

RESEARCH AND ANIMAL EXPERIMENTATION IN SWITZERLAND: DEGREES OF SEVERITY

Which degrees of severity exist?

In animal experiments in Switzerland four degrees of severity¹ are distinguished, measuring the level of constraint from 0 to 3 (DS 0, DS 1, DS 2 and DS 3):

- Degree of severity 0: no constraint
If no pain, suffering, injury or fear is inflicted on an animal during a procedure, a degree of severity 0 is assigned. This may include experiments such as behavioural observations to study the social and cognitive abilities of an animal.
- Degree of severity 1: slight constraint
If an animal is subjected to slight, short-term pain or injury or slight impairment of its general condition, a degree of severity 1 is assigned. This is the case, for example, if blood is repeatedly drawn from an animal within 24 hours.
- Degree of severity 2: moderate constraint
If an animal is subjected to a medium short term or a light medium to long term constraint, a degree of severity 2 is assigned. This is the case, for example, when an anaesthetic or surgical procedure is performed on an animal under anaesthesia. Studies with a degree of severity 2 are carried out, for example, to improve the healing of tendons, cartilage or bone.
- Degree of severity 3: severe constraint
If an animal is subjected to severe pain, continuous suffering, significant fear or severe impairment of its general condition, or if the constraint is moderate but persists in the medium or long term, a degree of severity 3 is assigned. The transplantation of a malignant tumour is an example of an experiment with a degree of severity 3.

Before the start of an experiment, every researcher has to indicate what is likely to be the highest degree of severity of the study. This prospective assessment is taken into account by the cantonal authorities when deciding whether or not to grant an authorisation. However, the determining factor for measuring the real constraints on the animals is not the prospective assessment but how the animals effectively react to an experimental process. The law therefore requires that suitable criteria for discontinuation of experiments be defined when the application for an animal experiment is submitted (Animal Protection Ordinance AniPO Art. 135). By consistently applying these criteria, researchers ensure that animals are not subjected to excessive stress in an animal experiment. After completion of the study, a retrospective evaluation is carried out by the researchers to

¹ Technical Information of FSVO (30/08/2018)

assess the actual degree of severity based on the observations made during the study. The guidelines for the classification of the various experimental procedures according to the corresponding severity degrees are regularly revised and updated by the federal authorities.

On 30 August, 2018, the Federal Food Safety and Veterinary Office (FSVO) updated its technical information on severity degrees,² which has led to a change on how researchers must classify animal experiments. As a result of this reclassification the figures until 2018 are only comparable to a limited extent with the numbers from 2019.

Figures

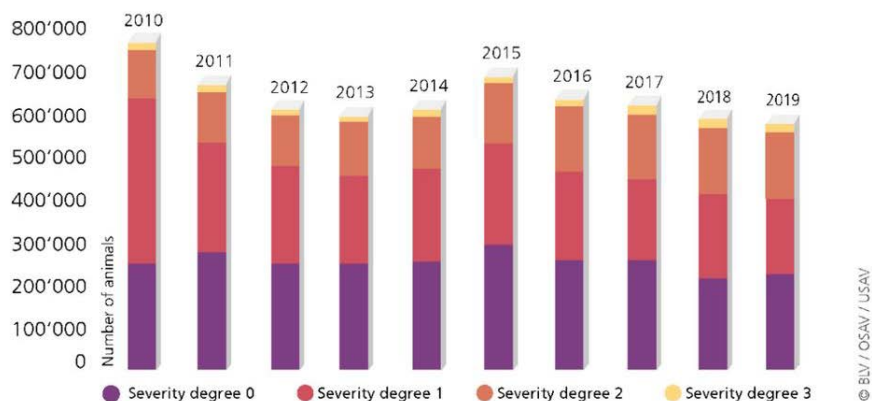
Share of degrees of severity according to animal species (2019)

Species	Total	SD 0	SD 1	SD 2	SD 3
Rodents	79.31%	29.62%	32.47%	34.15%	3.76%
Non-mammals (birds, fish, invertebrates, ...)	15.90%	73.78%	22.06%	2.85%	1.31%
Various mammals (spiny mice, hedgehogs, ...)	0.43%	61.70%	38.22%	0.08%	0.00%
Rabbits, dogs, cats, primates	0.66%	76.05%	13.31%	10.38%	0.26%
Livestock (cattle, pigs (including mini pigs), sheep, ...)	3.69%	82.14%	16.84%	0.96%	0.06%
Total	100%	39.03%	30.13%	27.64%	3.20%

Source: FSVO - <https://www.tv-statistik.ch/de/erweiterte-statistik/>
 Included institutions: universities, hospitals, federal and cantonal authorities, industry, others

Number of animals in research by severity degrees

The evolution of severity degrees has remained relatively stable since 2010.



² Technical information of FSVO (30/08/2018)

Experiments with the highest degree of severity

The current legal and ethical framework requires the protection of the well-being of all animals in research. It requires strict criteria to avoid any unnecessary suffering of animals in research.

- Each application for an animal experiment is subject to a weighing of interests between the burden caused to the animal and the expected gain for the society or the environment.
- An experiment involving animals is only authorized if there are no alternative methods to achieve the intended purpose.

Experiments with a degree of severity 3:

- contribute to scientific progress in various fields, in particular on serious and complex diseases such as cancer, epilepsy, Alzheimer's disease, multiple sclerosis and other autoimmune diseases as well as organ transplantations and infectious diseases;
- are essential for scientific studies that contribute to the understanding and development of innovative therapies that can improve the quality of life of patients or save lives (see below for examples);
- are usually conducted in mice or rats;
- concern about 3% of the animals used in animal research in 2019;
- may only be carried out if the expected objectives pursued in the previous trial are of sufficiently high importance to justify the constraints.

Three examples

- **Cancer** is the most common cause of death in Switzerland among people under 85 years of age. The new drug therapies developed every year represent a great source of hope for patients. Experiments with a degree of severity 3 have made this progress possible, including the development of immunotherapies, which are also used in the fight against cancer. In cancer, the primary tumour is rarely the cause of death. In most cases, the cause is the organs damage throughout the body due to the spread of the cancer (metastasis). The knowledge about what causes the spread of cancer in the body, which organs it tends to infiltrate and the characteristics of this metastatic tumour spread is yet far from complete. Although alternative methods exist to study the actual cancer cells (in particular cell cultures), animal experiments are essential to study the spread of cancer throughout the body. Animal studies with a degree of severity 3, typically in mice, are also essential to improve diagnostic procedures for early detection of organ metastases and to improve the survival and quality of life of patients by further developing therapies that are still in the research stage.
- Neurodegenerative diseases cover a broad spectrum and include well-known and widespread conditions such as **Parkinson's disease**. Other rare diseases such as Huntington's disease or amyotrophic lateral sclerosis (ALS) cause very severe and often fatal symptoms. There are no effective treatments for these diseases. Research activities, including animal experiments, are therefore all the more important. With regard to neurodegenerative diseases, cell culture approaches are inadequate, as they do not allow the examination of the entire organ and the effects of the damage or the various treatments/surgeries on the entire organism. Experiments with a degree of severity 3 in the field of neurosciences have recently been carried out on rats to advance the treatment of **spinal paralysis**. These trials contribute to the understanding and development of therapies that can cause new growth of nerve connections and restore mobility.

- In the field of **cardiac surgery**, the development of pulmonary valve transplants and heart valves requires animal experiments with a degree of severity 3 in sheep. Heart valves are first designed using computer models and computer-aided simulation in the laboratory and *in vitro* and tested for their technical properties. The implantation of the valves and in particular their functionality, longevity and growth over the years in an organism can only be studied in a living animal with similar size, vital functions and development as humans. These experiments allow the valves to be used in children or adolescents and to be implanted in adults in a minimally invasive manner without opening the chest and heart using a heart-lung machine. This means that a mitral valve can also be used in older people and high-risk patients for whom open heart surgery with the associated risks and subsequent intensive treatment and months of rehabilitation would not be acceptable.