Schweizerische Eidgenossenschaft
Confédération suisse
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Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Animal health and welfare

Information Animal Welfare

Explanatory notes to the Data sheet of genetically modified lines or constrained mutants (Form D)

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1. Purpose and scope

These explanatory notes are addressed to institutes, animal facilities and the competent cantonal authorities.

According to Article 124 of the Animal Protection Ordinance (TSchV; SR 455.1), in order to identify constrained lines and to take appropriate measures against the constraint, a constraint monitoring must be carried out. According to Article 23 of the Animal Experimentation Ordinance (TVV, SR 455.163), the most important information for genetically modified lines and constrained mutants must be recorded in a summary document (data sheet). The structure and content of this document are defined in the same article.

These legal requirements are now fulfilled by two forms implemented in the animex-ch system (Form D and Form M) which were previously uploaded to the system as electronic attachments. The two forms were digitized with a view to the introduction of the national register of constrained lines according to Art. 146 of the Animal Protection Ordinance (TSchV; SR 455.1). The Ordinance on the Electronic Information System for the Administration of Animal Experiments (VerTi-V; SR 455.61) governs the operation of the animex-ch information system.

2. Requirements and creation of a Form D

To start the Form D procedure in animex-ch, you must:

- Have access to an approved animal facility in animex-ch (i.e. you need to have a valid Form H).
- “Access” for institutes means having confirmation of an institute as a participating institute in Form H.
- You must have at least one of the following roles associated with that Form H:
    - IPI, SDI, RM, AWOI (Institute Users)
    - ACT, IPF, SDF, HAF, AWOF (Facility Users).
    - If the user is logged in with an animal facility specific role (IPF, SDF, ACT, HAF, AWOF), the system will display any Forms H directly associated with the logged-in role.
    - If the user is logged in with an institute specific role (IPI, SDI, RM, AWOI), the system will display any Forms H indirectly associated with the logged-in role through the list of participating institutes.

3. Versioning of Form D

The versioning of Form D meets the requirements of Article 124 of the Animal Protection Ordinance (TSchV; SR 455.1), which states that constraints must be recorded and assessed in good time and documented. In practice, each version of Form D is an update of the form with new relevant information.

In order to create a new version, users with access to the Form D must request a new versioning of the document. The request is forwarded to the HAF and AWOF roles. These are the only roles that can create a new version.
In institutes or laboratory animal facilities where the AWOF / HAF manage the entire process related to this document, versioning can also be performed directly.

After versioning, Form D becomes editable again for all users with editing rights and is saved as a separate version. This process should be carried out, for example, when the constraint monitoring is updated (i.e. because a new phenotype has been identified). It is also mandatory in order to be able to attach the Form D to a Form A or a Form M.

4. Explanations of the individual chapters

Header: **Form D National number**

CONTENT: National number - is assigned automatically by the system. Short name of the animal line - information is taken from Section 01. Status of the line - information is taken from Section 10

PURPOSE OF ENTRY: Unique identification of Form D

ADDITIONAL INFORMATION: All elements in the header are automatically filled in by the system.

BASICS

Section 01: **Short name of the animal line**

CONTENT: Name assigned by the producer of the animal line or animal facility (laboratory-internal name). The name can be freely chosen.

PURPOSE OF ENTRY: The use of a short name is to associate a short name to the scientific name and simplify the identification and use of the name of the animal line.

ADDITIONAL INFORMATION: Information according to Annex 2 Animal Experimentation Ordinance (SR 455.163)

Section 02: **Scientific notation of the animal line**

CONTENT: Correct scientific name of the animal line in accordance with international nomenclature for clear identification. For international nomenclature rules, see: http://www.informatics.jax.org/mgihome/nomen/

PURPOSE OF ENTRY: Clear identification of the animal line

Section 03: **Licensed animal facility**

CONTENT:

License numbers of animal facility

- National number: National license number (generated by the system) of the laboratory animal facility, license as per Art. 122 Animal Welfare Ordinance (SR 455.1).
- Cantonal number: Cantonal number of the laboratory animal facility.

Address of the animal facility

- Name, street, postal code, town: Prefilled according to the facility selected in the wizard. If the name of the facility cannot be selected in the pull-down list, the laboratory animal facility must be created in the system by the cantonal veterinary office via the master data administration process and in the follow-up approved by the cantonal veterinary office.

Head of animal facility:

- Name, E-mail, Tel. No. Name of the person responsible for the laboratory animal facility.

Creator group:

- Created by involved institute: Prefilled automatically by the system according to the form creator. Field Institute: Only visible when yes is selected, then it is prefilled with the institute name, selected on the wizard page.

PURPOSE OF ENTRY: Details of the owner of Form D.

BASIC SCIENTIFIC DATA

Section 04: **Animals**

CONTENT:

Indications associated with the involved animals

- Animal species to be selected in the pull-down menu according to the assigned species in the licence for the laboratory animal facility (Form H, section 12). Only a single selection of species possible per data sheet.

Species specification

- Scientifically correct name of the animal line, given according to international

nomenclature rules (see: http://www.informatics.jax.org/mgihome/nomen/)

PURPOSE OF ENTRY Identification of the animal species

ADDITIONAL INFORMATION Information according to Annex 2 Animal Experimentation Ordinance (SR 455.163)

Section 05: Purpose

CONTENT Indications associated with the purpose of the line, database references and literature references.

PURPOSE OF ENTRY According to Art. 142, para 1, let. b of the Animal Welfare Ordinance (SR 455.1) the purpose of the use of genetically modified animals has to be permissible and preserve the dignity of animals. Indications according to Annex 2 Animal Experimentation Ordinance (SR 455.163).

Section 06: Production

CONTENT Detailed information on production such as producer, method and year.

Producer / Origin of the line:

- Details of the producer or origin of the animal line.

Spontaneous

- Indicate ‘yes’ if mutation arose spontaneously and was not artificially created (i.e. genetically modified or chemically induced).

Method of production

- Indicate the method of production of the line.

Year of Production

- Insert the year of production, if available. If the year of production is unknown, insert some explanation.

PURPOSE OF ENTRY Indications according to Annex 1 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION The animals may have been produced using a recognised method (Annex 1 Animal Experiments Ordinance; SR 455.163) within the framework of the simplified authorisation for production of GMOs. If they were produced in Switzerland not using a recognised method in accordance with Annex 1 of the Ordinance on Animal Experiments, an animal experiment permit must be available for them.

Section 07: Number of generations

CONTENT Number of generations (approximate indications <3, 3-9, 10-50, >50) and status of breeding (ongoing, stopped, planned).

PURPOSE OF ENTRY Indications according to Art. 14 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION Contains two mandatory drop-down lists: number of generations and breeding status. May contain information from internal and external breeders.

Section 08: Genotype

CONTENT Genetic background and specific genotypes of each mutation of the animal line. Constrained phenotypes need to be further described in Section 11 and 14. Since the occurrence and severity of a phenotype is dependent on the genotype a complete overview of which genotypes are obtained must be given. The button "Add Genotype" opens a popup in which the following information needs to be entered:

- Gene: Mandatory reference to the official name of the gene as used in the official scientific nomenclature.
- Genotype: Entry of all possible genotypes that might occur in the breeding strategy. Mandatory multiple selection list; combination of gene and genotype is unique and no

duplicates are allowed. Entry of all possible genotypes that might occur in the breeding strategy.
- Genetic background: Mandatory multiple selection list; combination of gene and genotype is unique and no duplicates are allowed.
- Type of genetic modification: Mandatory drop-down list; single selection possible.

PURPOSE OF ENTRY

Indications according to Annex 2 Animal Experimentation Ordinance (SR 455.163).

Section 09: Hygiene status

CONTENT

Hygiene status of the animal line.
- SPF: In case SPF is selected, then a text field appears for further optional specification.
- Other: In case Other is selected, then a text field appears for further mandatory specification

PURPOSE OF ENTRY

Indications according to Annex 2 Animal Experimentation Ordinance (SR 455.167).

SUMMARY OF MONITORING OF GENETICALLY MODIFIED LINES AND CONSTRAINED MUTANTS

Section 10: Status of monitoring of constraint

CONTENT

Completed / constraint definitely reported; decision of authority pending
- The definitive announcement in accordance with Article 18 Animal Experimentation Ordinance (SR 455.163) has been made. The recording of constraint has been completed. The authority's decision is still pending.
- Purpose: If strain is confirmed by additional recordings, the head of the laboratory animal facility must submit a definitive report as stipulated in Article 18 Animal Experimentation Ordinance). The definitive report of strain in small rodent lines must be submitted at the latest when 100 animals have been checked as stipulated in Article 14 Animal Experimentation Ordinance (SR 455.163).

Completed / strained line according to decision of authority
- The definitive announcement in accordance with Article 18 Animal Experimentation Ordinance (SR 455.163) has been made. The recording of constraint has been completed. The authority's decision is: strained line.
- Purpose: The cantonal authority has to decide according to Article 122 Para 1 und Article 127 Animal Welfare Ordinance (SR 455.1) on the permissibility of the strained line.

Completed / not strained
- The animal line is not constrained.
- The recording of constraint in accordance with Art. 14 Animal Experimentation Ordinance (SR 455.163) has been completed and has shown that the animal line can be bred without genetically induced constraints. If initial strain is not confirmed by additional recordings after the provisional announcement, the head of the laboratory animal facility must withdraw the provisional announcement and likewise report this to the authorities (according to Article 17 Animal Experimentation Ordinance (SR 455.163)).
- Purpose: 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 (Article 14 Para 4 Animal Experimentation Ordinance (SR 455.163)).

Still subject to clarification
- Status after opening the data sheet for continuous monitoring of observed constraint in accordance with Article 14 Animal Experimentation Ordinance (SR 455.163) in a new or insufficiently characterized animal line. The announcement to the competent cantonal animal welfare office has not yet been made.
- Purpose: In new or insufficiently characterized lines of genetically modified animals or

mutants that have a significant clinical pathological phenotype, recording of strain according to Article 14 Animal Experimentation Ordinance (SR 455.163) is compulsory.

Still subject to clarification / constraint provisionally reported

- The provisional announcement to the cantonal licensing authority has been made in accordance with Article 17 Animal Experimentation Ordinance (SR 455.163). The recording of constraint in accordance with Article 14 Animal Experimentation Ordinance (SR 455.163) has not yet been completed.
- Purpose: If similar signs of strain are found in several animals of a new or insufficiently characterized 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 according to Article 17 Animal Experimentation Ordinance (SR 455.163) (SR 455.163)). The provisional report must be submitted within two weeks of the strain being observed.

Amount of observations conducted

- Details regarding the amount of conducted observations

Number of generations and animals observed

- Details regarding the number of generations and animals observed.

PURPOSE OF ENTRY

Information on the status of the constraint monitoring, including information on the scope of the observations carried out as part of the constraint monitoring in accordance with Annex 3 of the Animal Experiments Ordinance SR 455.163

Section 11: Phenotype

CONTENT

Description of the pathologic phenotype and assessment of constraint with regard to degree of severity and age of occurrence. Information on expression of the transgene (dominant/recessive, conditional, inducible).

In the description of the phenotype, indicate the differences between the genotypes (heterozygous, homozygous).

Assessment

- Internal (according to internal observations and assessment)
- External (according to external observations and assessment)
- Both

Results of monitoring of constraint in comparison to wild type

Mortality rate

- Similar to wild type
- Different from wild type

Reproduction rate

- Similar to wild type
- Different from wild type

Behaviour

- Similar to wild type
- Different from wild type

Feeding behaviour, body weight

- Similar to wild type
- Different from wild type

Clinical signs

- Yes
- No

For the categories "Mortality rate", "Reproduction rate", "Behaviour", "Feeding behaviour and Body weight", a new text field named "Please specify" appears when "Different from wild type" is selected. For the category "Clinical signs", new text fields named "Please specify", "Age at event"

and Other (please specify) appear when "Yes" is selected.

Assessment of constraint - Phenotype-specific assessments. Indication of the potential constraint due to genetic modification according to Article 25 Animal Experimentation Ordinance (SR 455.163).

PURPOSE OF ENTRY

Information according to Article 124 Animal Welfare Ordinance (SR 455.1) and Annex 3 Animal Experimentation Ordinance (SR 455.163).

Section 12: Mitigation of constraint

CONTENT

Mandatory indication of the details of strain-reducing measures and their expected impact. Description of the specific needs of the animal line.

PURPOSE OF ENTRY

According to Article 125 Animal Welfare Ordinance (SR 455.1) strain-reducing measures need always to be applied as far as possible and reported according to Article 17 and 18 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION

This section should specify which measures are taken to reduce or, if necessary, completely avoid these stresses. Adapted husbandry conditions, shortened husbandry periods, refraining from breeding certain genotypes, etc. are also to be classified as stress-reducing in this sense and indicated.

Section 13: Criteria for withdrawal

CONTENT

Description of the termination criteria for euthanasia of strained individuals. This means termination criteria for individual animals with an impaired phenotype, not any criteria adopted by the authorities in order to terminate the breeding of the line (decision of the authorities). Indicate appropriate parameters (i.e. disease symptoms) where individual measures are taken in the event of their occurrence (i.e. euthanasia, etc.).

PURPOSE OF ENTRY

According to Article 12 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION

Indicate general and specific parameters related to the phenotype (e.g. symptoms), the occurrence of which will lead to individual measures such as euthanasia of an individual.

Section 14: Degree of severity

CONTENT

Assessment of constraint considering mitigation measures. Categorization of genetic constraint in accordance with Art. 25 Animal Experimentation Ordinance (SR 455.163).

PURPOSE OF ENTRY

According to Article 124 Animal Welfare Ordinance (SR455.1) and Annex 3 Animal Experimentation Ordinance (SR 455.163).

ADDITIONAL INFORMATION

The constraint described in section 11 (phenotype) is assigned a degree of severity after taking into account the measures described in sections 12 and 13. In the case of constrained lines and strains, the constraint / burden on the animals must be reduced as much as possible by taking appropriate precautions in breeding, husbandry and care, or possibly even mitigated completely (strain-reducing measures). Even if the constraint can be completely avoided by implementing such measures, these lines are considered to be constrained and must be reported (i.e. with a SD 0). Possible constraints must be described in detail (section 11). Furthermore, the corresponding mitigating measures (section 12) and termination criteria (section 13) must be specified. This ensures that the cantonal authorities can evaluate the mitigating measures, demand adjustments or implement adjustments by means of conditions to the approved licence. The indicated degree of severity takes into account the stress-reducing measures and termination criteria.

DATASHEET REVISION HISTORY

Section 15: History

CONTENT

Each version is saved separately with a time stamp.

PURPOSE OF ENTRY

Requirements according to Article 124 Animal Welfare Ordinance (TSchV; SR 455.1).

ADDITIONAL INFORMATION

After versioning, Form D becomes editable again for all users with editing rights and is saved as a separate version. This process should be carried out, for example, when the constraint monitoring is updated (e.g. because a new phenotype has been identified).

ABBREVIATIONS:

1. IPI – Involved Person of Institute
2. SDI – Study Director of Institute
3. RM – Resource Manager
4. AWOI – Animal Welfare Officer of Institute
5. ACT – Animal Care Taker
6. IPF – Involved Person of Facility
7. SDF – Study Director of Facility
8. HAF – Head of Animal Facility
9. AWOF – Animal Welfare Officer of Facility