



Version 11.8.2020

Weighing of interests in animal experiments

1. Introduction

The current Swiss Animal Welfare Act (*Tierschutzgesetz*, TSchG¹) entered into force on 1 September 2008. Unlike its predecessor, it protects not only the welfare but also the dignity of the animal. The concept of dignity can also be found in the Federal Act on Non-Human Gene Technology (*Gentechnikgesetz*, GTG²), which has been in force since 1 January 2004. This Act governs the handling of genetically modified organisms (GMOs), i.e. their closed-system production, experimental releases and placing on the market. The legislature states that the use of GMOs must respect the dignity of living beings. The constitutional term "dignity of living beings" (thus including the "dignity of the animal") is not understood as an absolute value in either the TSchG or the GTG. Respect for dignity does not preclude the imposing of strain on animals. However, strain must be justified by overriding interests. The question of whether strain can be justified is answered by carrying out a weighing of interests. However, neither the TSchG nor the GTG provide detailed instructions on how to do so. Since the scope of the two Acts overlaps in the area of animal experiments using genetically modified vertebrates, a coordinated approach is required for the weighting of types of strain and legitimate interests.

Detailed information on how the concept of "dignity of the animal" is understood within animal welfare legislation and on the role that the weighing of interests plays in connection with this concept can be found in the document "Explanatory notes on the 'weighing of interests'"³.

The "Dignity of the animal" study group of the Federal Food Safety and Veterinary Office (FSVO) has devised a guide to ensure that the weighing of interests is carried out correctly and uniformly. This guide has proven its worth in dealing with a wide variety of issues. However, it has also been shown that the proposed approach is only partially suitable for carrying out the weighing of interests in animal experiments. But specifically in applications for animal experiments, the weighing of interests is always required. It must be carried out both by the applicant (i.e. the researcher) and by the committees on animal experiments or the cantonal animal welfare authorities. The study group has therefore revised the existing guide so that it can be used to carry out the weighing of interests in connection with animal experiments. The guide is addressed to researchers applying for an animal experiment, to members of committees on animal experiments and to employees of the cantonal animal welfare authorities.

¹ SR 455 Animal Welfare Act (*Tierschutzgesetz*) of 16 December 2005

² SR 814.91 Federal Act on Non-Human Gene Technology (*Gentechnikgesetz*) of 21 March 2003

³ <https://www.blv.admin.ch/blv/en/home/tiere/tierschutz/wuerde-des-tieres.html>

2. Weighing of interests: procedure

The weighing of interests is divided into seven stages. The considerations and explanations required in each stage are also requested in the application form for animal experiments (Form A) specified by FSVO. However, the requested information appear in Form A in a different order and, to some extent, weighted differently with regard to the degree of detail. The corresponding sections in Form A are indicated below by the numbers in brackets, e.g.: *[Form A: point ...]*

1. What is the objective of the animal experiment?

[Form A: points 20 and 22]

Since a weighing of interests must always be carried out with regard to the objective pursued by the animal experiment, this objective should be described as precisely and comprehensively as possible. This includes describing how the research project is embedded in a broader context: what is the state of research in the field in question? What does the proposed project tie in with? Has any preparatory work been done by the applicant or their group? How can the project expand the state of knowledge?

Clearly formulated hypotheses and/or specific questions should also be given with regard to the objective.

2. Conducting of the experiment: what precisely will be done?

[Form A: points 20 to 29]

An accurate presentation of the facts is important in order to conduct the weighing of interests correctly. This includes describing the experiment(s) and, in particular, all interventions and measures in the animal, e.g.:

- Operations
- Injections
- Behavioural tests
- Special housing conditions (e.g. individual housing, housing without nesting material, reduced space allowance)
- Dietetic measures (e.g. feed or water withdrawal)

Before the actual weighing of interests is carried out, it is important to clarify whether the planned procedure is appropriate and necessary for achieving the objective of the experiment.

3. Question of suitability

[Form A: point 38]

The next stage is to consider whether the procedure at issue is appropriate in order to achieve the intended aim in full, or at least in part.

The researcher must explain the suitability of his or her procedure. If based on the information available the suitability seems vague, further enquiry and precise questions by the committee on animal experiments may make this easier to gauge.

If the committee remains of the opinion that the intended aim cannot be achieved by means of the proposed procedure, the experiment must not be carried out. There is no need for the actual weighing of interests, i.e. the weighting and comparison of strain and interests. In such

a case, the experiment must be rejected. However, there must be clear arguments in favour of non-suitability.

4. Question of necessity

[Form A: point 39]

The question of necessity concerns the implementation of 3R principles. It is important that all 3R aspects are taken into account in every project involving animal experiments.

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

From the perspective of **refine**, it should be checked in this context, for example, whether better/more suitable anaesthesia and/or analgesia can reduce the strain on the animals. The information and considerations on this aspect of necessity can be found in the application form for an animal experimentation licence in the section on methods.

[Form A: point 26]

The question of necessity also arises from the perspective of **reduce**: could the experiment be carried out with fewer animals? However, it should be borne in mind that any reduction in the number of animals must not detract from the robustness of the results.

The information and considerations on this aspect of necessity can be found in the application form for an animal experimentation licence in the section on methods.

[Form A: point 30]

If the proposed experiment is demonstrably not necessary to achieve the intended objective, there is no need for a weighing of interests in the narrow sense. In such a case, the experiment must be rejected.

5. Identification and weighting of types of strain

When assessing strain, various types of strain must be taken into consideration in accordance with Article 3 letter a TSchG and, if necessary, considered in the weighing of interests. Not all types of strain need apply in every experiment. The types of strain are as follows:

- Causing pain, suffering or harm, exposing to anxiety
- Humiliation
- Major interference with the appearance
- Major interference with the abilities
- Excessive instrumentalisation

The application form for animal experiments (Form A) requests only information on the first category of strain ("causing pain, suffering or harm, exposing to anxiety"), described as

“pathocentric” strain criteria. The other “non-pathocentric” types of strain are not included in Articles 24 and 25 of the Animal Experimentation Ordinance (*Tierschutzverordnung*, TSchV)¹, which form the basis for assigning the degree of severity (SG) to the animal experiment and the explanations in the FSVO’s technical information² “Severity degrees 1.04”.

However, in the final weighing of interests for the animal experimentation licence all types of strain must be taken into account by the committees on animal experiments. This is referred to in Article 26 of the Animal Experimentation Ordinance as follows:

“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 humiliation, through major intervention with their appearance or their capabilities or through excessive instrumentalisation.”

Applicants should therefore include these aspects in their considerations and indicate them in point 33, even if they are not addressed directly in Form A. The relevant types of strain should be listed fully and explicitly. This makes the overall strain easier to gauge and its assessment transparent. If the committee on animal experiments is of the opinion that additional strain criteria apply to the types of strain mentioned by the applicant, it should request further information.

Examples of interventions that also entail non-pathocentric strain:

- Parabiosis
- Loss of pain receptors in genetically modified strains
- Immunodepressive animals
- Dorsal skinfold chambers (mouse model, used e.g. for *in vivo* vascularisation studies over an extended period)
- Interventions causing paralysis
- Killing female offspring where only male offspring are needed (or vice-versa)

Once it is established which types of strain apply, these must be weighted. Since “causing pain, suffering or harm, exposing to anxiety” is completely different in nature to the other types of strain, it makes sense to carry out the strain assessment in two stages.

Stage one: First, “causing pain, suffering or harm, exposing to anxiety” is assessed according to the severity classification. If the experiment involves different interventions carried out on the animals in parallel or within a short timeframe, it should be considered whether there is any cumulative strain and therefore a higher overall strain, with the result that a higher degree of severity should be assigned to the experiment. This must be assessed in each individual case; there are no systematic guidelines.

Stage two: In a second stage, the overall strain assessment is carried out, i.e. the assessment of strain also taking into consideration those types of strain that are not taken into account in the degree of severity. If such non-pathocentric types of strain apply, they are weighted very strongly. This is evident from their descriptions (“major interference”, “excessive instrumentalisation”). The presence of non-pathocentric types of strain does not change the severity classification of the experiment. However, it does lead to a higher overall assessment of the strain. This is given an additional dimension. For example, an experiment might be classed as SG2 (“degree of severity 2”) due to “causing pain, suffering or harm, exposing to anxiety”, but be weighted more heavily in the overall assessment due to the inclusion of

¹ SR 455.1 Animal Welfare Ordinance (*Tierschutzverordnung*) of 23 April 2008

² <https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/forschende.html>

non-pathocentric types of strain. It might also be possible for the total strain of an SG3 experiment to be weighted so strongly, taking into account non-pathocentric types of strain, that it does not seem justifiable from the outset.

[Form A: points 33 to 36 and 40]

Important: The overall assessment of strain determined by considering all types of strain should be presented descriptively, not as a value on a quantitative scale.

6. Identification and weighting of interests

The weighing of interests compares the strains on the animals with other values and interests and must show whether the latter can be regarded as overriding. It is important to note that morally relevant interests are involved not only on the strain side, but also on the interests side. Regarding animal experiments, Article 137 para. 1 TSchV specifies which interests can be taken into account:

- preservation or protection of the life and health of humans and animals;
- new knowledge on fundamental processes of life;
- protection of the natural environment.

This list is exhaustive, i.e. no interests other than those mentioned may be taken into account in connection with animal experiments. It is also important that the interests listed in Article 137 para. 1 TSchV are generally to be regarded as equivalent. They cannot and must not be played off against each other in abstract terms. Rather, it is a matter of weighting the specific interest pursued in each individual case.

In assessing the gain in knowledge with regard to the weighing of interests, the question is which arguments lend weight to that gain. The anticipated gain in knowledge should be explained by stating a clearly formulated expectation. An application must therefore contain a plausible scientific hypothesis. The gain in knowledge is further qualified by the embedding of the project in the scientific context. The applicant must therefore describe in a comprehensible manner how his or her project, i.e. the objective of the experiment, will fit into the existing state of knowledge and to what extent it will expand it. A positive assessment from a scientific perspective (e.g. by the Swiss National Science Foundation) also lends weight to the anticipated gain in knowledge.

The weighting of the gain in knowledge will be discussed in the committee on animal experiments and a majority decision will be taken.

[Form A: points 16 to 18 and 40]

7. Weighing of interests/Conclusion

In the final stage, the overall strain and the interests must be weighed against each other. The applicant should explain again which strain criteria are concerned in the experiment, and which is the resulting overall assessment for the strain side. On the interests side, the significance of the experiment with regard to the experimental objective must be considered again. The strain side and interests side need not be described again in detail. Rather, the applicant can refer to stages 5 and 6 or to the corresponding numbers in Form A. Finally, the applicant should set out arguments demonstrating that there is an overriding interest in his or her project and that the strain is therefore justified.

The weighing of interests will be discussed in the committee on animal experiments and a majority decision will be taken.

If the weighing of interests shows that there is an overriding interest and that the strain can therefore be justified, the committee requests approval of the application and the authority approves the experiment.

If the weighing of interests shows that there is no overriding interest and that the strain cannot therefore be justified, the committee requests rejection of the application and the authority rejects the experiment.

[Form A: point 40]