a clinical pathological phenotype

Table 1:
Recording strain in genetically modified small rodent lines and mutants that have a clinical pathological phenotype

	Nest inspections (Art. 14 para. 2 and 15 para. 2)	Inspections during cage changing (Art. 14 para. 1 and 15 para. 2)
Number of young, colour, size differences	x	x
Food intake (milk spot)	x	
General condition (size, tonus, nutritional status etc.)	x	x
External visible malformations	x	x
Dead animals, cannibalism, if necessary *post mortem* tests	x	x
Other noticeable problems, such as bite wounds	x	x
Clinical symptoms (tremor, convulsions, lameness etc.)	x	x
Other morphological traits according type of genetic modification	x	x
Behaviour during cage changing (apathy, nervousness etc.)		x
Nest building, condition of nest		x
Fur, eyes, body orifices		x